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Term	Related reference(s)	Definition
Abbreviated review		
	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	See abridged review.
Abridged regulatory pathways		
	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. This usually involves some work by the national regulatory authority (NRA) that is practising reliance (see section 5.4 Risk-based approach). It is expected that use of reliance in these pathways will save resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained.
Abridged review		
	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a reference authority or trusted institution to inform the local decision. The abridged review is based on assessment reports, and good manufacturing practices (GMP) inspection reports of reference authorities, plus specific parts of the Common Technical Document (CTD) (for example, stability data in Module 3 of the CTD (9)).
Accelerated (stress) stability studies		
	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	Studies designed to increase the rate of chemical or physical degradation of a drug by using degradation reactions and predicting the shelf-life under normal storage conditions. The design of accelerated studies may include elevated temperature (e.g., 37-49°C and up to 50-55°C), high humidity and light. Only a provisional shelf-life may be established on the basis of these studies. Therefore, accelerated studies should always be supplemented by real-time studies under expected storage conditions.
Accelerated stability testing		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	Studies designed to increase the rate of chemical degradation and physical change of a drug by using exaggerated storage conditions as part of the formal stability testing programme. The data thus obtained, in addition to those derived from real-time stability studies, may be used to assess longer-term chemical effects under no-accelerate conditions and to evaluate the impact of short-term excursions outside the label storage conditions, as might occur during shipping. The results of accelerated testing studies are not always predictive of physical changes.

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Term	Related reference(s)	Definition
Accelerated testing (1)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Studies designed to increase the rate of chemical degradation and physical change of an API or FPP by using exaggerated storage conditions as part of the stability testing programme. The data thus obtained, in addition to those derived from long-term stability studies, may be used to assess longer term chemical effects under non-accelerated conditions and to evaluate the impact of short-term excursions outside the label storage conditions, as might occur during shipping. The results of accelerated testing studies are not always predictive of physical changes.
Accelerated testing (2)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Studies designed to increase the rate of chemical degradation and physical change of an active pharmaceutical ingredient or finished pharmaceutical product by using exaggerated storage conditions as part of the stability testing programme. The data thus obtained, in addition to those derived from long-term stability studies, may be used to assess longerterm chemical effects under non-accelerated conditions and to evaluate the impact of short-term excursions outside the label storage conditions, as might occur during shipping. The results of accelerated testing studies are not always predictive of physical changes.
Acceptance criteria (1)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Numerical limits, ranges or other suitable measures for acceptance of test results.
Acceptance criteria (2)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Measurable terms under which a test result will be considered acceptable.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Measurable terms under which a test result will be considered acceptable.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Measurable terms under which a test result will be considered acceptable.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Measurable terms under which a test result will be considered acceptable.
Acceptance criteria (3)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Numerical limits, ranges or other suitable measures for acceptance of test results.

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Term	Related reference(s)	Definition
Acceptance criterion for an analytical result		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Predefined and documented indicators by which a result is considered to be within the limit(s) or to exceed the limit(s) indicated in the specification.
Acceptance quality limit (AQL)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling (ISO 2859-1). Note: Manufacturers should be consistently achieving a process average that is better than the AQL.
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling (ISO 2859-1). Note: Manufacturers should be consistently achieving a process average that is better than the AQL.
Accessory to a medical device		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	An article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use (1).
Accessory to an IVD medical device		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	An article intended specifically by its manufacturer to be used together with a particular IVD medical device to enable or assist that device to be used in accordance with its intended use (1).
Accountability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The obligation to account for one's conduct and actions, ussually to an individual or group, but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and transparency (see transparency).
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The obligation to account for one's conduct and actions, ussually to an individual or group, but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and transparency (see transparency).
Accreditation		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The term applied to third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (2).
Accuracy		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The degree of agreement of test results with the true value or the closeness of the results obtained by the procedure to the true value. Note: It is normally established on samples of the material to be examined that have been prepared to quantitative accuracy. Accuracy should be established across the specified range of the analytical procedure. It is generally acceptable to use a “spiked” placebo which contains a known quantity or concentration of a reference substance.

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Term	Related reference(s)	Definition
Action limit (1)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The action limit is reached when the acceptance criteria of a critical parameter have been exceeded. Results outside these limits will require specified action and investigation.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The action limit is reached when the acceptance criteria of a critical parameter have been exceeded. Results outside these limits will require specified action and investigation.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The action limit is reached when the acceptance criteria of a critical parameter have been exceeded. Results outside these limits will require specified action and investigation.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The action limit is reached when the acceptance criteria of a critical parameter have been exceeded. Results outside these limits will require specified action and investigation.
Action limit (2)		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An established relevant measure (for example, microbial or airborne particle limits) that, when exceeded, should trigger appropriate investigation and corrective action based on the investigation.
Active ingredients (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See sections I.5, 4.4 and 4.5 of the guidelines.
Active ingredients (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	The herbal material(s) or the herbal preparation(s) will be considered to be active ingredient(s) of a herbal medicine(s). However, if constituents with known therapeutic activities are known, the active ingredients should be standardized to contain a defined amount of this/ these constituent(s). (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Active ingredients (3)		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Active ingredients refer to constituents with known therapeutic activity, when they have been identified. Where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient.
Active ingredients (4)		
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Constituents with known therapeutic activity, when they have been identified. When it is not possible to identify the active ingredients, the whole herbal medicine may be considered as an active ingredient.

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Term	Related reference(s)	Definition
Active ingredients (5)		
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Refer to constituents with known therapeutic activity, when they have been identified. When it is not possible to identify the active ingredients, the whole herbal medicine may be considered as an active ingredient (3).
Active moiety		
	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	The term used for the therapeutically active entity in the final formulation of therapeutic goods, irrespective of the form of the API. The active is alternative terminology with the same meaning. For example,if the API is propranolol hydrochloride, the active moiety (the active) is propranolol.

Term	Related reference(s)	Definition
Active pharmaceutical ingredient (API) (1) Fall		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

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Term

Related reference(s)	Definition
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

Term

Related reference(s)	Definition
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

Active pharmaceutical ingredient (API) (2)

Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used in the production of a drug, becomes an active ingredient of that drug.Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

Active pharmaceutical ingredient (API) (3)

Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form. When so used the API becomes the active moiety as defined below, often termed simply the active. The API may be a salt, hydrate or other form of the active moiety, or may be the active moiety itself. Active moieties are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

Active pharmaceutical ingredient (API) (4)

A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A substance or compound intended to be used in the manufacture of a pharmaceutical product as therapeutically active compound (ingredient).
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A substance or compound intended to be used in the manufacture of a pharmaceutical product as therapeutically active compound (ingredient).

Active pharmaceutical ingredient (API) (5)

Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products. (Annex 4, 43rd report, 2009)	Any substance or combination of substances used in a finished product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

Active pharmaceutical ingredient (API) (6)

Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

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Term	Related reference(s)	Definition
Active pharmaceutical ingredient (API) (7)	Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	A substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
Active pharmaceutical ingredient (API) (8)	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A substance used in the FPP, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
Active pharmaceutical ingredient (API) (9)	Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance (Annex 6, 54th report, 2020)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.
Active pharmaceutical ingredient (API) (a10)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used in the production of a drug, becomes an active ingredient of that drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.
Active pharmaceutical ingredient (API) (a11)	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	With respect to radiopharmaceutical preparations, the active pharmaceutical ingredient is the radioactive molecule that is responsible for the radiopharmaceutical mechanism of action. This active pharmaceutical ingredient may be in the form of the radionuclide by itself, if its use by itself is clinically indicated, or in the form of a radionuclide coupled to a non-radioactive ligand or vector molecule.
Active pharmaceutical ingredient (API) (or pharmaceutical substance) (a12)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Any substance or mixture of substances intended to be used in the manufacture of a finished pharmaceutical product (FPP) and that, when used in the production of a pharmaceutical product, becomes an active ingredient of the pharmaceutical product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

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Term	Related reference(s)	Definition
Active pharmaceutical ingredient (API) starting material (1)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house (ICH Q7). See also starting materials for synthesis.
Active pharmaceutical ingredient (API) starting material (2)	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house.
Active substance gas	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	Any gas intended to be an active substance for a medical product or medicinal gas.
Active systems	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Actively powered systems using electricity or other fuel source to maintain a temperature-controlled environment inside an insulated enclosure under thermostatic regulation (e.g. cold rooms, refrigerators, temperature-controlled trucks, refrigerated ocean and air containers).
Addresses of competent authorities	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See sections 2.2 and 3.3 of the guidelines.
Adjustment factor (safety factors).	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	Numerical factor used in a quantitative risk assessment to represent or allow for the extrapolation, uncertainty, or variability of an observed exposure concentration and its associated health outcome in a particular laboratory species or exposed population to an exposure concentration for the target population (for example, from animals to human patients and short-term exposure to chronic exposure) that would be associated with the same delivered dose. Adjustment factors can also be used when dealing with clinical data, e.g. when a study population is not representative of the general population.
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	Numerical factor used in a quantitative risk assessment to represent or allow for the extrapolation, uncertainty, or variability of an observed exposure concentration and its associated health outcome in a particular laboratory species or exposed population to an exposure concentration for the target population (for example, from animals to human patients and short-term exposure to chronic exposure) that would be associated with the same delivered dose. Adjustment factors can also be used when dealing with clinical data, e.g. when a study population is not representative of the general population.

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Term	Related reference(s)	Definition
Adjuvants	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Adjuvants are adjunctive substances added during the herbal processing procedures for the purpose of altering the pharmacological or therapeutic properties of the herbal materials, neutralizing or reducing toxicity, or masking the taste, assisting formulation into suitable herbal dosage forms, maintaining stability or extending the storage time. Common adjuvants include water, wine, vinegar, honey, milk and clarified butter, among other materials.
Adulterant	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Adulterant is herbal material, a herbal constituent or other substance that is either deliberately or non-intentionally (through cross-contamination or contamination) added to a herbal material, herbal preparation, or finished herbal product.
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Adulterant is herbal material, a herbal constituent or other substance that is either deliberately or non-intentionally (through cross-contamination or contamination) added to a herbal material, herbal preparation, or finished herbal product.
Adverse event (1)	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Any untoward medical occurrence in a clinical trial subject administered a pharmaceutical product; it does not necessarily have a causal relationship with the treatment.
Adverse event (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational medical device (3).
Affordability	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The extent to which pharmaceutical products are available to the people who need them at a price they can pay.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The extent to which pharmaceutical products are available to the people who need them at a price they can pay.
Agent or local technical representative	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Every applicant who is not resident in the country of the national regulatory authority (NRA) should appoint a person in that country to be an agent (local technical representative). The appointment should be notified to the NRA by submitting a letter of appointment supported by powers of attorney duly notarized in the country of origin, and registered with the registrar of companies in the country of the NRA.

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Term	Related reference(s)	Definition
Agreement		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Arrangement undertaken by and legally binding on parties.
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Arrangement undertaken by and legally binding on parties.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Arrangement undertaken by and legally binding on parties.
Air changes per hour		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The flow rate of air supplied to a room, in m3/hour, divided by the room volume, in m3.
Air changes per hour (ACPH)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The volume of air supplied to a room, in m3/hr, divided by the room volume, in m3.
Air separation		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	The separation of atmospheric air into its constituent gases.
Airflow protection booth		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A booth or chamber, typically for purposes of carrying out sampling or weighing, in order to provide product containment and operator protection.
Air-handling unit (AHU) (1)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The air-handling unit serves to condition the air and provide the required air movement within a facility.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The air-handling unit serves to condition the air and provide the required air movement within a facility.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The air-handling unit serves to condition the air and provide the required air movement within a facility.

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Term

Related reference(s)	Definition
Air-handling unit (AHU) (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The AHU serves to condition the air and provide the required airflow within a facility.
Airlock (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
Airlock (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	An enclosed space with two or more doors, which is interposed between two or more rooms, for example, of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for and used by either people or goods (personnel airlock (PAL); material airlock (MAL)).
Airlock (3)	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An enclosed space with interlocked doors, constructed to maintain air pressure control between adjoining rooms (generally with different air cleanliness standards). The intent of an airlock is to preclude ingress of particle matter and microorganism contamination from a less controlled area.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
ALCOA		
	Good chromatography practices (Annex 4, 54th report, 2020)	A commonly used acronym for “attributable, legible, contemporaneous, original and accurate”.
ALCOA+ (1)		
	Good chromatography practices (Annex 4, 54th report, 2020)	A commonly used acronym for “attributable, legible, contemporaneous, original and accurate” that puts additional emphasis on the attributes of being complete, consistent, enduring and available – implicit basic ALCOA principles.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A commonly used acronym for “attributable, legible, contemporaneous, original and accurate” that puts additional emphasis on the attributes of being complete, consistent, enduring and available – implicit basic ALCOA principles.
ALCOA+ (2)		
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	A commonly used acronym for “attributable, legible, contemporaneous, original and accurate” which puts additional emphasis on the attributes of being complete, consistent, enduring and available throughout the data life cycle for the defined retention period.
Alert level		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An established relevant measure (such as microbial or airborne particle levels) giving early warning of potential drift from normal operating conditions and validated state, which does not necessarily give grounds for corrective action but triggers appropriate scrutiny and follow-up to address the potential problem. Alert levels are established based on routine and qualification trend data and are periodically reviewed. The alert level can be based on a number of parameters, including adverse trends, individual excursions above a set limit and repeat events.
Alert limit		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The alert limit is reached when the normal operating range of a critical parameter has been exceeded, indicating that corrective measures may need to be taken to prevent the action limit being reached.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The alert limit is reached when the normal operating range of a critical parameter has been exceeded, indicating that corrective measures may need to be taken to prevent the action limit being reached.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The alert limit is reached when the normal operating range of a critical parameter has been exceeded, indicating that corrective measures may need to be taken to prevent the action limit being reached.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The alert limit is reached when the normal operating range of a critical parameter has been exceeded, indicating that corrective measures may need to be taken to prevent the action limit being reached.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Ampoule	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container sealed by fusion and to be opened exclusively by breaking. The contents are intended for use on one occasion only.
Analytical performance	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The ability of an IVD medical device to detect or measure a particular analyte (4).
Analytical test report	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	An analytical test report usually includes a description of the test procedure(s) employed, results of the analysis, discussion and conclusions and/or recommendations for one or more samples submitted for testing (see Part three, sections 18.7–18.11).
Analytical worksheet (1)	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A printed form for recording information about the sample, test procedure and results of testing (see Part Three, section 15).
Analytical worksheet (2)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A printed form, an analytical workbook or electronic means (e-records) for recording information about the sample, as well as reagents and solvents used, test procedure applied, calculations made, results and any other relevant information or comments (see Part three, section 15).
antimicrobial resistance (AMR)	Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance (Annex 6, 54th report, 2020)	Antibiotic resistance develops when bacteria adapt and grow in the presence of antibiotics. The development of resistance is linked to how often antibiotics are used. Because many antibiotics belong to the same class of medicines, resistance to one specific antibiotic agent can lead to resistance to a whole related class. Resistance that develops in one organism or location can also spread rapidly and unpredictably through, for instance, the exchange of genetic material between different bacteria, and can affect antibiotic treatment of a wide range of infections and diseases. Drug-resistant bacteria can circulate in populations of human beings and animals, through food, water and the environment, and transmission is influenced by trade, travel and both human and animal migration. Resistant bacteria can be found in food, animals and food products destined for consumption by humans. Some of these features also apply to medicines that are used to treat viral, parasitic and fungal diseases, hence the broader term antimicrobial resistance.
Apheresis	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The process by which one or more blood components are selectively obtained from a donor by withdrawing whole blood, separating it by centrifugation and/or filtration into its components, and returning those not required to the donor.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
API starting material	
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in-house. API starting materials normally have defined chemical properties and structure.
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. An API starting material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in-house. API starting materials normally have defined chemical properties and structure.
Applicant (1)	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The party applying for a Product Certificate. This is normally the product-licence holder. Because certain data are confidential for commercial reasons, the competent authority in the exporting country must always obtain permission to release these data from the product-licence holder or, in the absence of a product licence, from the manufacturer.
Applicant (2)	
WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	The party applying for a certificate for a pharmaceutical starting material.
Applicant (3)	
Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	The person or company who submits an application for marketing authorization of a new pharmaceutical product, an update to an existing marketing authorization or a variation to an existing market authorization.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	The person or company who submits an application for marketing authorization of a new pharmaceutical product, an update to an existing marketing authorization or a variation to an existing market authorization.
Applicant (4)	
Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The person or company who submits an application for marketing authorization of a new medical product, an update to an existing marketing authorization or a variation to an existing marketing authorization.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Applicant (5)		
	Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	The person or entity who, by the deadline mentioned in the invitation, submits an expression of interest (EOI) to participate in this procedure in respect of the product(s) listed in the invitation, together with the required documentation on such product(s).
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	The person or entity who, by the deadline mentioned in the invitation, submits an expression of interest (EOI) to participate in this procedure in respect of the product(s) listed in the invitation, together with the required documentation on such product(s).
	Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	The person or entity who, by the deadline mentioned in the invitation, submits an expression of interest (EOI) to participate in this procedure in respect of the product(s) listed in the invitation, together with the required documentation on such product(s).
	Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	The person or entity who, by the deadline mentioned in the invitation, submits an expression of interest (EOI) to participate in this procedure in respect of the product(s) listed in the invitation, together with the required documentation on such product(s).
Applicant (6)		
	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	For the purposes of this document, the term applicant refers to any person or entity who has participated in the procedure for prequalification of FPPs by submission of the required documentation on a product that has been listed after evaluation as prequalified.
Applicant (7)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A person who applies for marketing authorization of a medical product to the national regulatory authority, who must be the owner of the product. The applicant may be a manufacturer or the party applying for a product certificate. After the product is registered, the applicant becomes the marketing authorization holder.
Application (1)		
	Guidelines on pre-approval inspections. (Annex 7, 36th report, 2002)	A marketing authorization for a new drug application.
Application (2)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The information provided by the applicant to the RA for evidence-based review and marketing authorization decision.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Archiving		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	Archiving is the process of protecting records from the possibility of being further altered or deleted, and storing these records under the control of independent data management personnel throughout the required retention period. Archived records should include, for example, associated metadata and electronic signatures.
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	Archiving is the process of long-term storage and protection of records from the possibility of deterioration, and being altered or deleted, throughout the required retention period. Archived records should include the complete data, for example, paper records, electronic records including associated metadata such as audit trails and electronic signatures. Within a GLP context, the archived records should be under the control of independent data management personnel throughout the required retention period.
As low as reasonably achievable (1)		
	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	ALARA is an acronym standing for "as low as reasonably achievable", used to define the principle of underlying optimization of radiation protection. This is practised based on the principles of time, distance and shielding, as well as an emphasis on creating adequate awareness among all stakeholders.
As low as reasonably achievable (2)		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	This term is used to define the principle of underlying optimization of radiation protection for occupational workers and the public, including patients. This is practised based on the principles of time, distance and shielding, while placing an emphasis on creating adequate awareness among all stakeholders.
As-built		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
Asepsis		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A state of control attained by using an aseptic work area and performing activities in a manner that precludes microbial contamination of the exposed sterile product.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Aseptic preparation or processing		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The handling of sterile product, containers or devices in a controlled environment in which the air supply, materials and personnel are regulated to prevent microbial, endotoxin/pyrogen and particle contamination.
Aseptic process simulation (APS)		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A simulation of the entire aseptic manufacturing process in order to verify the capability of the process to ensure product sterility. APS includes all aseptic operations associated with routine manufacturing (for example, equipment assembly, formulation, filling, lyophilization and sealing processes, as necessary)
Assessment		
	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	For the purpose of this document, this term covers any evaluation conducted for a regulatory function (e.g. evaluation of a clinical trial application or of an initial marketing authorization for a medical product or any subsequent post-authorization changes, evaluation of safety data, evaluation as part of an inspection).
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A systematic, independent and documented process for obtaining assessment evidence and evaluating it objectively to determine the extent to which assessment criteria are fulfilled.
aterial		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A general term used to denote starting materials (APIs and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.
At-line		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Measurement where the sample is removed, isolated from, and analysed in close proximity to the process stream.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Measurement where the sample is removed, isolated from, and analysed in close proximity to the process stream.
At-rest		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.

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Term	Related reference(s)	Definition
Audit	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (5).
Audit of a trial	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A systematic examination, carried out independently of those directly involved in the trial, to determine whether the conduct of a trial complies with the agreed protocol and whether the data reported are consistent with the records on site, e.g. whether data reported or recorded in the case-report forms (CRFs) are consonant with those found in hospital files and other original records.
Audit trail	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The audit trail is a form of metadata containing information associated with actions that relate to the creation, modification or deletion of GxP records. An audit trail provides for a secure recording of life cycle details such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record regardless of its medium, including the “who, what, when and why” of the action.
Audit trail (1)	Validation of computerized systems (Annex 3, 53rd report, 2019)	The audit trail is a form of metadata that contains information associated with actions that relate to the creation, modification or deletion of GXP records. An audit trail provides for secure recording of life- cycle details, such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record, regardless of its medium, including the “who”, “what”, “when” and “why” of the action. For example, in a paper record, an audit trail of a change would be documented via a single-line cross-out that allows the original entry to remain legible and documents the initials of the person making the change, the date of the change and the reason for the change, as required to substantiate and justify the change. In electronic records, secure, computer-generated, time-stamped audit trails should allow for reconstruction of the course of events relating to the creation, modification and deletion of electronic data. Computer-generated audit trails should retain the original entry and document the user identification and the time/date stamp of the action, as well as the reason for the change, as required to substantiate and justify the action. Computer-generated audit trails may include discrete event logs, history files, database queries or reports, or other mechanisms that display events related to the computerized system, specific electronic records or specific data contained within the record.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Audit trail (2)		
	Good chromatography practices (Annex 4, 54th report, 2020)	A form of metadata that contains information associated with actions that relate to the creation, modification or deletion of GXP records. An audit trail provides for secure recording of life-cycle details such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates reconstruction of the history of such events relating to the record, regardless of its medium, including the “who, what, when and why” of the action.
Auditing (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	An independent and objective activity designed to add value and improve an organization's operations by helping an organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	An independent and objective activity designed to add value and improve an organization's operations by helping an organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Auditing (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	An independent and objective activity designed to add value and improve an organization’s operations by helping it to accomplish its objectives, using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.
Authentication of certificates		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 4.9 of the guidelines.
Authorization, licence, registration		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Because of lack of uniformity in national legal requirements and administrative practices, the term registered, “licenced”and “authorized”have been used in these guidelines as if they were interchangeable. When the guidelines are being used as a basis for drawing up national guidelines, more precise terminology applicable to the country concerned should be used. In some countries, for example, “certificate of drug registration”has been replaced by term such as “marketing authorization”.
Authorized person (1)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A person responsible for the release of batches of finished product for sale. In certain countries the batch documentation of a batch of finished product must be signed by an authorized person from the production department and the batch test results by an authorized person from the quality control department for batch release.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Authorized person (2)	
Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale.
Authorized person (3)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.
Authorized person (4)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale. In some good manufacturing practice (GMP) guides and legal texts, the term qualified person is used to describe analogous functions.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale. In some good manufacturing practice (GMP) guides and legal texts, the term qualified person is used to describe analogous functions.
Authorized product	
WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	A product in compliance with national and regional regulations and legislation. National or regional regulatory authorities can, according to national or regional regulations and legislation, permit the marketing or distribution of medical products with or without registration and/or licence.
Authorized representative	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his or her behalf for specified tasks, with regard to the latter’s obligations under that country or jurisdiction’s legislation (6).
Automatic or live update	
Validation of computerized systems (Annex 3, 53rd report, 2019)	A process used to bring up-to-date software and system functionalities in a silent or announced way. More specifically, the update takes place automatically with or without the user’s knowledge.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Available sample		
	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Whatever total quantity of sample materials is available.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Whatever total quantity of sample materials is available.
Backup		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	A backup means a copy of one or more electronic files created as an alternative in case the original data or system are lost or become unusable (e.g. in the event of a system crash or corruption of a disk). It is important to note that backup differs from archiving, in that backup copies of electronic records are typically only temporarily stored for the purposes of disaster recovery and may be periodically overwritten. Such temporary backup copies should not be relied upon as an archiving mechanism.
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The copying of live electronic data, at defined intervals, in a secure manner to ensure that the data are available for restoration.
Back-up		
	Good chromatography practices (Annex 4, 54th report, 2020)	A copy of one or more electronic files created as an alternative in case the original data or system are lost or become unusable (for example, in the event of a system crash or corruption of a disk). It is important to note that back-up differs from archival, in that back-up copies of electronic records are typically only temporarily stored for the purposes of disaster recovery and may be periodically overwritten. Such temporary back-up copies should not be relied upon as an archival mechanism.
Bacterial retention testing.		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	This test is performed to validate that a filter can remove bacteria from a gas or liquid. The test is usually performed using a standard organism, such as Brevundimonas diminuta, at a minimum concentration of 107 colony-forming units/cm2
Bag		
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container consisting of surfaces, whether or not with a flat bottom, made of flexible material, closed at the bottom and at the sides by sealing; the top may be closed by fusion of the material, depending on the intended use.
Barrier		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A physical partition that affords aseptic processing area (usually grade A) protection by separating it from the background environment. Such systems frequently use in part or totally the barrier technologies known as RABS (restricted access barrier systems) or isolators.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Barrier technology		
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A system designed to segregate people from the product, contain contaminants or segregate two areas, which could be a barrier isolator (BI) or a restricted access barrier system (RABS): • A BI is a unit supplied with high-efficiency particulate air HEPA) filtered air that provides uncompromised continuous isolation of its interior from the external environment, including surrounding clean room air and personnel. • A RABS is a type of barrier system that reduces or eliminates interventions into the critical zone. In practice, its level of contamination control is less than that of a barrier isolator.
Batch (1)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	A defined quantity of starting material, packaging material or product, processed in a single process or series of processes, so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	A defined quantity of starting material, packaging material or product, processed in a single process or series of processes, so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Batch (2)		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	A defined quantity of product processed in a single process or series of processes and therefore expected to be homogeneous. In continuous manufacture, the batch must correspond to a defined fraction of production, characterized by its intended homogeneity.
Batch (3)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous (adapted from GMP).
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous (adapted from GMP).

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Batch (4)	
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A defined quantity of starting material, packaging material or finished pharmaceutical product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Batch (5)	
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A defined quantity of starting material, packaging material or finished pharmaceutical product (FPP) processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Batch (6)	
Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	A quantity of any drug produced during a given cycle of manufacture. The essence of a manufacturing batch is its homogeneity.
Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	A quantity of any drug produced during a given cycle of manufacture. The essence of a manufacturing batch is its homogeneity.
Batch (7)	
Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A defined quantity of any drug product processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality.
Batch (8)	
Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	A quantity of any drug produced during a given cycle of manufacture. If the manufacturing process is continuous, the batch originates in a defined period of time during which the manufacturing conditions are stable and have not been modified.
WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	A quantity of any drug produced during a given cycle of manufacture. If the manufacturing process is continuous, the batch originates in a defined period of time during which the manufacturing conditions are stable and have not been modified.
Batch (9)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A defined quantity of pharmaceutical products processed in a single process or series of processes, so that it is expected to be homogeneous.

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Term	Related reference(s)	Definition
Batch (or lot) (1)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.
Batch (or lot) (2)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.

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Term

Related reference(s)	Definition
Batch (or lot) (3)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.

Term	Related reference(s)	Definition
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave.In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Batch (x10)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A term sometimes used in place of “lot” (see definition of “lot”). WHO recommends that the term “lot” be used when referring to medical devices. “Batch” can also refer to a quantity of individual raw materials.
Batch certificate		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A document containing information, as set out in Appendix 3 of the guidelines, will normally be issued for each batch by the manufacturer. Furthermore, a batch certificate may exceptionally be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate accompanies every major consignment (see also section 3.14 of the guidelines).
Batch number (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
Batch number (2)		
	Good practice in the manufacture and quality control of drugs. (Annex 2, 24th report,1972)	A designation (in numbers and /or letters) printed on the labelling of the drug, that identifies the batch and that permits the production history of the batch, including all stages of manufacture and control, to be traced and reviewed.
Batch number (3)		
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	A designation printed on the label of the drug, that identifies the batch and that permits the production history of the batch, including all stages of manufacture and control, to be traced and reviewed.

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Term	Related reference(s)	Definition
Batch number (4)		
	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	A designation (in numbers and/or letters) that identifies the batch and that permit the production history of the batch, including all stages of manufacture and control, to be traced and reviewed.
Batch number (5)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A distinctive combination of numbers and/or letters that uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
Batch number (or lot number) (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, the batch records, the certificates of analysis, etc.
Batch number (or lot number) (2)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
Batch number (or lot number) (3)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.

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Term	Related reference(s)	Definition
Batch number (or lot number) (4)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A unique combination of numbers, letters and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined.
Batch numbering system		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Standard operating procedure describing the details of the batch numbering.
Batch records		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
BCS highly soluble		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	An API for which the highest dose recommended by WHO (if the API appears on the WHO Model List of essential medicines (EML)) or highest dose strength available on the market as an oral solid dosage form (if the API does not appear on the EML) is soluble in 250 ml or less of aqueous media over the Ph range of 1.2–6.8 at 37 °C (8).
Bead		
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The thickened ring formed at the open end of the condom.
Bioavailability (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	The rate and extent of availability of an active drug ingredient from a dosage form as determined by its concentration-time curve in the systemic circulation or by its excretion in urine.

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Term	Related reference(s)	Definition
Bioavailability (2)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The rate and extent at which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The rate and extent at which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action.
Bioavailability (3)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The rate and extent to which the active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action. Reliable measurements of drug concentrations at the site(s) of action are usually not possible. The substance in the general circulation, however, is considered to be in equilibrium with the substance at the site(s) of action. Bioavailability can be therefore defined as the rate and extent to which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available in the general circulation. Based on pharmacokinetic and clincial considerations it is generally accepted that in the same subject an essentially similar plasma concentration time course will result in an essentially similar concentration time course at the site(s) of action.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	The rate and extent to which the active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action. Reliable measurements of drug concentrations at the site(s) of action are usually not possible. The substance in the general circulation, however, is considered to be in equilibrium with the substance at the site(s) of action. Bioavailability can be therefore defined as the rate and extent to which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available in the general circulation. Based on pharmacokinetic and clincial considerations it is generally accepted that in the same subject an essentially similar plasma concentration time course will result in an essentially similar concentration time course at the site(s) of action.
Biobatch		
	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	The batch used to establish bioequivalence or similarity to the comparator product as determined in bioequivalence or biowaiver studies, respectively.
Bioburden (1)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The level and type (e.g. objectionable or not) of microorganisms that can be present in raw materials, API starting materials, intermediates or APIs. Bioburden should not be considered contamination unless the levels have been exceeded or defined objectionable organisms have been detected.

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Term	Related reference(s)	Definition
Bioburden (2)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The population of microorganisms on a raw material, component, product, packaging or equipment.
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The population of microorganisms on a raw material, component, product, packaging or equipment.
Bioburden (3)		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The total number of microorganisms associated with a specific item, such as personnel, manufacturing environments (air and surfaces), equipment, product packaging, raw materials (including water), in-process materials or finished products.
Biodecontamination		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A process that eliminates viable bioburden via the use of sporicidal chemical agents.
Bioequivalence (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability), after administration in the same moral dose, are similar to such a degree that their effects can be expected to be essentially the same.
Bioequivalence (2)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (Cmax and Tmax) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (Cmax and Tmax) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (Cmax and Tmax) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.

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Term	Related reference(s)	Definition
Bioequivalence (3)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives, and their bioavailabilities, in terms of rate (Cmax and tmax) and extent of absorption (area under the curve (AUC)), after administration of the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.
Bioequivalence (4)	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Two medical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives, and their bioavailability, in terms of rate (C max and t max) and extent of absorption (area under the curve), after administration of the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.
Bioequivalence test	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.
Biological API	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	A substance that is produced by or extracted from a biological source and for which a combination of physicochemical-biological testing and the production process and its control is needed for its characterization and the determination of its quality.
biological indicator	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A population of microorganisms inoculated onto a suitable medium (for example, solution, container or closure) and placed within a sterilizer or load or room location to determine the sterilization or disinfection cycle efficacy of a physical or chemical process. The challenge microorganism is selected and validated based upon its resistance to the given process. Incoming lot D-value, microbiological count and purity define the quality of the biological indicator.
Biological pharmaceutical product (1)	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	A product, the API of which is a biological substance.

Term	Related reference(s)	Definition
Biological pharmaceutical product (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	A biological pharmaceutical product is a synonym for biological product or biological (as described in the reports of the Expert Committee on Biological Standardization in the World Health Organization (WHO) Technical Report Series). The definition of a pharmaceutical substance used in treatment, prevention or diagnosis as a “biological” has been variously based on criteria related to its source, its amenability to characterization by physicochemical means alone, the requirement for biological assays or arbitrary systems of classification applied by regulatory authorities. For the purposes of WHO, including the current document, the list of substances considered to be biologicals is derived from their earlier definition as “substances which cannot be fully characterized by physicochemical means alone and which therefore require the use of some form of bioassay”. However, developments in the utility and applicability of physicochemical analytical methods, improved control of biological and biotechnology-based production methods and an increased applicability of chemical synthesis to larger molecules, have made it effectively impossible to base a definition of a biological on any single criterion related to methods of analysis, source or method of production. Nevertheless many biologicals are produced using in vitro culture systems.
Biopharmaceutics Classification System		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The Biopharmaceutics Classification System (BCS) is a scientific framework for classifying APIs based upon their aqueous solubility and intestinal permeability. When combined with the dissolution of the pharmaceutical product and the critical examination of the excipients of the pharmaceutical product, the BCS takes into account the major factors that govern the rate and extent of API absorption (exposure) from immediate-release oral solid dosage forms: excipient composition, dissolution, solubility and intestinal permeability.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	The Biopharmaceutics Classification System (BCS) is a scientific framework for classifying APIs based upon their aqueous solubility and intestinal permeability. When combined with the dissolution of the pharmaceutical product and the critical examination of the excipients of the pharmaceutical product, the BCS takes into account the major factors that govern the rate and extent of API absorption (exposure) from immediate-release oral solid dosage forms: excipient composition, dissolution, solubility and intestinal permeability.
Biopharmaceutics Classification System (BCS) highly soluble		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	An API for which the highest dose recommended by WHO (if the API appears on the WHO Model list of essential medicines) or highest dose strength available on the market as an oral solid dosage form (if the API does not appear on the WHO Model list of essential medicines) is soluble in 250 ml or less of aqueous media over the pH range of 1.2–6.8 at 37 ºC.
Biotherapeutic		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A biological product with the indication of treating human diseases.

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Term	Related reference(s)	Definition
Biowaiver (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	The term biowaiver is applied to a regulatory drug approval process when the dossier (application) is approved based on evidence of equivalence other than through in vivo equivalence testing.
Biowaiver (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The term biowaiver is applied to a regulatory pharmaceutical product approval process when the dossier (application) is approved based on evidence of equivalence other than through in vivo equivalence testing.
Blending (1)	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Blending is the process of combining materials or different batches to produce a homogenous intermediate or finished product.
Blending (2)	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	The process of combining materials or different batches to produce a homogeneous intermediate or finished product.
Blister	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A multi-dose container consisting of two layers, of which one is shaped to contain the individual doses. Strips are excluded.
Blood collection	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The procedure whereby a single donation of blood is collected in an anticoagulant and/or stabilizing solution, under conditions designed to minimize microbial contamination, cellular damage and/or coagulation activation of the resulting blood donation.
Blood component	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	A constituent of blood (erythrocytes, leukocytes, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods and under such conditions that it can be used either directly for therapeutic purposes or for further processing/manufacturing.
Blood establishment	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release and/or distribution of human blood or blood components when intended for transfusion or further industrial manufacturing.
Blood products	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	Any therapeutic substances derived from human blood, including whole blood, blood components and plasma-derived medicinal products.

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Term	Related reference(s)	Definition
blow-fill-seal (BFS)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A technology in which containers are formed from a thermoplastic granulate, filled with product, and then sealed in a continuous, integrated, automatic operation. The two most common types of BFS machines are the shuttle type (with parison cut) and the rotary type (closed parison).
Bottle	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container with a more or less pronounced neck and usually a flat bottom.
Bracketing (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The design of a stability schedule such that only samples at the extremes of certain design factors, e.g. strength and package size, are tested at all time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. Where a range of strengths is to be tested, bracketing is applicable if the strengths are identical or very closely related in composition (e.g. for a tablet range made with different compression weights of a similar basic granulation, or a capsule range made by filling different plug fill weights of the same basic composition into different size capsule shells). Bracketing can be applied to different container sizes or different fills in the same container-closure system (refer to ICH Q1D).
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The design of a stability schedule such that only samples at the extremes of certain design factors, e.g. strength and package size, are tested at all time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. Where a range of strengths is to be tested, bracketing is applicable if the strengths are identical or very closely related in composition (e.g. for a tablet range made with different compression weights of a similar basic granulation, or a capsule range made by filling different plug fill weights of the same basic composition into different size capsule shells). Bracketing can be applied to different container sizes or different fills in the same container-closure system (refer to ICH Q1D).
Bracketing (2)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	An experimental design to test only the extremes of, for example, dosage strength. The design assumes that the extremes will be representative of all the samples between the extremes.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	An experimental design to test only the extremes of, for example, dosage strength. The design assumes that the extremes will be representative of all the samples between the extremes.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	An experimental design to test only the extremes of, for example, dosage strength. The design assumes that the extremes will be representative of all the samples between the extremes.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Broker	Good chromatography practices (Annex 4, 54th report, 2020)	A person or organization that arranges transactions in relation to the sale or purchase of medical products that consist of negotiating, independently and on behalf of another legal or natural person, and that do not include physical handling.
Bulk harvest	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A homogeneous pool of individual harvests or lysates processed in a single manufacturing run.
Bulk product (1)	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	The product following purification, but before final formulation. It is obtained from a bulk harvest, and is kept in a single container and used in the preparation of the final dosage form.
Bulk product (2)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any product that has completed all processing stages up to, but not including, final packaging.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any product that has completed all processing stages up to, but not including, final packaging.
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	Any product that has completed all processing stages up to, but not including, final packaging.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Any product that has completed all processing stages up to, but not including, final packaging.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Any product that has completed all processing stages up to, but not including, final packaging.
Bulk product (3)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A product that has completed all processing stages up to, but not including, final packaging. (Reference to (should conform with) "Good manufacturing practices for pharmaceutical products")
Bulk product (4)	General guidance on hold-time studies (Annex 4, 49th report, 2015)	Any pharmaceutical product that has completed all processing stages up to, but not including, final packaging.
Bulk product (5)	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Any product that has completed all processing stages, usually not including final packaging and labelling.

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Term	Related reference(s)	Definition
Business continuity plan	Validation of computerized systems (Annex 3, 53rd report, 2019)	A documented plan that defines the ongoing process supported by management and funded to ensure that the necessary steps are taken to identify the impact of potential losses, maintain viable recovery strategies and recovery plans, and assure continuity of services through personnel training, plan testing and maintenance.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Calibration (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

Term

Related reference(s)	Definition
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

Calibration (2)

Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The performance of tests and retests to ensure that measuring equipment (e.g. for temperature, weight, pH) used in a manufacturing process or analytical procedure (in production or quality control) gives measurements that are correct within established limits.

Calibration (3)

Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (for example, weight, temperature and pH), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

Calibration (4)

WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Calibration (5)

WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

Calibration (6)

Good chromatography practices (Annex 4, 54th report, 2020)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

Calibration of equipment

Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	The documented act of proving that the equipment is performing to predefined tolerances or criteria.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
campaign manufacture	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The manufacture of a series of batches of the same product in sequence in a given period of time with strict adherence to established and validated control measures.
Cartridge	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container, usually cylindrical, suitable for liquid or solid pharmaceutical dosage forms; generally for use in a specially designed apparatus (e.g. a prefilled syringe).
Case-report form (CRF)	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A document that is used to record data on each trial subject during the course of the trial, as defined by the protocol. The data should be collected by procedures which guarantee preservation, retention and retrieval of information and allow easy access for verification, audit and inspection.
CE mark (1)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	On condom packaging, a mark certifying that the product conforms to the essential requirements of the European Commission Directive 93/42/EEC on medical devices (4).
CE mark (2)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	On medical product packaging, a mark certifying that the product conforms to the essential requirements of European Medical Device Directive 93/42/EEC.
Central air-conditioning unit	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	See Air-handling unit.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	See Air-handling unit.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	See Air-handling unit.
Certificate of a pharmaceutical starting material	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	A document containing the information (as set out in Appendix 1 of these Guidelines) that is validated and issued for a specific starting material by the competent authority of the exporting country and intended for use by the competent authority in the importing country or in the absence of such an authority by, for example, the manufacturer of the finished product when exporting.

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Term	Related reference(s)	Definition
Certificate of analysis (1)	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Report of the results obtained, including the final conclusion of the examination of a sample issued by the manufacturer and repacker/trader (see Model certificate of analysis. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report. Geneva, World Health Organization, 2002, Annex 10 (WHO Technical Report Series 902)).
Certificate of analysis (2)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The list of test procedures applied to a particular sample with the results obtained and the acceptance criteria applied. It indicates whether or not the sample complies with the specification.
Certificate of analysis (COA)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A document listing the results of testing a representative sample drawn from the batch to be delivered. A COA should be equivalent to the WHO Model COA (Model certificate of analysis. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report. Geneva, World Health Organization, 2002, Annex 10 (WHO Technical Report Series 902)).
Certificate of pharmaceutical product	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A WHO-type certificate of the form described in Guidelines for implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva,World Health Organization, 1998.
Certification (1)	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The final review and formal approval of a validation or revalidation, followed by approval of a process for routine use.
Certification (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The term applied to third party attestation related to products, processes, systems or persons (2).
Certified reference material	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.
Certified reference substances	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Certified reference substances are primary reference substances certified by regulatory bodies.

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Term	Related reference(s)	Definition
Certified true copy or true copy	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	A copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.
Certifying authority	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The competent authority that issues product certificates. It must ensure that it possesses the capacities listed in section 2.4 of the guidelines.
Chain of custody	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	A chronological and continuous record of the seizure and custody of the suspect product and the subsequent transfer of a sample of the suspect product to the laboratory as well as the handling of the sample within the laboratory.
Challenge tests/worst case	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	A condition or set of conditions encompassing upper and lower processing limits and circumstances, within standard operating procedures, that pose the greatest chance of process or product failure when compared with ideal conditions.
Change control (1)	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The processes and procedures to manage system changes.
Change control (2)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
Change control (3)	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the registration and validated status. The intent is to determine the need for action that would ensure that the system is maintained in a regulatory compliant and validated state.

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Term	Related reference(s)	Definition
Change control/Change control (C/C)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.
Characteristic constituents		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Characteristic constituents are chemically defined substances or group(s) of substances that are specific for one medicinal plant or for certain plant species, families or genera.
Charges for product certificates		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.11 of the guidelines.
Chemical reference substance		
	General guidelines for the establishment, maintenance and distribution of chemical reference substances (Annex 3, 41st report, 2007)	The term chemical reference substances, as used in this text, refers to an authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use.
Chemical reference substance (or standard)		
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	An authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use.
Child-resistant container		
	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	A form of packaging difficult for young children to open but not unduly difficult for adults to open properly.

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Term	Related reference(s)	Definition
CJD/vCJD	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	Creutzfeld-Jakob-Disease/variant Creutzfeld-Jakob-Disease.
classified area	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An area that contains a number of cleanrooms [see also cleanroom definition].
Clean area (1)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
Clean area (2)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An area with defined particle and microbiological cleanliness standards, usually containing a number of joined cleanrooms.
Clean area (clean room) (2)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	An area (or room) with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area. *Note: Clean area standards, such as ISO 14644-1 provide details on how to classify air cleanliness by means of particle concentrations, whereas the GMP standards provide a grading for air cleanliness in terms of the condition (at-rest or operational), the permissible microbial concentrations, as well as other factors such as gowning requirements. GMP and clean area standards should be used in conjunction with each other in order to define and classify the different manufacturing environments.

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Term

Related reference(s)	Definition
Clean area (clean room) (3)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	An area (or room or zone) with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	An area (or room or zone) with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.
Clean room (1)	
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A room or area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.
Cleanability	
Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The ability of a cleaning procedure to effectively remove material, cleaning agent residue and microbial contamination.
Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The ability of a cleaning procedure to effectively remove material, cleaning agent residue and microbial contamination.
Cleanability (2)	
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	The factors that impact the ability to remove a residue from surfaces, including material of construction, the solubility of the material in different agents and the matrix of the material being cleaned.
cleaning	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A process for removing contamination (for example, product residues or disinfectant residues).
Cleaning validation	
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented evidence to establish that cleaning procedures are removing residues to predetermined levels of acceptability, taking into consideration factors such as batch size, dosing, toxicology and equipment size.
Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The collection and evaluation of data, from the cleaning process design stage through cleaning at commercial scale, which establishes scientific evidence that a cleaning process is capable of consistently delivering clean equipment, taking into consideration factors such as batch size, dosing, toxicology and equipment size.
Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented evidence to establish that cleaning procedures are removing residues to predetermined levels of acceptability, taking into consideration factors such as batch size, dosing, toxicology and equipment size.

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Term	Related reference(s)	Definition
Cleaning verification	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	The act of demonstrating that cleaning was done to an acceptable level, for example, between two batches.
Cleanroom (2)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A room designed, maintained and controlled to prevent particle and microbial contamination of drug products. Such a room is assigned and reproducibly meets an appropriate air cleanliness level.
cleanroom classification	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A method of assessing the level of air cleanliness against a specification for a cleanroom or clean air equipment by measuring the total particle concentration.
cleanroom qualification	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A method of assessing the level of compliance of a classified cleanroom or clean air equipment with its intended use.
Clean-up	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	(see recovery)
Climatic zone (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The zones into which the world is divided based on the prevailing annual climatic conditions (see Appendix 1: Long-term stability testing conditions as identifi ed by WHO Member States1).
Climatic zone (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The zones into which the world is divided based on the prevailing annual climatic conditions (see reference to the living document “Long-term stability testing conditions as identified by WHO Member States” 4)
Climatic zones	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The four zones into which the world is divided based on the prevailing annual climatic conditions.(see section 2)
Clinical evaluation	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer (7).

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Term

Related reference(s)	Definition
Clinical investigation	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device (7).
Clinical performance	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user (4).

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Term	Related reference(s)	Definition
Clinical trial (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	Any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. Clinical trials are generally divided into Phases I-IV. It is not possible to draw clear distinctions between these phases, and different opinions about details and methodology do exist. However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows: Phase I. These are the first trials of a new active ingredient or new formulations in humans, often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, and an initial pharmacokinetic/ pharmacodynamic profile of the active ingredient. Phase II. The purpose of these therapeutic pilot studies is to determine activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which it is intended. The trials are preformed in a limited number of subjects and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. This phase is also concerned with the determination of appropriate dose ranges/ regimens and (if possible) the clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials. Phase III. This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety-efficacy balance of formulation(s) of the active ingredient, and assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated, and special features of the product must be explored (e.g. clinically relevant drug interactions, factors leading to differences in effect, such as age). The trials should preferably be randomized double-blind, but other designs may be acceptable, e.g. long-term safety studies. In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use. Phase IV. In this phase studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance, and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to Phase IV studies as are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally regarded as trials of new pharmaceutical products.

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Term

Related reference(s)	Definition
Clinical trial (2)	
IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	Any systematic study on (radio)pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, or identify any adverse reaction to, investigational products; and to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. Clinical trials are generally divided into phases I–IV, although phase IV studies usually do not apply to investigational radiopharmaceuticals, and thus are not mentioned further in this guideline. It is not always possible to draw clear distinctions between these phases, and different opinions about the details and methodology exist. However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows: •Phase I. These are the first trials for new radiopharmaceuticals (also called “first in human”), often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, an initial pharmacokinetic and pharmacodynamic profile, and an initial safety assessment of the active ingredient and radiation dosimetry. •Phase II. The purpose of studies in phase II is to determine activity and to assess short-term safety. The trials are performed in a limited number of subjects, but a greater number than in phase I, and aim to determine the optimal administered dose. In the case of therapeutic radiopharmaceuticals, they also aim to clarify the dose–response relationships in order to provide an optimal background for the design of extensive therapeutic trials. •Phase III. This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety and efficacy, and assessing the overall and relative diagnostic accuracy and therapeutic value of the intended radiopharmaceutical. Phase III studies are often multicentric. The pattern and profile of any frequent adverse reaction must be investigated and special features of the product must be explored (for example, clinically relevant drug interactions and factors leading to differences in effect, such as age). In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use.

Term	Related reference(s)	Definition
Clinical trial (3)		
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	Any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, or identify any adverse reaction to, investigational products; and to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. Clinical trials are generally divided into phases I–IV. It is not possible to draw clear distinctions between these phases, and different opinions about details and methodology exist. However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows: •Phase I. These are the first trials of a new active ingredient or new formulation in humans, often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, and an initial pharmacokinetic and pharmacodynamic profile of the active ingredient. •Phase II. The purpose of these therapeutic pilot studies is to determine activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which it is intended. The trials are performed in a limited number of subjects and are often, at a later stage, of a comparative (for example, placebo-controlled) design. This phase is also concerned with the determination of appropriate dose ranges and regimens and (if possible) the clarification of dose–response relationships in order to provide an optimal background for the design of extensive therapeutic trials. •Phase III. This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety and efficacy balance of formulations of the active ingredient, and assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (for example, clinically relevant drug interactions and factors leading to differences in effect, such as age). The trials should preferably be randomized double-blind trials, but other designs may be acceptable, such as long-term safety studies. In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use. •Phase IV. In this phase, studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to phase IV studies as are applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations are normally regarded as trials of new pharmaceutical products.
Clinical trial (or clinical study)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

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Term	Related reference(s)	Definition
Closed system (1)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A system where the product or material is not exposed to the manufacturing environment.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A system where the product or material is not exposed to the manufacturing environment.
Closed system (2)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A system developed for aseptic collection and separation of blood and blood components, manufactured under clean conditions, sealed to the external environment and sterilized by a validated and approved method.
Closed system (3)		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A system in which the product is not exposed to the surrounding environment. For example, this can be achieved by the use of bulk product holders (such as tanks or bags) that are connected to each other by pipes or tubes as a system. Where used for sterile products, the full system is sterilized after the connections are made. Examples of these can be large-scale reusable systems, such as those seen in active substance manufacturing, or disposable bag and manifold systems, such as those seen in the manufacture of biological products. Closed systems are not opened until the conclusion of an operation. The use of the term “closed systems” in this guideline does not refer to systems such as RABS or isolator systems.
Cloud based		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	A model for enabling on-demand network access to a shared pool of configurable computing resources that can be rapidly provisioned and released with minimal management effort or service provider interaction. These computing resources should be appropriately qualified.
Collaborative procedure (Procedure)		
	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	The collaborative procedure to accelerate the national registration of prequalified pharmaceutical products and vaccines, or the collaborative procedure to accelerate the national registration of products approved by stringent regulatory authorities (10, 11). The collaborative registration procedures cover initial registrations and post-registration variations/ post-approval changes.
Collaborative procedure of reference SRA-approved pharmaceutical products and vaccines (Procedure)		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	Registration procedure in which assessment and national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (reference SRAs) is facilitated and accelerated by sharing of detailed assessment and inspection outcomes generated by a reference SRA

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Term	Related reference(s)	Definition
colony-forming unit (cfu) (1)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A unit of measure of the level of microbial contamination of a product.
colony-forming unit (CFU) (2)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A microbiological term that describes a single detectable colony that originates from one or more microorganisms. CFUs are typically expressed as CFU per millilitre (mL) for liquid samples, CFU per square metre (m3) for air samples and CFU per sample for samples captured on solid medium, such as settle or contact plates.
Combined sample	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample resulting from combining all or parts of two or more samples of the material.
Commercial off-the-shelf software (COTS)	Validation of computerized systems (Annex 3, 53rd report, 2019)	Avendor-supplieds oftware component of a computerized system for which the user cannot claim complete control ofthe software life-cycle.
Commingling	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (Annex 5, 35th report, 1999)	The blending of carry-over material from one grade of an excipient with another, usually due to a continuous process.
Commissioning (1)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Commissioning is the documented process of verifying that the equipment and systems are installed according to specifications, placing the equipment into active service and verifying its proper action. Commissioning takes place at the conclusion of project construction but prior to validation.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Commissioning is the documented process of verifying that the equipment and systems are installed according to specifications, placing the equipment into active service and verifying its proper action. Commissioning takes place at the conclusion of project construction but prior to validation.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Commissioning is the documented process of verifying that the equipment and systems are installed according to specifications, placing the equipment into active service and verifying its proper action. Commissioning takes place at the conclusion of project construction but prior to validation.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Commissioning is the documented process of verifying that the equipment and systems are installed according to specifications, placing the equipment into active service and verifying its proper action. Commissioning takes place at the conclusion of project construction but prior to validation.

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Term	Related reference(s)	Definition
Commissioning (2)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	The setting up, adjustment and testing of equipment or a system to ensure that it meets all the requirements, as specified in the user requirement specification, and capacities as specified by the designer or developer. Commissioning is carried out before qualification and validation.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The setting up, adjustment and testing of equipment or a system to ensure that it meets all the requirements, as specified in the user requirement specification, and capacities as specified by the designer or developer. Commissioning is carried out before qualification and validation.
Commitment batches (1)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Production batches of an active pharmaceutical ingredient or finished pharmaceutical product for which the stability studies are initiated or completed post-approval through a commitment made in a regulatory application.
Commitment batches (2)		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Production batches of an API or FPP for which the stability studies are initiated or completed post-approval through a commitment made in a regulatory application.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	Production batches of an API or FPP for which the stability studies are initiated or completed post-approval through a commitment made in a regulatory application.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Production batches of an API or FPP for which the stability studies are initiated or completed post-approval through a commitment made in a regulatory application.
Common carrier		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	A seller of distribution services.
Comparator		
	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	The finished pharmaceutical product with which an FDC-FPP is to be compared. The comparison may be by means of bioequivalence studies or clinical studies of safety and/or effectiveness. A single study may use more than one comparator, for example several single entity FPPs. A comparator may be a placebo.

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Term	Related reference(s)	Definition
Comparator product (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The comparator product is a pharmaceutical product with which the multisource product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. The selection of the comparator product is usually made at the national level by the medicines regulatory authority. (For the WHO Prequalification of Medicines Programme, the selection of the comparator product is based on the information presented under Guidance on bioequivalence studies available on the Prequalification web site.)
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	The comparator product is a pharmaceutical product with which the multisource product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. The selection of the comparator product is usually made at the national level by the medicines regulatory authority. (For the WHO Prequalification of Medicines Programme, the selection of the comparator product is based on the information presented under Guidance on bioequivalence studies available on the Prequalification web site.)
Comparator product (2)		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A pharmaceutical product with which the generic product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. For the Prequalification of Medicines Programme, the selection of the comparator product is based on the information presented under Guidance on bioequivalence studies available on the Prequalification web site.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A pharmaceutical product with which the generic product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. For the Prequalification of Medicines Programme, the selection of the comparator product is based on the information presented under Guidance on bioequivalence studies available on the Prequalification web site.
Comparator product (3)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A pharmaceutical or other product (which may be a placebo) used as a reference in a clinical trial.
Competence		
	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Knowledge, skills and attitude required for successful work performance.
Competence and evaluation of national authority		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See sections 2.4, 2.5 and 4.2 of the guidelines.

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Term	Related reference(s)	Definition
Competent authority (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The national authority as identified in the formal letter of acceptance in which each Member State informs WHO of its intention to participate in the Scheme. The extent of its participation should be indicated in the letter of acceptance (see section 2.1 of the guidelines). The competent authority can issue or receive certificates. WHO makes available on request a continuously updated list of addresses of competent authorities and, when applicable, the specific conditions for participation.
Competent authority (2)	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	The national regulatory authority in the Member State. The competent authority can issue or receive certificates.
Competent regulatory authority	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Any organization that has a legal authority or power to perform a designated regulatory function for authorization of a medical product: the national regulatory authority in the Member State.
Competitive tender	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A procedure for procuring pharamceutical products which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by the suppliers in response to a public notice.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A procedure for procuring pharamceutical products which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by the suppliers in response to a public notice.
Compliance testing (1)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Analysis of active pharmaceutical ingredients (APIs), pharmaceutical excipients, packaging material or pharmaceutical products according to the requirements of a pharmacopoeial monograph or a specification in an approved marketing authorization.
Compliance testing (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A regime of testing to verify that a lot complies with the specification.
Compressed gas	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A gas that, when packaged under pressure for transport, is entirely gaseous at –50 °C; this category includes all gases with a critical temperature less than or equal to –50 °C.

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Term	Related reference(s)	Definition
Computer system	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A group of hardware components and associated software, designed and assembled to perform a specific function or group of functions.
Computer validation	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented evidence which provides a high degree of assurance that a computerized system analyses, controls and records data correctly and that data processing complies with predetermined specifications.
Computerized system (1)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A process or operation integrated with a computer system.
Computerized system (2)	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A system including the input of data, electronic processing and the output of information to be used either for reporting or for automatic control.
Computerized system (3)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A computerized system collectively controls the performance and execution of one or more automated processes and/or functions. It includes computer hardware, software, peripheral devices, networks and documentation, for example, manuals and standard operating procedures, as well as personnel interacting with hardware and software.
	Guidelines on qualification (Annex 3, 53rd report, 2019)	A computerized system collectively controls the performance and execution of one or more automated processes and/or functions. It includes computer hardware, software, peripheral devices, networks and documentation, for example, manuals and standard operating procedures, as well as personnel interacting with hardware and software.
	Validation of computerized systems (Annex 3, 53rd report, 2019)	A computerized system collectively controls the performance and execution of one or more automated processes and/or functions. It includes computer hardware, software, peripheral devices, networks and documentation, for example, manuals and standard operating procedures, as well as personnel interacting with hardware and software.
Computerized system validation (1)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Confirmation by examination and provision of objective documented evidence that specifications for computerized systems conform to user needs and intended uses, and that all requirements can be consistently fulfilled.
Computerized systems validation (2)	Validation of computerized systems (Annex 3, 53rd report, 2019)	Confirmation by examination and provision of objective and documented evidence that a computerized system’s predetermined specifications conform to user needs and intended use and that all requirements can be consistently fulfilled.

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Term	Related reference(s)	Definition
Concurrent validation (1)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Validation carried out during routine production of products intended for sale.
Concurrent validation (2)	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Validation carried out during routine production of products intended for sale in exceptional circumstances when data from replicate production runs are unavailable because only a limited number of batches have been produced, batches are produced infrequently or batches are produced by a validated process that has been modified. Individual batches may be evaluated and released before completion of the validation exercise, based on thorough monitoring and testing of the batches.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Validation carried out during routine production of products intended for sale in exceptional circumstances when data from replicate production runs are unavailable because only a limited number of batches have been produced, batches are produced infrequently or batches are produced by a validated process that has been modified. Individual batches may be evaluated and released before completion of the validation exercise, based on thorough monitoring and testing of the batches.
Condom	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A medical device that is intended to be worn on the penis during sexual activity, for purposes of contraception and to prevent the spread of sexually transmitted infections. Condoms are usually made from natural rubber latex but may also be made from synthetic materials, such as polyurethane.
Configuration management	Validation of computerized systems (Annex 3, 53rd report, 2019)	A discipline applying technical and administrative direction and surveillance to identify and document the functional and physical characteristics of a configuration item, control changes to those characteristics, record and report change processing and implementation status, and verify compliance with specified requirements.
Confirmation testing	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	An execution of tests that confirm and validate the results obtained by another test.
Conformity Assessment	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The systematic examination of evidence generated, and procedures undertaken, by the manufacturer, under requirements established by the regulatory authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore conforms to the Essential principles of safety and performance for medical devices (32).
Conformity assessment body (CAB)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Conformity assessment body (CAB). A body, other than a regulatory authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled (32).

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Term	Related reference(s)	Definition
Consignment (1)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The quantity of a pharmaceutical starting material made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (2)	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	The quantity of a bulk starting material, or of a drug product, made by one manufacturer or supplied by an agent, and supplied at one time in response to a particular request or order. A consignment may comprise one or more lot-identified packages or containers and may include material belonging to more than one lot-identified batch.
Consignment (3)	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Quantity of a bulk starting material, or of a drug product, made by one manufacturer that is supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (4)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.
Consignment (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The quantity of medical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.
Consignment (or delivery) (1)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The quantity of a medical product(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The quantity of a medical product(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (or delivery) (2)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The quantity of starting material, or of a drug product, made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

Term	Related reference(s)	Definition
Consignment (or delivery) (3)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (or delivery) (4)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch (adapted from GMP).
Constituents (1)		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Constituents are chemically defined substances or group(s) of substances found in a herbal material or herbal preparations.
Constituents (2)		
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Chemically defined substances or group/group(s) of substances found in a herbal material or herbal preparation.
Constituents with known therapeutic activity (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (Annex 8, 34th report, 1996)	Substances or groups of substances which are chemically defined and known to contribute to the therapeutic activity of a plant material or of a preparation.
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Substances or groups of substances which are chemically defined and known to contribute to the therapeutic activity of a plant material or of a preparation.
Constituents with known therapeutic activity (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Constituents with known therapeutic activity are substances or group of substances which are chemically defined and known to contribute to the therapeutic activity of a herbal material or of a preparation. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).

Term	Related reference(s)	Definition
Constituents with known therapeutic activity (3)	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Constituents with known therapeutic activity are substances or group(s) of substances which are chemically defined and known to contribute to the therapeutic activity of the herbal material or of a preparation (3, 4).
Constituents with recognized pharmacological (biological) activities	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Constituents with recognized pharmacological (biological) activities are characteristic constituents (substances or group(s) of substances) which are chemically defined and where the relevance of the pharmacological (biological) activities for the therapeutic or toxicological effects of the herbal material or herbal preparation has not yet been fully established.
Consumer pack (1)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A wallet or carton into which one or more foil packages are inserted for marketing purposes.
Consumer pack (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A wallet or carton into which one or more foil packages are inserted for marketing purposes.
Container	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A cryogenic vessel (tank, tanker or other type of mobile cryogenic vessel), a cylinder, a cylinder bundle or any other package that is in direct contact with a gas.
Container (1)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.
Container (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The material employed in the packaging of a medical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

Term	Related reference(s)	Definition
Container closure system		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The sum of packaging components that together contains and protects the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the FPP. A packaging system is equivalent to a container closure system.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The sum of packaging components that together contains and protects the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the FPP. A packaging system is equivalent to a container closure system.
Containers		
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container for pharmaceutical use is an article which holds or is intended to contain and protect a drug and is or may be in direct contact with it. The closure is a part of the container. The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers (see the reference below): • Well-closed containers must protect the contents from extraneous matter or from loss of the substance under normal conditions of handling, shipment or storage. • Tightly closed containers must protect the contents from extraneousmatter, from loss of the substance, and from efflorescence, deliquescence or evaporation under normal conditions of handling, shipment or storage. If the container is intended to be opened on several occasions, it must be designed to be airtight after reclosure. • Hermetically closed containers must protect the contents from extraneous matter and from loss of the substance, and be impervious to air or any other gas under normal conditions of handling, shipment or storage. Substances and dosage forms requiring protection from light should be maintained in a light-resistant container that — either by reason of the inherent properties of the material of which it is composed, or because a special coating has been applied to it — shields the contents from the effects of light. Alternatively, the container may be placed inside a suitable light-resistant (opaque) covering and/or stored in a dark place. (Reference: The international pharmacopoeia, 3rd ed. Vol. 4. Tests, methods, and general requirements. Quality specifications for pharmaceutical substances, excipients, and dosage forms. Geneva, World Health Organization, 1994).

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Term

Related reference(s)	Definition
Containment	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A process or device to contain product, dust or contaminants in one zone, preventing it from escaping to another zone.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A process or device to contain product, dust or contaminants in one zone, preventing it from escaping to another zone.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A process or device to contain product, dust or contaminants in one zone, preventing it from escaping to another zone.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A process or device to contain product, dust or contaminants in one zone, preventing it from escaping to another zone.
Contamination (1)	
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, or intermediate or finished product during production, sampling, packaging or repackaging, storage or transport.
Contamination (2)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The undesired introduction of impurities of a chemical or microbial nature, or of foreign matter, into or on to a starting material or intermediate, during production, sampling, packaging or repackaging, storage or transport.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The undesired introduction of impurities of a chemical or microbial nature, or of foreign matter, into or on to a starting material or intermediate, during production, sampling, packaging or repackaging, storage or transport.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The undesired introduction of impurities of a chemical or microbial nature, or of foreign matter, into or on to a starting material or intermediate, during production, sampling, packaging or repackaging, storage or transport.

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Term	Related reference(s)	Definition
Contamination (3)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transport.
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transport.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transport.
Contamination (4)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter into or on to a raw material, intermediate or API during production, sampling, packaging or repackaging, storage or transport.
Contamination (5)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
Contamination (6)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transportation.
Contamination (7)		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The presence of undesired foreign entities of a chemical, microbiological or physical nature in or on equipment, a starting material, or an intermediate or pharmaceutical product during handling, production, sampling, packaging, repackaging, storage or transport.

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Term

Related reference(s)	Definition
contamination (8)	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The undesired introduction of impurities of a microbiological nature (quantity and type of microorganisms, pyrogen) or of foreign particle matter into or onto a raw material, intermediate, active substance or drug product during production, sampling, packaging or repackaging, storage or transport with the potential to adversely impact product quality.
Contamination control strategy (CCS)	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A planned set of controls for microorganisms, endotoxin/pyrogen and particles, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to active substance, excipient and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.
Continued process verification	
Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Documented scientific evidence that the process remains in a state of control during commercial manufacture.
Non sterile process validation (Annex 3, 53rd report, 2019)	Documented scientific evidence that the process remains in a state of control during commercial manufacture.
Continuous culture production	
Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A system in which the number of passages or population doublings after production has been started is not restricted. Strict criteria for terminating production must be specified by the manufacturer.
Contract (1)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Business agreement for the supply of goods or performance of work at a specified price.
Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	Business agreement for the supply of goods or performance of work at a specified price.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Business agreement for the supply of goods or performance of work at a specified price.
Contract (2)	
Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A document, dated and signed by the investigator, institution and sponsor, that sets out any agreements on financial matters and delegation/distribution of responsibilities. The protocol may also serve as a contract when it contains such information and is signed.
Contract (3)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Business agreement for the supply of goods or performance of work at a specified price; this may include quality elements in the agreement, or in a separate contract.

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Term	Related reference(s)	Definition
Contract acceptor	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An establishment or institution that performs particular work or services under a contract for a different institution.
Contract giver	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An establishment or institution that is subcontracting particular work or services to a different institution and sets up a contract defining the duties and responsibilities of each side.
Contract manufacturer	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A manufacturer performing some aspect of manufacturing on behalf of the original manufacturer.
Contract research organization	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A scientific organization (commercial, academic or other) to which a sponsor may transfer some of its tasks and obligations. Any such transfer should be defined in writing.
Contract research organization (CRO) (1)	Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	An organization (commercial, academic or other) to which an applicant may have transferred some of its tasks and obligations in relation to the conduct of clinical studies with the product submitted to WHO for assessment under the current procedure.
	Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	An organization (commercial, academic or other) to which an applicant may have transferred some of its tasks and obligations in relation to the conduct of clinical studies with the product submitted to WHO for assessment under the current procedure.
Control (noun)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The state wherein correct procedures are being followed and criteria are being met.
Control (verb)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The taking of all necessary actions to ensure and maintain compliance with the criteria established in the HACCP plan.
Control measure	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	Any action and activity that can be used to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.
Control sample	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A sample used for testing the continued accuracy and precision of the procedure. It should have a matrix similar to that of the samples to be analysed. It has an assigned value with its associated uncertainty.

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Term

Related reference(s)	Definition
Control strategy (1)	
Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.
Control strategy (2)	
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to materials and components related to drug substances and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.
Control strategy (3)	
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A planned set of controls, derived from current product and process understanding that ensures process performance and product quality. The controls can include parameters and attributes related to active pharmaceutical ingredient and finished pharmaceutical product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.
WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A planned set of controls, derived from current product and process understanding that ensures process performance and product quality. The controls can include parameters and attributes related to active pharmaceutical ingredient and finished pharmaceutical product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.
Control strategy (4)	
Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	A planned set of controls, derived from current product and process understanding that assures process performance and product quality. The controls can include parameters and attributes related to API and finished pharmaceutical product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications and the associated methods and frequency of monitoring and control.
Non sterile process validation (Annex 3, 53rd report, 2019)	A planned set of controls, derived from current product and process understanding that assures process performance and product quality. The controls can include parameters and attributes related to API and finished pharmaceutical product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications and the associated methods and frequency of monitoring and control.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A planned set of controls, derived from current product and process understanding that assures process performance and product quality. The controls can include parameters and attributes related to API and finished pharmaceutical product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications and the associated methods and frequency of monitoring and control.

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Term	Related reference(s)	Definition
Controlled area	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	An area within the facility in which specific environmental facility conditions and procedures are defined, controlled, and monitored to prevent degradation or cross-contamination of the product.
Controlled area (classified area)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	An area within the facility in which specific procedures and environmental parameters, including viable and nonviable particles, are defined, controlled and monitored to prevent degradation, contamination or cross-contamination of the product.
Controlled drugs	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	Narcotic drugs and psychotropic substances regulated by provisions of national drug laws.
Controlled not classified	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	An area where some environmental conditions or other attributes (such as temperature) are controlled, but the area has no cleanroom classification.
Controlled or hazardous time- and temperature-sensitive pharmaceutical products	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Time- and temperature-sensitive pharmaceutical products (TTSPPs) with high illicit value: poisons, narcotics, psychotropic products, inflammable or explosive substances and radioactive materials.
Convergence (regulatory)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Convergence (regulatory). Represents a process whereby the regulatory requirements across countries or regions become more similar or “aligned” over time as a result of the gradual adoption of internationally-recognized technical guidance documents, standards and scientific principles, common or similar practices and procedures, or adaptation of regulatory mechanisms, that might be specific to a local legal context but that align with shared principles to achieve a common public health goal. It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation (9).
Cooperation agreement	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A formal business document outlining the basic terms of an agreement with another individual, group or entity. It is one of the first steps towards a more detailed contract. Alternative names include, but are not limited to, memorandum of understanding, cooperation contract or collaboration agreement.

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Term	Related reference(s)	Definition
Co-packaged product	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A product consisting of two or more separate pharmaceutical products in their final dosage form that are packaged together for distribution to patients in the co-packaging.
Co-regulation	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	A system of shared regulatory responsibilities in which an industry association or professional group assumes some regulatory functions, such as surveillance and enforcement or setting regulatory standards.
Correction	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Any action that is taken to eliminate a nonconformity. However, corrections do not address causes.
Corrective action (1)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	Any action to be taken when the results of monitoring at the CCP (critical control point) indicate a loss of control.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Any action to be taken when the results of monitoring at the CCP (critical control point) indicate a loss of control.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Any action to be taken when the results of monitoring at the CCP (critical control point) indicate a loss of control.
Corrective action (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Action to eliminate the cause of a detected nonconformity or other undesirable situation (10).
Corrective actions (1)	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	Steps taken to eliminate the cause of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations do not happen again.
Corrective actions (2)	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to ensure that existing nonconformities and potentially undesirable situations do not happen again.
Corrective and preventative actions (CAPA)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.

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Term	Related reference(s)	Definition
Corrective intervention	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An intervention that is performed to correct or adjust an aseptic process during its execution. This may not occur at a set frequency in the routine aseptic process. Examples include clearing component jams, stopping leaks, adjusting sensors and replacing equipment components.
Counterfeit	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
Counterfeit pharmaceutical product (1)	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A pharmaceutical product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an insufficient quantity of active ingredient or with fake packaging.
Counterfeit pharmaceutical product (2)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A pharmaceutical product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging.
Counterfeit product	Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	A pharmaceutical product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.
Critical (1)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Describes a process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the API meets its specification.

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Term	Related reference(s)	Definition
Critical (2)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Having the potential to impact on product quality or performance in a significant way.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Having the potential to impact on product quality or performance in a significant way.
Critical control point (CCP)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	A step at which control can be applied and is essential to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A step at which control can be applied and is essential to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.
Critical defect		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A defect that might affect the safety, acceptability or effectiveness of the product is classified as a critical defect, causing the device to be rejected.
Critical intervention		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An intervention (corrective or inherent) into the critical zone.
Critical limit		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	A criterion which separates acceptability from unacceptability.
Critical operation		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An operation in the manufacturing process that may cause variation in the quality of the pharmaceutical product.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	An operation in the manufacturing process that may cause variation in the quality of the pharmaceutical product.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	An operation in the manufacturing process that may cause variation in the quality of the pharmaceutical product.

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Term	Related reference(s)	Definition
Critical parameter or component (1)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A processing parameter (such as temperature or humidity) that affects the quality of a product, or a component may have a direct impact on the quality of the product.
Critical parameter or component (2)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A processing parameter (such as temperature or relative humidity) that affects the quality of a product, or a component that may have a direct impact on the quality of the product.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A processing parameter (such as temperature or relative humidity) that affects the quality of a product, or a component that may have a direct impact on the quality of the product.
Critical process		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A process that may cause variation in the quality of the pharmaceutical product.
Critical process parameter (4)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored and controlled to ensure the process produces the desired quality.
Critical process parameter (CPP) (1)		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored and/or controlled to ensure the process produces the desired quality.
Critical process parameter (CPP) (2)		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	A process parameter whose variability has an impact on a critical quality attribute and, therefore, should be monitored or controlled to ensure the process produces the desired quality.
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A process parameter whose variability has an impact on a critical quality attribute and, therefore, should be monitored or controlled to ensure the process produces the desired quality.
Critical process parameter (CPP) (3)		
	Non sterile process validation (Annex 3, 53rd report, 2019)	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored and/or controlled to ensure the process produces the desired quality.

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Term	Related reference(s)	Definition
Critical quality attribute (CQA)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
	Non sterile process validation (Annex 3, 53rd report, 2019)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.
Critical surface		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A surface that may come directly into contact with, or directly affect, a sterile product or its containers or closures. Critical surfaces are rendered sterile prior to the start of the manufacturing operation and sterility is maintained throughout processing.
Critical zone		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A location within the aseptic processing area in which product and critical surfaces are exposed to the environment.
Cross-contamination		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	Contamination of a starting material, intermediate product or finished product with another starting material or product.

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Term

Related reference(s)	Definition
Cross-contamination (1)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Cross-contamination (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Cross-contamination (3)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Contamination of a material or product with another material or product.

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Term	Related reference(s)	Definition
Cross-contamination (4)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Contamination of a starting material, intermediate product or finished pharmaceutical product with another starting material or product during production, storage and transportation.
Cross-contamination (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Contamination of a starting material, intermediate product or finished pharmaceutical product or medical product with another starting material or product, during production, storage and transportation.
Cross-over bench	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Cross-over or step-over bench in the changing room to demarcate the barrier between different garment change procedures.
Cryogenic gas	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A gas that liquefies at 1.013 bar at temperatures below –150 °C .
Curie	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The unit of radioactivity. This is defined in terms of the number of nuclear transformations that occur in a quantity of radioactive material in unit time. One Curie (Ci) is 3.7 x 1010 nuclear transformations per second. Convenient subunits are the milliCurie (mCi, 10-3Ci) and microCurie (µCi, 10-6Ci).
Customer	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. Customers of an NRA include individuals or parties who receive or could receive and use products and services that are provided and offered by the NRA. These parties include the general public, patients, manufacturers, distributors, health practitioners, researchers, the ministry of health and other individuals and institutions that rely on the NRA's products and services to make public health decisions.
Customer satisfaction	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	A customer's perception of the degree to which the customer's expectations have been fulfilled. This relates to the expectations that different parties have of the NRA. The expectations include assurance that safe, efficacious and high-quality medical products will be available under the NRA mandate to regulate, and that the NRA will provide other products such as guidelines, public reports and related regulatory services that meet the expectations of different types of customers.
Cylinder	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A container, usually cylindrical, suited for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.

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Term	Related reference(s)	Definition
Cylinder bundle	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	An assembly of cylinders that are fastened together, interconnected by a manifold, transported and used as a unit.
Data	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	All original records and true copies of original records, including source data and metadata, and all subsequent transformations and reports of these data which are generated or recorded at the time of the GMP activity and which allow full and complete reconstruction and evaluation of the GMP activity. Data should be accurately recorded by permanent means at the time of the activity. Data may be contained in paper records (such as worksheets and logbooks), electronic records and audit trails, photographs, microfilm or microfiche, audio or video files or any other media whereby information related to GMP activities is recorded.
Data (1)	Validation of computerized systems (Annex 3, 53rd report, 2019)	All original records and true copies of original records, including source data and metadata, and all subsequent transformations and reports of these data, which are generated or recorded at the time of the GMP activity and allow full and complete reconstruction and evaluation of the GMP activity. Data should be accurately recorded by permanent means at the time of the activity. Data may be contained in paper records (such as worksheets and logbooks), electronic records and audit trails, photographs, microfilm or microfiche, audio or video files or any other media whereby information related to GMP activities is recorded.
Data (2)	Good chromatography practices (Annex 4, 54th report, 2020)	All original records and true copies of original records, including source data and metadata and all subsequent transformations and reports of these data, that are generated or recorded at the time of the good manufacturing practices (GMP) activity and allow full and complete reconstruction and evaluation of the GMP activity. Data should be accurately recorded by permanent means at the time of the activity. Data may be contained in paper records (such as worksheets and logbooks), electronic records and audit trails, photographs, microfilm or microfiche, audio- or video-files, or any other media whereby information related to GMP activities is recorded.
Data criticality	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	This is defined by the importance of the data for the quality and safety of the product and how important data are for a quality decision within production or quality control
Data governance	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The sum total of arrangements which provide assurance of data quality. These arrangements ensure that data, irrespective of the process, format or technology in which it is generated, recorded, processed, retained, retrieved and used will ensure an attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available record throughout the data life cycle.

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Term	Related reference(s)	Definition
Data integrity (1)	Validation of computerized systems (Annex 3, 53rd report, 2019)	The degree to which data are complete, consistent, accurate, trustworthy and reliable and to which these characteristics of the data are maintained throughout the data life-cycle. The data should be collected and maintained in a secure manner, such that they are attributable, legible, contemporaneously recorded, original or a true copy and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices (1).
Data integrity (2)	General guidance on hold-time studies (Annex 4, 49th report, 2015)	The degree to which data are complete, consistent, accurate, trustworthy and reliable and to which these characteristics of the data are maintained throughout the data life-cycle. The data should be collected and maintained in a secure manner, such that they are attributable, legible, contemporaneously recorded, original or a true copy and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices.
Data integrity risk assessment (DIRA)	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The process to map out procedures, systems and other components that generate or obtain data; to identify and assess risks and implement appropriate controls to prevent or minimize lapses in the integrity of the data.
Data life cycle	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	All phases of the process by which data are created, recorded, processed, reviewed, analysed and reported, transferred, stored and retrieved and monitored, until retirement and disposal. There should be a planned approach to assessing, monitoring and managing the data and the risks to those data, in a manner commensurate with the potential impact on patient safety, product quality and/or the reliability of the decisions made throughout all phases of the data life cycle.
Data life-cycle	Validation of computerized systems (Annex 3, 53rd report, 2019)	All phases of the process by which data are created, recorded, processed, reviewed, analysed and reported, transferred, stored and retrieved and monitored, until retirement and disposal. There should be a planned approach to assessing, monitoring and managing the data and the risks to those data, in a manner commensurate with potential impact on patient safety, product quality and/or the reliability of the decisions made throughout all phases of the data life-cycle.
Date of manufacture (1)	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	A date fixed for the individual batch, indicating the completion date of the manufacture. It is normally expressed by a month and a year. The date of the release analysis may be taken as a date of manufacture, provided that the period between the beginning of production and the release of the product is not longer than one-twentieth of the shelf-life.

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Term	Related reference(s)	Definition
Date of manufacture (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The date on which the condoms were dipped.
Dead leg	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Length of non-circulating pipe (where fluid may remain static) that is greater than three internal pipe diameters.
Declaration of conformity	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The manufacturer's written attestation that it has correctly applied the conformity assessment elements relevant to the classification of the device (32).
Decommission	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	To close and remove from use a process, equipment or cleanroom.
Decontamination	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The overall process of removal or reduction of any contaminants (chemical, waste, residue or microorganisms) from an area, object or person. The method of decontamination used (for example, cleaning, disinfection, sterilization) should be chosen and validated to achieve a level of cleanliness appropriate to the intended use of the item decontaminated [see also biodecontamination]

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Term

Related reference(s)	Definition
Defined storage instructions	
Stability of drug dosage forms.(Annex 1, 31st report, 1990)	Drug products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated, e.g., continuous maintenance of cold storage, deviation may be tolerated only during short-term interruptions, for example during local transportation. The following instructions are recommended: On the label: — Means: “Do not store over 30°C” — from +2°C to + 30°C “Do not store over 25°C” — from +2°C to + 25°C “Do not store over 15°C” — from +2°C to + 15°C “Do not store over 8°C” — from +2°C to + 8°C “Do not store below 30°C ” — from +2°C to + 30°C “Protect from moisture” — no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture-resistant container. “Protect from light” — to be provide to the patient in a light-resistant container.
Depyrogenation	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A process designed to remove or inactivate pyrogenic material (such as endotoxin) to a specified minimum quantity.

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Term	Related reference(s)	Definition
Design condition		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Design condition relates to the specified range or accuracy of a controlled variable used by the designer as a basis to determine the performance requirements of an engineered system.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Design condition relates to the specified range or accuracy of a controlled variable used by the designer as a basis to determine the performance requirements of an engineered system.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Design condition relates to the specified range or accuracy of a controlled variable used by the designer as a basis to determine the performance requirements of an engineered system.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Design condition relates to the specified range or accuracy of a controlled variable used by the designer as a basis to determine the performance requirements of an engineered system.
Design qualification (DQ) (1)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The documented check of planning documents and technical specifications for design conformity with the process, manufacturing, good manufacturing practices and regulatory requirements.
Design qualification (DQ) (2)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	DQ is the documented check of planning documents and technical specifications for design conformity with the process, manufacturing, GMP and regulatory requirements.
Design qualification (DQ) (3)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented evidence that the premises, supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of GMP.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Documented evidence that the premises, supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of GMP.
Design qualification (DQ) (4)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Documented collection of activities that define the functional and operational specifications of the instrument and criteria for selection of the vendor, based on the intended purpose of the instrument.
Design qualification (DQ) (5)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Design qualification is the documented check of planning documents and technical specifications for conformity of the design with the process, manufacturing, GMP and regulatory requirements.

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Term	Related reference(s)	Definition
Design qualification (DQ) (6)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented verification that the proposed design of facilities, systems and equipment is suitable for the intended purpose.
Design qualification (DQ) (7)	Guidelines on qualification (Annex 3, 53rd report, 2019)	Documented evidence that, for example, the premises, supporting systems, utilities and equipment have been designed for their intended purposes and in accordance with the requirements of good manufacturing practices.
Design requirements	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	Characteristics of the condom that are specified according to the buyer's requirements.
Design space	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	The multidimensional combination and interaction of input variables (e.g.material attributes) and process parameters that have been demonstrated to provide assurance of quality.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The multidimensional combination and interaction of input variables (e.g.material attributes) and process parameters that have been demonstrated to provide assurance of quality.
Desk assessment	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	The evaluation of documentary evidence by a competent regulatory authority recognized by the national regulatory authority, for compliance with the required good practices (good manufacturing practices (GMP), good laboratory practices and good clinical practices) in support of marketing authorization and other regulatory decisions. Desk assessment may be performed in support of a new marketing authorization, or for routine GMP inspection (including in the frame of specified product(s) life-cycle management as required).
Deviation (1)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	Failure to meet a critical limit.
Deviation (2)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Departure from an approved instruction or established standard.
Differential pressure	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The difference in pressure between two points, such as the pressure difference between an enclosed space and an independent reference point, or the pressure difference between two enclosed spaces.

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Term	Related reference(s)	Definition
Direct impact system		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A system that is expected to have a direct impact on product quality. These systems are designed and commissioned in line with good engineering practice (GEP) and, in addition, are subject to qualification practices.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A system that is expected to have a direct impact on product quality. These systems are designed and commissioned in line with good engineering practice (GEP) and, in addition, are subject to qualification practices.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A system that is expected to have a direct impact on product quality. These systems are designed and commissioned in line with good engineering practice (GEP) and, in addition, are subject to qualification practices.
Disaster recovery		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	A documented process or set of procedures to recover and protect a business IT infrastructure in any event causing the system to be unavailable. It appropriately defines resources and actions to be taken before, during and after a disaster, to return the system to operational use.
Disinfection		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The process by which a reduction of the number of microorganisms is achieved by the irreversible action of a product on their structure or metabolism to a level deemed to be appropriate for a defined purpose.
Dispensing		
	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	The generation of a patient-specific unit dose, which involves physical withdrawal of the radiopharmaceutical from the bulk single-use or multidose vial into a syringe; dilution with an appropriate diluent as necessary; measurement of the radioactivity content; and labelling of the syringe.
Distribution (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.
Distribution (2)		
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent.
Distribution (3)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The act of delivery of blood and blood components to other blood establishments, hospital blood banks or manufacturers of blood- and plasma-derived medicinal products. It does not include the issuing of blood or blood components for transfusion.

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Term	Related reference(s)	Definition
Distribution chain	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Distribution chain. A collective term for local manufacturers, authorized representatives, importers and distributors established within the jurisdiction.
Distributor	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end-user (6).
Donor	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A person in defined good health conditions who voluntarily donates blood or blood components, including plasma for fractionation.
Dosage form (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The form of the FPP, e.g. tablet, capsule, elixir or suppository.
Dosage form (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir, injection, suppository.
Dosage form (3)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The form of the completed pharmaceutical preparation, e.g. tablet, capsule, elixir, suppository.
Dosage form (4)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir or suppository.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir or suppository.
Dosage form (5)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The form of the finished pharmaceutical product, e.g. tablet, capsule, elixir or suppository.

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Term	Related reference(s)	Definition
Dossier	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	The regulatory submission package submitted to the national regulatory authority as an application for marketing authorization in line with the applicable country requirements and requirements specified in the respective Procedure guidelines (2, 3).
Drug (1)	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	An active pharmaceutical ingredient or a pharmaceutical product (see also pharmaceutical excipient and pharmaceutical product).
Drug (2)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Any substance or product for human or veterinary use that is intended to modify or explore physiological states for the benefit of the recipient.
Drug (3)	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the term drug, medicine and pharmaceutical product (see below) are used interchageably.
Drug (4)	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	Any substance or mixture of substances that is manufactured, sold, offered for sale, or represented for use in: (1) the treatment, mitigation, prevention, or diagnosis of disease, an abnormal physical state, or the symptoms thereof in man or animal; or (2) the restoration, correction or modification of organic functions in man or animal.
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	Any substance or mixture of substances that is manufactured, sold, offered for sale, or represented for use in: (1) the treatment, mitigation, prevention, or diagnosis of disease, an abnormal physical state, or the symptoms thereof in man or animal; or (2) the restoration, correction or modification of organic functions in man or animal.
Drug (pharmaceutical product)	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	Any substance or mixture of substances that is manufactured for sale or distribution, sold, supplied, offered for sale of presented for use in: (i) the treatment, mitigation, cure , prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in human or animal; or (ii) the restoration, correction or modification of organic functions in human or animal.
Drug legislation	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The legal conditions under which pharmaceutical activities should be organized. (See also legislation below.)

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Term	Related reference(s)	Definition
Drug master file (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (Annex 5, 35th report, 1999)	Detailed information concerning a specific facility, process or product submitted to the drug regulatory authority, intended for the incorporation into the application for marketing authorization.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Detailed information concerning a specific facility, process or product submitted to the drug regulatory authority, intended for the incorporation into the application for marketing authorization.
Drug master file (2)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Detailed information concerning a specific facility, process, packaging material or product submitted to the medicines regulatory authority, intended for incorporation into the application for marketing authorization.
Drug regulatory authority (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	An authority appointed by the government of a Member State to administer the granting of marketing authorizations for pharmaceutical products in that country.
Drug regulatory authority (2)		
	Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	The national agency responsible for the registration of and other regulatory activities concerning pharmaceutical products.
Drug regulatory authority (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A national body that administers the full spectrum of drug regulatory activities, including at least all of the following functions in conformity with national drug legislation: •□marketing authorization of new products and variation of existing products; •□quality control laboratory testing; •□adverse drug reaction monitoring; •□provision of drug information and promotion of rational drug use; •□good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels; •□enforcement operations; •□monitoring of drug utilization.
Dunnage		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Loose packing material used to protect TTSPPs from damage during transport.
D-value		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The value of a parameter of sterilization (duration or absorbed dose) required to reduce the number of viable organisms to 10% of the original number.

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Term	Related reference(s)	Definition
Dynamic data	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	Dynamic formats, such as electronic records, allow an interactive relationship between the user and the record content. For example, electronic records in database formats allow the user to track, trend and query data; chromatography records maintained as electronic records allow the user or reviewer (with appropriate access permissions) to reprocess the data and expand the baseline to view the integration more clearly.
Earliest expiry/first out principle concept (EEFO)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A distribution procedure to ensure that the stock with the earliest expiry date is distributed and/or utilized before an identical stock item with a later expiry date is distributed and/or utilized.
Effectiveness	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	An expression of the degree to which activities have produced the effects planned.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	An expression of the degree to which activities have produced the effects planned.
Efficiency	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The relationship between the results of activities and the corresponding effort expended in terms of money, resources and time.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The relationship between the results of activities and the corresponding effort expended in terms of money, resources and time.
Electronic signatures	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	A signature in digital form (bio-metric or non-biometric) that represents the signatory. In legal terms, it is the equivalent of the handwritten signature of the signatory.
Endotoxin	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A pyrogenic product (lipopolysaccharide) present in the Gram-negative bacterial cell wall. Endotoxin can lead to reactions in patients receiving injections ranging from fever to death
Enforcement	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Action taken by an authority to protect the public from products of suspect quality, safety and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards and commitments made as part of the approval to market a product (11).

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Term	Related reference(s)	Definition
Environmental control system (ECS)		
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Environmental control system, also referred to as heating, ventilation and air-conditioning (HVAC).
Equilibration time.		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The period that elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load.
Equivalence of regulatory systems		
	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	Implies strong similarity between two regulatory systems, as mutually established and documented through objective evidence. Equivalence can be established using criteria and approaches such as similarity of the regulatory framework and practices, adherence to the same international standards and guidelines, experience gained in use of assessments for regulatory decision making, joint activities and exchanges of staff. It is expected that equivalent regulatory systems will result in similar standards and levels of regulatory oversight or “control”.
Equivalence requirements		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	In vivo and/or in vitro testing requirements for approval of a multisource pharmaceutical product and marketing authorization.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	In vivo and/or in vitro testing requirements for approval of a multisource pharmaceutical product and marketing authorization.
Equivalence test		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.

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Term	Related reference(s)	Definition
Essential pharmaceutical products		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Those pharmaceutical products that satisfy the health care needs of the majority of the population. WHO's Expert Committee on the Selection and Use of Essential Medicines updates the WHO Model List of Essential Medicines at two-year intervals. Each country may use this model to generate its own list of essential pharmaceutical products.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Those pharmaceutical products that satisfy the health care needs of the majority of the population. WHO's Expert Committee on the Selection and Use of Essential Medicines updates the WHO Model List of Essential Medicines at two-year intervals. Each country may use this model to generate its own list of essential pharmaceutical products.
Established multisource (generic) product		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A multisource product that has been marketed by the applicant or manufacturer associated with the dossier for at least five years and for which at least 10 production batches were produced over the previous year, or, if less than 10 batches were produced in the previous year, not less than 25 batches were produced in the previous three years.
Ethics committee		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	An independent body (a review board or a committee, institutional, regional or national), constituted of medical professionals and non medical members, whose responsibility is to verify that the safety, integrity and human rights of the subjects participating in a particular trial are protected and to consider the general ethics of the trial, thereby providing public reassurance. Ethics committees should be constituted and operated so that their tasks can be executed free from bias and from any influence of those who are conducting the trial.
Evacuate		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	To remove residual gas from a container or system to a vacuum level of 0.84 bar absolute at sea level using a vacuum system.
Excipient (1)		
	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to: — aid in the processing of the drug delivery system during its manufacture; — protect, support or enhance stability, bioavailability, or patient acceptability; — assist in product identification; or — enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.
Excipient (2)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a pharmaceutical product.
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a pharmaceutical product.

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Term	Related reference(s)	Definition
Excipient (3)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a finished pharmaceutical product.
Excipient (4)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A substance or compound, other than the API and packaging materials, that is intended or designated to be used in the manufacture of a FPP.
Excipient (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system, to aid in the processing of the drug delivery system during its manufacture; protect, support or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.
Exfiltration (1)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Exfiltration is the egress of air from a controlled area to an external zone.
Exfiltration (2)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The egress of air from a controlled area to an external zone.
Existing active pharmaceutical ingredient	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	An active pharmaceutical ingredient that is not considered a new active substance, which has been previously approved through a finished product by a stringent regulatory authority or by the World Health Organization, but requires the filing of a dossier. This would include, for example, new product dossiers and variations to multisource products.
Existing API (1)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	An API that is not considered a new active substance, which has been previously approved through a finished product by a stringent regulatory authority or by WHO, but requires the filing of a dossier. This would include, for example, new PDs and variations to multisource products.
Existing API (2)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	An API that is not considered a new active substance, that has been previously approved through a finished product by an SRA or WHO, but requires the filing of a dossier. This would include, for example, new PDs and variations to multisource products.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Expiry (expiration) date (1)	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	The expiry date placed on the container of a drug product designates the date up to and including which the product is expected to remain within specification if stored correctly. It is established for every batch by adding the shelf-life period to the manufacturing date.
Expiry date (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The date at which the product is no longer considered acceptable for use.
Expiry date (3)	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	The date given on the individual container (usually on the label) of a drug product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life period to the date of manufacture.
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The date given on the individual container (usually on the label) of a drug product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life period to the date of manufacture.
Expiry date (4)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The expiry date displayed on the container of a pharmaceutical starting material is the date up to and including which the pharmaceutical starting material is expected to remain within specification if stored correctly. It is established for every batch by adding the shelf-life to the date of manufacture.
Expiry date (5)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Expiry date (6)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The date given on the individual container (usually on the label) of a product up to and including which the API and FPP are expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Expiry date (7)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Expiry date (8)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The date given on the individual container (usually on the label) of a product up to and including which the active pharmaceutical ingredient and finished pharmaceutical product are expected to remain within specifications if stored under the long-term conditions at which stability was established. It is set for each batch by adding the shelf life to the date of manufacture.
Expiry date (9)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The date given on the individual container (usually on the label) of a medical product, up to and including the date on which the product is expected to remain within specifications if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Expiry date (or expiration date) (x10)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The date placed on the container or labels of a medical product designating the time during which it is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The date placed on the container or labels of a medical product designating the time during which it is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used.
Expiry date (or expiration date) (x11)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The date placed on the container or labels of an API designating the time during which the API is expected to remain within established shelf-life specifications if stored under defined conditions and after which it should not be used.
Expiry date (x12)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	The date placed on the container or label of an investigational product designating the time during which the investigational product is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used.
Expiry date (x13)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	In the context of IUD manufacture, the expiry date is the date after which raw materials, components, and so on, are no longer considered acceptable for manufacturing iuds.
Exterior shipping carton	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The container into which a number of inner boxes are packed.
External distribution	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Transport of TTSPPs through various steps in the customer's supply chain (i.e. transport from a pharmaceutical manufacturer's distribution centre to commercial customers (including wholesalers, retailers and buying groups),to clinical facilities or direct to the patient).

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Extract air	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Air leaving a space, which could be either return air or exhaust air. Return air refers to air that is returned to the air-handling unit and exhaust air is air that is vented to the atmosphere.
Extractable	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A chemical entity that migrates from the surface of the process equipment, exposed to an appropriate solvent at extreme conditions, into the product or material being processed.
Facility	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The built environment within which the clean area installation and associated controlled environments operate together with their supporting infrastructure.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The built environment within which the clean area installation and associated controlled environments operate together with their supporting infrastructure.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The built environment within which the clean area installation and associated controlled environments operate together with their supporting infrastructure.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The built environment within which the clean area installation and associated controlled environments operate together with their supporting infrastructure.
Factory acceptance test	Guidelines on qualification (Annex 3, 53rd report, 2019)	A test conducted, usually at the vendor's premises, to verify that the system, equipment or utility, as assembled or partially assembled, meets approved specifications.
Failure mode	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Different ways that a process or subprocess can fail to provide the anticipated result.
Failure mode, effects and criticality analysis (FMECA)	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A systematic method of identifying and preventing product and process problems.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Falsified medical products	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	Medical products that deliberately or fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate or fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product. -This definition reflects the ongoing discussion in the Member State mechanism under the auspices of the World Health Assembly; see Appendix 3 in reference (11).
Falsified product (1)	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	For the purposes of this document, a product that has been deliberately and/or fraudulently misrepresented as to its identity, composition or source, and which therefore requires testing beyond the routine quality control testing. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized product or the manufacture of a product that is not an authorized product. “Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized product. “Composition” shall refer to any ingredient or component of the product in accordance with applicable specifications authorized/recognized by the NRA. “Source” shall refer to the identification, including name and address, of the marketing authorization. Holder, manufacturer, importer, exporter, distributor or retailer, as applicable.3
Falsified product (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A product that has been deliberately and/or fraudulently misrepresented as to its identity, composition or source. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorized product, or the manufacture of a product that is not an authorized product. “Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized product. “Composition” shall refer to any ingredient or component of the product in accordance with applicable specifications authorized/recognized by the national regulatory authority (NRA). “Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable (7).
Field safety corrective action (FSCA)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Field safety corrective action (FSCA). An action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market (12).
Filter integrity test	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A test to confirm that a filter (product, gas, or heating, ventilation and air-conditioning (HVAC) filter) retains its retentive properties and has not been damaged during handling, installation or processing.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Final dosage form	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	The finished formulated product; it may be freeze-dried and contain excipients, which should have been shown not to affect stability adversely.
Final intermediate	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	The last reaction intermediate in the synthetic pathway that undergoes synthetic transformation to the API or the crude API. Purification is not considered to be a synthetic transformation.
Final report	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A comprehensive description of the trial after its completion including a description of experimental methods (including statistical methods) and materials, a presentation and evaluation of the results, statistical analysis and a critical, ethical, statistical and clinical appraisal.
Final sample	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample ready for the application of the test procedure.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample ready for the application of the test procedure.
Finished herbal products (1)	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term “mixture herbal product” can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished herbal products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).

Term

Related reference(s)	Definition
Finished herbal products (2)	
Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Finished herbal products consist of one or more herbal preparations made from one or more herbs (i.e. from different herbal preparations made of the same plant as well as herbal preparations from different plants. Products containing different plant materials are called “mixture herbal products”). Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be “herbal”.
Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Finished herbal products consist of one or more herbal preparations made from one or more herbs (i.e. from different herbal preparations made of the same plant as well as herbal preparations from different plants. Products containing different plant materials are called “mixture herbal products”). Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be “herbal”.
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Finished herbal products consist of one or more herbal preparations made from one or more herbs (i.e. from different herbal preparations made of the same plant as well as herbal preparations from different plants. Products containing different plant materials are called “mixture herbal products”). Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be “herbal”.
Finished herbal products (3)	
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Finished herbal products consist of one or more herbal preparations made from one or more herbs (i.e. from different herbal preparations made of the same plant as well as herbal preparations from different plants. Products containing different plant materials are called “mixture herbal products”). Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be “herbal”.
Finished pharmaceutical product (1)	
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more APIs.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more APIs.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Finished pharmaceutical product (2)	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A pharmaceutical product that has undergone all stages of production and quality control, including being packaged in its final container and labelled.
Finished pharmaceutical product (3)	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.
Finished pharmaceutical product (4)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A product that has undergone all stages of production, including packaging in its final container and labelling. A finished pharmaceutical product may contain one or more active pharmaceutical ingredients.
Finished pharmaceutical product (FPP) (5)	Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance (Annex 6, 54th report, 2020)	A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.
Finished pharmaceutical product (FPP) (6)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more active pharmaceutical ingredients.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more active pharmaceutical ingredients.
Finished pharmaceutical product (FPP) (7)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more actives.
Finished pharmaceutical product (FPP) (8)	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	The acronym FPP always represents a pharmaceutical product after final release (manufacturing control release, quality control release, packaging control release).

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Term

Related reference(s)	Definition
Finished pharmaceutical product (FPP) (9)	
Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labelling.
Finished pharmaceutical product (FPP) (x10)	
Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products. (Annex 4, 43rd report, 2009)	A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.
WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A finished dosage form of a pharmaceutical product that has undergone all stages of manufacture, including packaging in its final container and labelling.
Finished pharmaceutical product (x11)	
IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	With respect to radiopharmaceutical preparations, the finished pharmaceutical product is a combination of the active pharmaceutical ingredient and other components of the formulation such as diluents, radioprotectants and other formulation excipients. In some instances, the active pharmaceutical ingredient is co-produced concurrently with the finished pharmaceutical product in a single seamless process. In other cases, the active pharmaceutical ingredient is synthesized first and then formulated further as a separate process to yield the finished pharmaceutical product. In all cases, the finished pharmaceutical product is created once the active pharmaceutical ingredient is formulated in the final formulation form.

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Term

Related reference(s)	Definition
Finished product (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A product that has undergone all stages of production, including packaging in its final container and labelling.
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A product that has undergone all stages of production, including packaging in its final container and labelling.
Finished product (2)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.
First air.	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Filtered air that has not been interrupted prior to contacting exposed product and product contact surfaces with the potential to add contamination to the air prior to reaching the critical zone.
First expiry/first out (FEFO) (1)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used; earliest expiry/first out (EEFO) has a similar meaning.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used; earliest expiry/first out (EEFO) has a similar meaning.
First expiry/first out (FEFO) (2)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.
First in/first out (FIFO) (1)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A distribution procedure to ensure that the oldest stock is distributed and/or used before a newer and identical stock item is distributed and/or used.

Term	Related reference(s)	Definition
First in/first out principle concept (FIFO) (2)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A distribution procedure to ensure that the oldest stock is distributed and/or utilized before a newer and identical stock item is distributed and/or utilized.
First-time (tested) donor	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A donor whose blood or plasma is tested for the first time for infectious disease markers in a blood establishment.
Fixed-dose combination (FDC) (1)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A combination of two or more actives in a fixed ratio of doses. This term is used generically to mean a particular combination of actives irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product.
Fixed-dose combination (FDC) (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	A combination of two or more active pharmaceutical ingredients in a fixed ratio of doses. This term is used generically to mean a particular combination of active pharmaceutical ingredients irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product.
Fixed-dose combination (FDC) (3)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	A combination of two or more APIs in a fixed ratio of doses. This term is used generically to mean a particular combination of APIs irrespective of the formulation or brand. It may be administered as singleentity products given concurrently or as a finished pharmaceutical product (FPP).
Fixed-dose combination finished pharmaceutical product (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	An FPP that contains two or more APIs.
Fixed-dose combination finished pharmaceutical product (FDC-FPP) (2)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A finished pharmaceutical product that contains two or more actives.
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A finished pharmaceutical product that contains two or more actives.
Flexible dosage form	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	A solid dosage form that can be administered to patients in more than one manner, e.g. may be dispersed or taken orally as a whole.

Term	Related reference(s)	Definition
Flow diagram	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	A systematic representation of the sequence of steps or operations used in the production, control and distribution of a particular pharmaceutical.
Fnished pharmaceutical product (12)	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A product that has undergone all stages of production, including packaging in its final container and labelling. A finished pharmaceutical product may contain one or more APIs. In some cases, it may be in combination with a medical device.
Forensic	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	Related to analysis for law enforcement purposes.
Formal experimental design	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A structured, organized method for determining the relationship between factors affecting a process and the output of that process. Also known as “design of experiments”.
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A structured, organized method for determining the relationship between factors affecting a process and the output of that process. Also known as “design of experiments”.
Form-fill-seal (FFS).	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An automated filling process, typically used for terminally sterilized products, that constructs the primary container out of a continuous flat roll of packaging film while simultaneously filling the formed container with product and sealing the filled containers in a continuous process. FFS processes may utilize a single web system (whereby a single flat roll of film is wrapped around itself to form a cavity) or a dual web system (whereby two flat rolls of film are brought together to form a cavity), often with the aid of vacuum moulds or pressurized gases. The formed cavity is filled, sealed and cut into sections. Films typically consist of a polymeric material, polymeric coated foil or other suitable material.
Forwarding agent (1)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and includes a consignment agent.
Forwarding agent (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person; this includes a consignment agent.

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Term	Related reference(s)	Definition
Free sale certificate	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.2 of the guidelines.
Functional specifications	Validation of computerized systems (Annex 3, 53rd report, 2019)	The functional specifications define functions and technological solutions that are specified for the computerized system, based upon technical requirements needed to satisfy user requirements (e.g. specified bandwidth required to meet the user requirement for anticipated system usage).
Gap analysis (1)	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Identification of critical elements of a process which are available at the sending unit (SU) but are missing from the receiving unit (RU).
Gap analysis (2)	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	The identification of the critical elements of a process that are available at the sending unit (SU) but are missing from the receiving unit (RU) with the objective of assessing which gaps have a potential impact on the process or method and to mitigate those gaps, as appropriate.
Gas	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	Any substance that is completely gaseous at 1.013 bar and +20 °C or has a vapour pressure exceeding 3 bar at +500 °C.
Gas cylinder	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container, usually cylindrical, suitable for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.
General requirements	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The general quality characteristics of condoms that are verified before supply commences and that are not expected to vary from lot to lot.
Generic device group	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Aset of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics (13).

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Term	Related reference(s)	Definition
Generic product (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	The term "generic product" has somewhat different meanings in different jurisdictions. In this document, therefore, use of this term is avoided as much as possible, and the term "multisource pharmaceutical product" (see definition below) is used instead. Generic products may be marketed either under the nonproprietary approved name or under a new brand (proprietary) name. They may sometimes be marketed in dosage forms and/or strengths different from those of the innovator products. However, where the term "generic product" has had to be used in this document, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights.
Generic product (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	See multisource pharmaceutical products.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	See multisource pharmaceutical products.
Generic product (3)	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	See multisource (generic) pharmaceutical products
Generic products (1)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	The term generic product has somewhat different meanings in different jurisdictions. Use of this term has therefore been avoided as far as possible, and the term multisource pharmaceutical product is used instead (see the definition below). Multisource products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different to those of the innovator products.Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.

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Term

Related reference(s)	Definition
Generic products (2)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The term generic product has somewhat different meanings in different jurisdictions. The use of this term is therefore avoided as much as possible, and the term multisource pharmaceutical product (see below) is used instead. Generic products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products (see below). Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The term generic product has somewhat different meanings in different jurisdictions. The use of this term is therefore avoided as much as possible, and the term multisource pharmaceutical product (see below) is used instead. Generic products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products (see below). Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.
Generic substitution	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Practice of substituting a product, whether marketed under a trade name or generic name, with an equivalent product, usually a cheaper one, containing the same active ingredient(s).
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Practice of substituting a product, whether marketed under a trade name or generic name, with an equivalent product, usually a cheaper one, containing the same active ingredient(s).
GMP certificate	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.2 of the guidelines.
Good clinical practice (GCP) (1)	
Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analysis, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented.

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Term	Related reference(s)	Definition
Good clinical practices (2)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	In this context the term means a standard for design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials in a way that provides assurance that the data and reported results are credible, accurate and that the rights, safety and well-being of trial subjects are protected.
Good distribution practices (GDP) (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Good distribution practices are that part of quality assurance that ensures that the quality of a pharmaceutical products is maintained by means of adequate control of the numerous activities which occur throughout the distribution process.
Good distribution practices (GDP) (2)		
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.
Good distribution practices (GDP) (3)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	That part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/or misbranded medical products.
Good engineering practice (GEP)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.

Term	Related reference(s)	Definition
Good laboratory practice (GLP)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
Good manufacturing practice (5)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A code of practice aimed at ensuring that product is consistently manufactured to the required standard.
Good manufacturing practice (GMP) (1)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
Good manufacturing practice (GMP) (2)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	All elements in the established practice that will collectively lead to final products or services that consistently meet appropriate specifications and compliance with defined regulations.

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Related reference(s)	Definition
Good manufacturing practice (GMP) (3)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
Good manufacturing practice (GMP) (4)	
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	GMP is that part of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. GMP is concerned with both production and quality control. GMP is aimed primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products.
Good manufacturing practices (GMP) (1)	
Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	That part of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. GMP are concerned with both production and quality control. GMP are aimed primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products.
Good manufacturing practices (GMP) (2)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	That part of quality assurance that ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	That part of quality assurance that ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

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Term	Related reference(s)	Definition
Good manufacturing practices for radiopharmaceutical products		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	Good manufacturing practices (GMP) for radiopharmaceutical products are a set of practices, using a traceable process, that ensure that radiopharmaceutical products are consistently produced and controlled to the quality standards appropriate for their intended use, and designed to consistently yield the radiopharmaceutical product. GMP fall under the umbrella of the overall quality management system (QMS).
	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	Good manufacturing practices (GMP) for radiopharmaceutical products are a set of practices, using a traceable process, that ensure that radiopharmaceutical products are consistently produced and controlled to the quality standards appropriate for their intended use, and designed to consistently yield the radiopharmaceutical product. GMP fall under the umbrella of the overall quality management system (QMS).
Good pharmacy practice (GPP) (1)		
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.
Good pharmacy practice (GPP) (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The practice of pharmacy aimed at providing and promoting the best use of medicines and other health-care services and products by patients and members of the public. It requires that the welfare of the patient is the pharmacist’s prime concern at all times.
Good practices (GXP) (1)		
	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	The group of good practice guides governing the preclinical, clinical, manufacturing, testing, storage, distribution and post-market activities for regulated pharmaceuticals, biologicals and medical devices, such as good laboratory practices (GLP), good clinical practices (GCP), good manufacturing practices (GMP), good pharmacovigilance practices (GPP) and good distribution practices (GDP).
Good practices (GXP) (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The group of good practice guides governing the preclinical, clinical, manufacture, testing, storage, distribution and post-market activities for regulated medical products, such as good laboratory practices (GLP), good clinical practices (GCP), good manufacturing practices (GMP), good pharmacy practice (GPP), good distribution practices (GDP) and other good practices.
Good practices (GxP) (3)		
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	An acronym for the group of good practice guides governing the preclinical, clinical, manufacturing, testing, storage, distribution and post-market activities for regulated pharmaceuticals, biologicals and medical devices, such as GLP, GCP, GMP, good pharmacovigilance practices (GVP) and good distribution practices (GDP).

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Term	Related reference(s)	Definition
Good practices (GxP) (4)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A collection of quality guidelines and regulations in order to ensure that products are safe, effective, and of required quality; meet their intended use; and adhere to quality processes during production, control, storage and distribution.
Good regulatory practices (GRP)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	Reference definition in WHO GRP guidelines (currently under development)
Good review practices (GRevP)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	Documented best practices for any aspect related to the process, format, content and management of a medical product review.
Good storage practices (GSP) (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	(Good storage practices are) that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	(Good storage practices are) that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.
Good storage practices (GSP) (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	That part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the storage thereof.
Good trade and distribution practices (GTDP)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	(Good trade and distribution practices are) that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	(Good trade and distribution practices are) that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process.
Governance		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Refers to the different ways that organizations, institutions, businesses and governments manage their affairs. Governance is the act of governing and thus involves the application of laws and regulations, but also of customs, ethical standards and norms. Good governance means that affairs are managed well, not that the laws, regulations or norms are themselves necessarily “good” (14).

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Term	Related reference(s)	Definition
Gowning qualification.	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A programme that establishes, both initially and on a periodic basis, the capability of an individual to don the complete gown.
Grade A air supply.	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Air that is passed through a filter qualified as capable of producing grade A total particle quality air, but where there is no requirement to perform continuous total particle monitoring or meet grade A viable monitoring limits. Specifically used for the protection of fully stoppered vials where the cap has not yet been crimped.
GTDP	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	Good Trade and Distribution Practices (Annex 2, WHO Technical Report Series, No. 917).
GuideGeneric	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Guideline on submission of documentation for prequalification of multisource (generic) finished pharmaceutical products (FPPs) used in the treatment of HIV/AIDS, malaria and tuberculosis (GuideGenericRev1_Final.doc). Available at: http://mednet3.who.int/ prequal/info_applicants/Guidelines/GuideGenericSubmitDocFPPs_08_2005_WoAnnexes.pdf
GuideGeneric supplement 1	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Supplementary, separate document 1 (dissolution requirements) to the Guideline on submission of documentation for prequalification of multisource (generic) finished pharmaceutical products (FPPs) used in the treatment of HIV/AIDS, malaria and tuberculosis (GuideGeneric-Dissolution_Suppl1.doc). Available at: http://mednet3.who.int/prequal/info_ applicants/Guidelines/GuideGenericSubmitDocFPPs_Supplement1_08_2005.pdf
GuideGeneric supplement 2	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Supplementary, separate document 2 (stability implications) to the Guideline on submission of documentation for prequalification of multisource (generic) finished pharmaceutical products (FPPs) used in the treatment of HIV/AIDS, malaria and tuberculosis (GuideGeneric_Suppl2.doc). Available at: http://mednet3.who.int/prequal/info_applicants/ Guidelines/GuideGenericSubmitDocFPPs_Supplement2.pdf
Guidelines/guidace documents	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Non-statutory advisory publications intended to assist those parties affected by legislation to interpret requirements.
HACCP plan	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	A document prepared in accordance with the principles of HACCP to ensure the control of hazards which are significant for pharmaceutical quality in the production and supply chain.

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Term	Related reference(s)	Definition
Half-finisehd product	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	Any material or mixture of materials that must undergo further manufacture.
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	Any material or mixture of materials that must undergo further manufacture.
Half-life	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The time in which the radioactivity decreases to one-half the original value.
Harm	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A physical injury or damage to the health of people or damage to property or the environment (15).
Harmonization (regulatory)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Harmonization (regulatory). The process by which technical guidelines are developed to be uniform across participating authorities (9).
HAV, hepatitis A virus	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A non-enveloped single-stranded RNA virus that is the causative agent of hepatitis A.
Hazard (1)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	Any circumstance in the production, control and distribution of a pharmaceutical which can cause an adverse health effect.
Hazard (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A potential source of harm (15).
Hazard analysis	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The process of collecting and evaluating information on hazards which should be addressed in the HACCP plan.

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Term	Related reference(s)	Definition
Hazardous substance or product		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A product or substance that may present a substantial risk of injury, to health or to the environment.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A product or substance that may present a substantial risk of injury, to health or to the environment.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A product or substance that may present a substantial risk of injury, to health or to the environment.
HBsAg, hepatitis B surface antigen		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The antigen on the periphery of the hepatitis B virus.
HBV, hepatitis B virus		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An enveloped double-stranded DNA virus that is the causative agent of hepatitis B.
HCV, hepatitis C virus		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An enveloped single-stranded, RNA virus that is the causative agent of hepatitis C.
Health Based Exposure Limits (HBELs)		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	See definition of Permitted Daily Exposure (PDE)
Health establishment		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A health establishment is the whole or part of a public or private facility, building or place, whether operated for profit or not, that is operated or designed to provide health care services including the supply of pharmaceutical products to the end user.
Health Technologies		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives (16).
Health-care facility		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Health-care facility. Any party within the country providing healthcare services.

Term	Related reference(s)	Definition
Heating	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	ventilation and air conditioning systems. Heating, ventilation and air conditioning, also referred to as environmental control systems.
Heating, ventilation and air-conditioning (HVAC)	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Heating, ventilation and air-conditioning, also referred to as environmental control system (ECS).
HEPA filter (1)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	High-efficiency particulate air filter.
HEPA filter (2)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A high-efficiency particulate air filter specified in accordance with a relevant international standard.
Herbal dosage forms	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Herbal dosage forms are the physical form (liquid, solid, semi-solid) of herbal products produced from herbs, with or without excipients, in a particular formulation (such as decoctions, tablets and ointments). They are produced either from herbal materials (such as dried roots or fresh juices) or herbal preparations (such as extracts).
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbal dosage forms are the physical form (liquid, solid, semi-solid) of herbal products produced from herbs, with or without excipients, in a particular formulation (such as decoctions, tablets and ointments). They are produced either from herbal materials (such as dried roots or fresh juices) or herbal preparations (such as extracts).

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Related reference(s)	Definition
Herbal materials (1)	
Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Herbal materials (2)	
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Herbal materials include, in addition to herbs, other crude plant materials. Examples of these other plant materials include gums, resins, balsams and exudates.
Herbal materials (3)	
Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Herbal materials include, in addition to herbs: fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other plant materials (5).
Herbal medicinal plant materials	
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	see Herbal materials
Herbal medicinal product	
Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (Annex 8, 34th report, 1996)	Medicinal product containing, as active ingredients, exclusively plant material and/or preparations. This term is generally applied to a finished product. If it refers to an unfinished product, this should be indicated.
Herbal medicines (1)	
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Herbal medicines include herbs and/or herbal materials and/or herbal preparations and/or finished herbal products in a form suitable for administration to patients (Box A1.1). Note: In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).

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Term	Related reference(s)	Definition
Herbal medicines (2)	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbal medicines include herbs and/or herbal materials and/or herbal preparations and/or finished herbal products in a form suitable for administration to patients (3). Note: In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (for example, animal and mineral materials, fungi, algae or lichens, among others).
Herbal medicines (3)	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	These include herbs and/or herbal materials and/or herbal preparations and/or finished herbal products in a form suitable for administration to patients (10). Note: In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (for example, animal and mineral materials, fungi, algae, lichens, etc.).
Herbal medicines (4)	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Herbal medicines include herbs and/or herbal materials and/or herbal preparations and/or finished herbal products in a form suitable for administration to patients. Note: In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials, fungi, algae or lichens).
Herbal preparations (1)	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.
Herbal preparations (2)	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Herbal preparations are the basis for finished herbal products and may include comminuted or cut herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Herbal preparations (3)		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Herbal preparations are produced from herbal materials by physical or biological processes. These processes may be extraction (with water, alcohol, supercritical carbon dioxide (CO2)), fractionation, purification, concentration, fermentation and other processes. They also include processing herbal materials with a natural vehicle or steeping or heating them in alcoholic beverages and/or honey, or in other materials.The resulting herbal preparations include, among others, simply comminuted (fragmented) or powdered herbal materials as well as extracts, tinctures, fatty (fixed) or essential oils, expressed plant juices, decoctions, cold and hot infusions.
Herbal processing		
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbal processing refers to the overall treatment in the course of production of herbal materials, herbal preparations and herbal dosage forms. For the purpose of the present guidelines, herbal processing includes “post-harvest processing” described in the WHO guidelines on GACP for medicinal plants (1), as well as “processing” procedures and protocols set out in the WHO guidelines on GMP for herbal medicines (4–6, 8).
Herbs (1)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Herbs include crude materials which could be derived from lichen, algae, fungi and higher plants, such as leaves, flowers, fruit, fruiting bodies, seeds, stems, wood, bark, roots, rhizomes or other parts, which may be entire, fragmented or powdered. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Herbs (2)		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Herbs are crude plant material which may be entire, fragmented or powdered. Herbs include, e.g. the entire aerial part, leaves, flowers, fruits, seeds, roots, bark (stems) of trees, tubers, rhizomes or other plant parts.
Herbs (3)		
	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Herbs include crude plant materials such as leaves, flowers, fruits, seed, stem wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Herbs include crude plant materials such as leaves, flowers, fruits, seed, stem wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Herbs include crude plant materials such as leaves, flowers, fruits, seed, stem wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
High efficiency particulate air (HEPA) filter		
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	High efficiency particulate air filter.

Term	Related reference(s)	Definition
HIV, human immunodeficiency virus	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An enveloped, single-stranded RNA virus that is the causative agent of the acquired immunodeficiency syndrome (AIDS).
Home cryogenic vessel	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A mobile cryogenic vessel designed to hold liquid oxygen and dispense gaseous oxygen at a patient's home.
Homogeneity	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	A material is regarded as homogeneous when it is all of the same origin (e.g. from the same batch) and as non-homogeneous when it is of differing origins.
Homogeneous material	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Material of uniform consistency and composition throughout a batch.
HTLV 1 and 2, human T-cell lymphotropic virus, types 1 and 2	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	Enveloped, single stranded RNA viruses that are typically cell-associated.
HVAC	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Heating, ventilation and air-conditioning. Also referred to as "environmental control systems"
Hybrid system	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The use of a combination of electronic systems and paper systems.
Hydrostatic pressure test	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A test performed, as required by national or international regulations, in order to ensure that pressure containers are able to withstand pressures up to the container's design pressure.
Impermeable containers	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Containers that provide a permanent barrier to the passage of gases or solvents, e.g. sealed aluminium tubes for semisolids, sealed glass ampoules for solutions and luminium/aluminium blisters for solid dosage forms.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Containers that provide a permanent barrier to the passage of gases or solvents, e.g. sealed aluminium tubes for semisolids, sealed glass ampoules for solutions and luminium/aluminium blisters for solid dosage forms.

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Term

Related reference(s)	Definition
Import authority	
Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	The national agency responsible for authorizing imports (e.g. the ministry or department of trade or of imports and exports).
Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	The national agency responsible for authorizing imports (e.g. the ministry or department of trade or of imports and exports).
Importation (1)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
Importation (2)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
Importer (1)	
Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	An individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A "licensed" or "registered" importer is one who has been granted a licence or registration status for the purpose. In addition to a general licence or permit as an importer, some countries require an additional licence to be issued by the national drug regulatory authority if pharmaceutical products are to be imported.
Importer (2)	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed (6).
Importer (3)	
Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	An individual or company or similar legal entity importing or seeking to import a medical product. A “licensed” or “registered” importer is one who has been granted a licence for the purpose.
Importing agents, guidelines for	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.4 of the guidelines.

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Term	Related reference(s)	Definition
Impurity	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Any component present in the intermediate or API that is not the desired entity.
Impurity profile	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A description of the identified and unidentified impurities present in an API.
In use	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	See Utilization period
In vitro diagnostic (IVD)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	In vitro diagnostic (IVD) medical device. A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes (1).
In vitro equivalence test	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	An in vitro equivalence test is a dissolution test that includes comparison of the dissolution profile between the multisource product and the comparator product in three media: pH1.2, pH 4.5 and pH 6.8.
In vitro equivalence testing	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	An in vitro equivalence test is a dissolution test that includes comparison of the dissolution profile between the multisource product and the comparator product, typically in at least three media: pH 1.2, pH 4.5 and pH 6.8 buffer solutions.
In vitro quality control dissolution test (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	A dissolution test procedure identified in the pharmacopoeia, generally a one time point dissolution test for immediate-release products and a three or more time points dissolution test for modified release products.
In vitro quality control dissolution test (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	A dissolution test procedure identified in the pharmacopoeia for routine QC of product batches, generally a one time-point dissolution test for immediate-release products and a three or more time-points dissolution test for modified-release products.

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Term

Related reference(s)	Definition
Indicator	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Criterion used to measure changes, directly or indirectly, and to assess the extent to which the targets or objectives of a programme or project are being attained. Indicators should meet the criteria of clarity, usefulness, measurability, reliability, validity (see below) and acceptance by key stakeholders.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Criterion used to measure changes, directly or indirectly, and to assess the extent to which the targets or objectives of a programme or project are being attained. Indicators should meet the criteria of clarity, usefulness, measurability, reliability, validity (see below) and acceptance by key stakeholders.
Indirect impact system (1)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	This is a system that is not expected to have a direct impact on product quality, but typically will support a direct impact system. These system are designed and commissioned according to GEP only.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	This is a system that is not expected to have a direct impact on product quality, but typically will support a direct impact system. These system are designed and commissioned according to GEP only.
Indirect impact system (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A system that is not expected to have a direct impact on product quality, but typically will support a direct impact system. These systems are designed and commissioned according to good engineering practice only.
Infiltration (1)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Infiltration is the ingress of contaminated air from an external zone into a clean area.
Infiltration (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Infiltration is the ingress of air from an external zone into a controlled area.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Infiltration is the ingress of air from an external zone into a controlled area.

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Term	Related reference(s)	Definition
Information sharing	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	An exchange of data between individuals or entities outside the traditional organizational boundaries, to achieve a common goal in terms of better policies and to deliver better services. This may mean that one party is disclosing information while the other is collecting the information or both parties are mutually disclosing and collecting information.
Informed consent	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A subject's voluntary confirmation of willingness to participate in a particular trial, and the documentation thereof. This consent should be sought only after all appropriate information has been given about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.
Inherent intervention.	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An intervention that is an integral part of the aseptic process and is required for set-up, routine operation or monitoring (for example, aseptic assembly, container replenishment or environmental sampling). Inherent interventions are required by procedure or work instruction for the execution of the aseptic process.
Injection needle	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A hollow needle with a locking device intended for the administration of liquid pharmaceutical dosage forms.
Injection syringe	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A cylindrical device with a cannula-like nozzle, with or without a fixed needle and a movable piston, used for the administration, usually parenteral, of an accurately measured quantity of a liquid pharmaceutical form. The syringe may be prefilled, and can be for single-dose or multi-dose use.
In-line	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Measurement where the sample is not removed from the process stream: can be invasive or non-invasive.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Measurement where the sample is not removed from the process stream: can be invasive or non-invasive.
inner box	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A box used to contain a convenient number of condoms in packages or consumer packs. Inner boxes typically contain 100–200 condoms; where a gross (144 condoms) is used as the unit of purchase, inner boxes are usually specified to contain one gross.

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Term

Related reference(s)	Definition
Innovator pharmaceutical product (1)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	Generally, the innovator pharmaceutical product is that which was first authorized for marketing (normally as a patented drug) on the basis of documentation of efficacy, safety and quality (according to contemporary requirements). When drugs have been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Innovator pharmaceutical product (2)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Generally the pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorization. When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Generally the pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorization. When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Innovator pharmaceutical product (3)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Generally, the innovator pharmaceutical product is that which was first authorized for marketing, on the basis of documentation of quality, safety and efficacy.
Innovator pharmaceutical product (4)	
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Generally the pharmaceutical product that was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	Generally the pharmaceutical product that was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality.
Innovator pharmaceutical product (5)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Innovator pharmaceutical product (5)

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Term

Related reference(s)	Definition
In-process control (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
In-process control (2)	
WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	Check performed during manufacture to monitor or to adjust the process in order to ensure that the final product conforms to its specifications.
In-process control (or process control)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Checks performed during production in order to monitor and, if appropriate,to adjust the process and/or to ensure that the intermediate or API conforms to its specifications.

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Term	Related reference(s)	Definition
Insert before date	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	(referred to in previous editions of the specification as “latest insertion date”). The date after which the device should not be inserted into the uterus. (Occasionally, the term “expiry date” is used, but this can be confused with the latest date by which the device has to be removed from the uterus. The use of “expiry date” is therefore discouraged in this context.)
Inspection (1)	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	An officially conducted examination (i.e. review of the conduct of the trial, including quality assurance, personnel involved, any delegation of authority and audit) by relevant authorities at the site of investigation and/or at the site of the sponsor in order to verify adherence to GCP and GLP as set out in this document.
Inspection (2)	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	An official examination, normally conducted on site, of the compliance with WHO good manufacturing practices as referred to in this document. In some cases, an off-site review of documentation may be done in lieu of the on-site examination.
Inspection (3)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	An on-site evaluation by a regulatory authority of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with regulatory requirements and or commitments made as part of the approval to market a product (11).
inspection level (1)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The degree of examination of the lot, as specified in ISO 2859-1. The higher the inspection level, the more samples will be tested and, hence, the lower the risk of faulty products reaching the end-user.
Inspection level (2)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The degree of examination of the lot, as specified in ISO 2859-1. The higher the inspection level, the more samples that will be tested and, hence, the lower the risk of faulty products reaching the consumer.
install by date	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The date by which an instrument, device or other has to be installed.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The date by which an instrument, device or other has to be installed.
Installation qualification (1)	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities, manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.

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Term	Related reference(s)	Definition
Installation qualification (2)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Documented verification that the premises, HVAC system, supporting utilities and equipment have been built and installed in compliance with their approved design specification.
Installation qualification (3)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented verification that the installations (such as machines equipment and instruments, computer system components, measuring devices, utilities and manufacturing) used in a processor system are appropriately selected and correctly installed, in accordance with established specifications.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Documented verification that the installations (such as machines equipment and instruments, computer system components, measuring devices, utilities and manufacturing) used in a processor system are appropriately selected and correctly installed, in accordance with established specifications.
Installation qualification (IQ) (4)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	IQ is documented verification that the premises, HVAC system, supporting utilities and equipment have been built and installed in compliance with their approved design specification.
Installation qualification (IQ) (5)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities and manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities and manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities and manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.
Installation qualification (IQ) (6)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Installation qualification is documented verification that the premises, heating, ventilation and air-conditioning (HVAC) system, supporting utilities and equipment have been built and installed in compliance with their approved design specification.
Installation qualification (IQ) (7)		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with the operating instructions.

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Related reference(s)	Definition
Installation qualification (IQ) (8)	
Guidelines on qualification (Annex 3, 53rd report, 2019)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities and manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed.
Instructions for use	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Instructions for use. Information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken (17). Inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken (17).
Intended use/purpose	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer (18).
Interchangeability	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	An interchangeable pharmaceutical product is one that is therapeutically equivalent to a comparator (reference) product.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	An interchangeable pharmaceutical product is one that is therapeutically equivalent to a comparator (reference) product.
Interchangeable pharmaceutical product (1)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	An interchangeable pharmaceutical product is one which is therapeutically equivalent to a reference product.
Interchangeable pharmaceutical product (2)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	An interchangeable pharmaceutical product is one which is therapeutically equivalent to a comparator product and can be interchanged with the comparator in clinical practice.
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	An interchangeable pharmaceutical product is one which is therapeutically equivalent to a comparator product and can be interchanged with the comparator in clinical practice.

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Term

Related reference(s)	Definition
Intercompany transfer (1)	
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A transfer of technology between sites of different companies.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A transfer of technology between sites of different companies.
Intermediate	
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated (5).
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated (5).
Intermediate product (1)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Intermediate product (2)	
General guidance on hold-time studies (Annex 4, 49th report, 2015)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Internal audit (1)	
Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	An examination and assessment of all or part of a quality system, with the specific purpose of improving it. An internal audit should be conducted by an independent (of the function to be audited) and qualified team of experts designated by the management for this purpose.
Internal audit (2)	
WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	An examination and assessment of all or part of a QMS with the specific purpose of improvement. An internal audit should be conducted by an independent (i.e. of the function to be audited) team of competent auditors as designated by the management for this purpose.
Internal distribution	
Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Transport of a TTSPP within a pharmaceutical manufacturer’s internal supply chain (i.e. all internal transports from manufacturing facility to packaging facility to warehouse to distribution centre).

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Term

Related reference(s)	Definition
International Chemical Reference Substance	
General guidelines for the establishment, maintenance and distribution of chemical reference substances (Annex 3, 41st report, 2007)	International Chemical Reference Substances (ICRS) are primary chemical reference substances established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied primarily for use in physical and chemical tests and assays described in the specifications for quality control of drugs published in The International Pharmacopoeia or proposed in draft monographs. The ICRS may be used to calibrate secondary standards.
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	International Chemical Reference Substances (ICRS) are primary chemical reference substances established on the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. They are supplied primarily for use in physical and chemical tests and assays described in the specifications for quality control of drugs published in The International Pharmacopoeia or proposed in draft monographs. The ICRS may be used to calibrate secondary standards.
International Nonproprietary Name	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances.
International standards and guidelines	
Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	For the purpose of this document, the term includes relevant WHO standards and guidelines and any other relevant, internationally recognized standards (e.g. International Organization for Standardization or pharmacopoeial standards) and guidelines (e.g. the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme).
Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	For the purpose of this document, the term includes relevant WHO standards and guidelines and any other relevant internationally recognized standards (e.g. International Organization for Standardization or pharmacopoeial standards) and guidelines (e.g. International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH] or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co operation Scheme [PIC/S]).

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Term	Related reference(s)	Definition
Intracompany transfer		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A transfer of technology between sites of the same group of companies.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A transfer of technology between sites of the same group of companies.
Intrinsic sterile connection device.		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A device that reduces the risk of contamination during the connection process. The device can be mechanical or fusion sealing.
In-use period		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A period of time during which a reconstituted preparation of the finished dosage form in a multidose container, or a moisture-sensitive product in a large-format final container (e.g. high-density polyethylene (HDPE) bottles of 500) can be used after opening.
Investigational labelling		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Labelling developed specifcally for products involved in a clinical trial.
Investigational product (1)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Any pharmaceutical product (new product or reference product) or placebo being tested or used as a reference in a clinical trial.
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	Any pharmaceutical product (new product or reference product) or placebo being tested or used as a reference in a clinical trial.
Investigational product (2)		
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	Any pharmaceutical product, including a new product, existing product for a new indication, reference product or placebo, being tested or used as a reference in a clinical trial.
Investigational radiopharmaceutical		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	Any radiopharmaceutical product (new compound or a commercial product) being evaluated in a clinical trial.

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Term

Related reference(s)	Definition
Investigator (1)	
IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	The person responsible for the trial and for protecting the rights, health and welfare of the subjects in the trial. The investigator must be an appropriately qualified person legally allowed to practice medicine/dentistry.
Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	The person responsible for the trial and for protecting the rights, health and welfare of the subjects in the trial. The investigator must be an appropriately qualified person legally allowed to practice medicine/dentistry.
WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	The person responsible for the trial and for protecting the rights, health and welfare of the subjects in the trial. The investigator must be an appropriately qualified person legally allowed to practice medicine/dentistry.
Investigator (2)	
Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and the provision of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practise medicine or dentistry.
Invitation for expressions of interest or invitation	
Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	Invitation calling upon interested parties (e.g. manufacturers or other applicants) to submit an expression of interest (EOI) to WHO by a specified deadline for the purpose of participating in the WHO prequalification procedure in respect of the product(s) listed in the invitation. Such an EOI should be accompanied by the required documentation on the product(s) in question.
Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	Invitation calling upon interested parties (e.g. manufacturers or other applicants) to submit an expression of interest (EOI) to WHO by a specified deadline for the purpose of participating in the WHO prequalification procedure in respect of the product(s) listed in the invitation. Such an EOI should be accompanied by the required documentation on the product(s) in question.
ISO 14644 (1)	
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	International standard relating to the design, classification and testing of clean environments.
ISO 14644 (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The International Standards Organization (ISO) has developed a set of standards for the classification and testing of cleanrooms. Where ISO 14644 is referenced it implies the latest revision and all its separate parts.

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Term	Related reference(s)	Definition
Isokinetic sampling head	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A sampling head designed to disturb the air as little as possible so that the same particles go into the nozzle as would have passed the area if the nozzle had not been there (that is, the sampling condition in which the mean velocity of the air entering the sample probe inlet is nearly the same (± 20%) as the mean velocity of the airflow at that location).
Isolator	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An enclosure capable of being subject to reproducible interior biodecontamination, with an internal work zone meeting grade A conditions that provide uncompromised continuous isolation of its interior from the external environment (for example, surrounding cleanroom air and personnel). There are two major types of isolators: •Closed isolator systems exclude external contamination of the isolator's interior by accomplishing material transfer via aseptic connection to auxiliary equipment rather than use of openings to the surrounding environment. Closed systems remain sealed throughout operations. •Open isolator systems are designed to allow for the continuous or semicontinuous ingress or egress of materials during operations through one or more openings. Openings are engineered (for example, using continuous overpressure) to exclude the entry of external contaminant into the isolator.
IVD for self-testing	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any IVD medical device intended by the manufacturer for use by laypersons (19).
Knowledge management	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components.
Label	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Written, printed or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices (17).
Labelling (1)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The action involving the selection of the correct label, with the required information, followed by line-clearance and application of the label.
	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	The action involving the selection of the correct label, with the required information, followed by line-clearance and application of the label.

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Term	Related reference(s)	Definition
Labelling (2)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Process of identifying a pharmaceutical product including the following information, as appropriate: name, active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier. (adapted from GMP)
Labelling (3)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.
Labelling (4)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents (17).
Labelling (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The process of identifying a medical product, including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; and names and addresses of the manufacturer and/or supplier.
Labelling information	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	Information to the user provided on the package label or in the patient information leaflet.
Labels	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	All finished drug products should be identified by labelling, as required by the national legislation, bearing at least the following information:(a) the name of the drug product; (b) a list of the active ingredients (if applicable, with the International Nonproprietary Names (INNs)), showing the amount of each present, and a statement of the net contents, e.g. number of dosage units, mass or volume; (c) the batch number assigned by the manufacturer; (d) the expiry date in an uncoded form; (e) any special storage conditions or handling precautions that may be necessary; (f) the directions for use, and any warnings and precautions that may be necessary; (g) the name and address of the manufacturer or the company or person responsible for placing the product on the market.
Laminar airflow (LAF)	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow).

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Term	Related reference(s)	Definition
Language of product certificate		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.10 of the guidelines.
Large-volume parenterals		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
Law		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Binding and enforceable legislation passed by a legislative body.
Layperson		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Individual who does not have formal training in a specific field or discipline (17).
Leachable		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A chemical entity that migrates into a product from the product contact surface of the process equipment or containers under normal condition of use or storage.
Legacy system		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	This refers to a mature computer system, programming language, application software, or processes that are used instead of available upgraded versions, and that have not been qualified according to current regulatory requirements.

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Term

Related reference(s)	Definition
Legislation	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The first state of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter, e.g. control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also regulations below).
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The first state of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter, e.g. control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also regulations below).
Length	
World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The length of the condom measured from the open end to the tip, excluding any reservoir.
Licence holder	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	An individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.
Licensee	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	An individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable, for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.
Licensing system	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	National legal provisions on who should manufacture, import or supply pharmaceutical products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	National legal provisions on who should manufacture, import or supply pharmaceutical products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.

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Term	Related reference(s)	Definition
Life cycle (1)		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	All phases in the life of a product from the initial development through marketing until the product's discontinuation (ICH Q8 (4))
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	All phases in the life of a product from the initial development through marketing until the product's discontinuation (ICH Q8 (4))
Life cycle (2)		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.
Life-cycle (3)		
	Non sterile process validation (Annex 3, 53rd report, 2019)	All phases in the life of a product from the initial development through marketing until the product's discontinuation (4).
Limit of detection		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The lowest number of microorganisms that can be detected, but in numbers that cannot be estimated accurately.
Limits		
	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Acceptance criteria
Limits of certification by competent authority		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See sections 3.12 and 4.8 of the guidelines.
Liquefied gas		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A gas that, when packaged for transport, is partially liquid (or solid) at a temperature above –50 °C.
Listing		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The process whereby a party submits information to the regulatory authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction (20).

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Term	Related reference(s)	Definition
Local isolates	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Suitably representative microorganisms of the site that are frequently recovered through environmental monitoring within the classified zone or areas (especially grade A and B areas), personnel monitoring, or positive sterility test results.
Long-term stability studies (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Experiments on the physical, chemical, biological, biopharmaceutical and microbiological characteristics of an active pharmaceutical ingredient or finished pharmaceutical product, during and beyond the expected shelf life and storage periods of samples under the storage conditions expected in the intended market. The results are used to establish the retest period or the shelf life, to confirm the projected retest period and shelf life, and to recommend storage conditions.
Long-term stability studies (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Experiments on the physical, chemical, biological, biopharmaceutical and microbiological characteristics of an API or FPP, during and beyond the expected shelf-life and storage periods of samples under the storage conditions expected in the intended market. The results are used to establish the re-test period or the shelf-life, to confirm the projected re-test period and shelf-life, and to recommend storage conditions.
Lot (1)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	See batch.
Lot (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A collection of condoms of the same design, colour, shape, size and formulation. A lot must be manufactured at essentially the same time, using the same process, same specification of raw materials, common equipment, same lubricant and any other additive or dressing, and be packed in the same type of individual container, using the same packaging materials.
Lot (3)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A quantity of raw materials, components or iuds made at essentially the same time and having a single lot identification code or number. Clear lot identification and recording are required to permit effective product recall in the event of a quality problem with the device. The definition of a lot of manufactured iuds is given in section 3 on general requirements.
Lot number	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	See batch number.

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Term	Related reference(s)	Definition
Lot number or code		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A unique identifying alphanumeric code assigned to a lot.
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A unique identifying alphanumeric code assigned to a lot.
Lowry method		
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A method for determining the water-extractable protein levels in latex products.
Lyophilization		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A physical-chemical drying process designed to remove solvents, by way of sublimation, from both aqueous and non-aqueous systems, primarily to achieve product or material stability. Lyophilization is synonymous with the term “freeze-drying”.
Management review		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A formal, documented review of the key performance indicators of a quality management system performed by top management.
Manifold		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	Equipment or apparatus designed to enable one or more gas containers to be emptied and filled at the same time.
Manual aseptic processing		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An aseptic process whereby the operator manually compounds, fills, places or seals an open container with sterile product.
Manufacture (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	All operations of purchase of materials, production, quality control,release, storage, and distribution of pharmaceutical starting materials, and the related controls.
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	All operations of purchase of materials and starting materials, production, quality control, release, storage, shipment of finished starting materials, and the related controls.

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Term

Related reference(s)	Definition
Manufacture (2)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
Manufacture (3)	
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products, and the related controls.
Manufacture (4)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
Manufacture (5)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	All operations of receipt of materials, production, packaging, repackaging,labelling, relabelling, quality control, release, storage and distribution of APIs and related controls.
Manufacture (6)	
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	All operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
Manufacture (7)	
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	All operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical products, and the related controls.

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Term	Related reference(s)	Definition
Manufacture (8)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	All operational processes or steps — including purchase or selection of materials and products, production, quality control, release, storage and distribution of products and the related controls — used to produce a blood product. This includes also the donation process.
Manufacture (manufacturing) (9)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	All or any operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products and the related controls.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	All or any operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products and the related controls.
Manufacture (x10)		
	Guidelines on pre-approval inspections. (Annex 7, 36th report, 2002)	All operations concerned with the purchase of materials and products, production (including packaging), quality control, release, storage, the distribution of pharmaceutical products, and the related controls. (Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2. Good manufacturing practices and inspection. Geneva, World Health Organization, 1999.).
Manufacture (x11)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	All operations of purchase of materials and products, production, packaging, labelling, quality control, release, and storage of medical products and the related controls.
Manufacture (x12)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of medical products.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of medical products.
Manufacture or production (x13)		
	Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products. (Annex 4, 43rd report, 2009)	All operations of purchase of materials and starting materials, preparation of the API and of the pharmaceutical product, including packaging and repackaging, labelling and re-labelling, quality control, release, storage and distribution and the related controls. The terms “manufacture” and “production” are used interchangeably in this document.
Manufacture/manufacturing (x14)		
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Includes all operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage, distribution and related controls.

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Term

Related reference(s)	Definition
Manufacturer (1)	
Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of medical products.
Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of medical products.
Manufacturer (2)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.

Term	Related reference(s)	Definition
Manufacturer (3)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A company that carries out at least one step of manufacture.
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A company that carries out at least one step of manufacture.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A company that carries out at least one step of manufacture.
	Guidelines on pre-approval inspections. (Annex 7, 36th report, 2002)	A company that carries out at least one step of manufacture.
Manufacturer (4)		
	Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	A company that produces, packages, repackages, labels and/or relabels pharmaceutical products.
	Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	A company that produces, packages, repackages, labels and/or relabels pharmaceutical products.
	Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	A company that produces, packages, repackages, labels and/or relabels pharmaceutical products.
Manufacturer (5)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A company that carries out operations such as production, packaging, testing, repackaging, labelling and/or relabelling of pharmaceuticals.
Manufacturer (6)		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under its name; whether or not such a medical device is designed and/or manufactured by that person himself or herself or on his or her behalf by another person(s) (6). Note: This “natural or legal person” has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the regulatory authority within that jurisdiction.
Manufacturer (7)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A manufacturer is a natural or legal person who holds a manufacturing authorization and has responsibility for manufacturing of a medical product or active pharmaceutical ingredient.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Manufacturer (8)		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	Any person or legal entity engaged in the manufacture of a product subject to marketing authorization or licensure; or any person or legal entity that is an applicant or holder of a marketing authorization or product licence where the applicant assumes responsibility for compliance with the applicable product and establishment standards.
	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	Any person or legal entity engaged in the manufacture of a product subject to marketing authorization or licensure; or any person or legal entity that is an applicant or holder of a marketing authorization or product licence where the applicant assumes responsibility for compliance with the applicable product and establishment standards.
Manufacturer (IVD)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	Any natural or legal person with responsibility for design and/or manufacture of an IVD product with the intention of making it available for use, under his or her name, whether or not such an IVD product is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s).
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	Any natural or legal person with responsibility for design and/or manufacture of an IVD product with the intention of making it available for use, under his or her name, whether or not such an IVD product is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s).
Manufacturer of active pharmaceutical ingredient (API)		
	Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products. (Annex 4, 43rd report, 2009)	A company that produces, packages and labels active pharmaceutical ingredients (APIs).
Manufacture's working cell bank		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A homogeneous suspension of the seed material derived from the master seed bank(s) at a finite passage level, dispensed in aliquots into individual containers for storage. All containers are treated identically and, once removed from storage, are not returned to the seed stock.
Manufacturing		
	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	All operations involved in the production of a drug, including processing, compounding, formulating, filling, packaging, and labelling.
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	All operations involved in the production of a drug, including processing, compounding, formulating, filling, packaging, and labelling.

Term	Related reference(s)	Definition
Manufacturing date		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The date of production of a batch is defined as the date that the first step is performed involving combination of the active ingredient with other ingredients. Where there are no other ingredients than an active ingredient, the date of the start of the processing or filling operation is considered as the date of production.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The date of production of a batch is defined as the date that the first step is performed involving combination of the active ingredient with other ingredients. Where there are no other ingredients than an active ingredient, the date of the start of the processing or filling operation is considered as the date of production.
Manufacturing or production		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	Within the scope of this guidance, these terms refer to all the operations performed leading up to the finished radiopharmaceutical product, including the purchase of starting materials, production, quality control, release and storage of radiopharmaceuticals.
	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	Within the scope of this guidance, these terms refer to all the operations performed leading up to the finished radiopharmaceutical product, including the purchase of starting materials, production, quality control, release and storage of radiopharmaceuticals.
Manufacturing process*		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The transformation of starting materials into finished products (drug substances or pharmaceutical dosage forms) through a single operation or a sequence of operations involving installations, personnel, documentation and environment. * For the purpose of this Annex, "manufacturing process" is used as synonym of "production process".
Margin of safety		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The margin of safety is the ratio between the cleaning acceptance limit based on HBEL and the process residue data.
Markers (1)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Constituents of a medicinal plant material which are chemically defined and of interest for control purposes. Markers are generally employed when constituents of known therapeutic activity are not found or are uncertain, and may be used to calculate the quantity of plant material or preparation in the finished product. When starting materials are tested, markers in the plant material or preparation must be determined quantitatively.
Markers (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Markers are chemically defined constituents of a herbal material utilized for control purposes. They may or may not contribute to the clinical efficacy. In the first case, however, evidence that they are solely responsible for the clinical efficacy may or may not be available. Markers are generally employed when constituents of known therapeutic activity are not found or are uncertain, and may be used to identify the herbal material or preparation or calculate their quantity in the finished product.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Markers (marker substances) (1)	
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Markers (marker substances) are reference substances that are chemically defined constituents of a herbal material. They may or may not contribute to the therapeutic activity. However, even when they contribute to the therapeutic activity, evidence that they are solely responsible for the clinical efficacy may not be available.
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Markers (marker substances) are reference substances that are chemically defined constituents of a herbal material. They may or may not contribute to the therapeutic activity. However, even when they contribute to the therapeutic activity, evidence that they are solely responsible for the clinical efficacy may not be available.
Markers (marker substances) (2)	
Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Reference substances that are chemically defined constituents of a herbal material. They may or may not contribute to their therapeutic activity. However, even when they contribute to the therapeutic activity, evidence that they are solely responsible for the material's clinical efficacy may not be available (10).
Market surveillance	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in legislation and do not endanger health, safety or any other aspect of public interest protection (based on EU Council Directive EC No 756/2008 of 9 July 2008 concerning the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93) (21).
Marketing authorization (1)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A legal document issued by the NRA for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, performance (where applicable) and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form; the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names or national generic names where they exist); the shelf-life and storage conditions; and packaging characteristics, or other details as required by the product category. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "licence" or "product licence".
Marketing authorization (2)	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See product licence.

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Term

Related reference(s)	Definition
Marketing authorization (3)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.
Marketing authorization (4)	
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A legal document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

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Term	Related reference(s)	Definition
Marketing authorization (5)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	Also referred to as product licence or registration certificate. A legal document issued by the competent medicines RA that authorizes the marketing or free distribution of a medical product in the respective country after evaluation of safety, efficacy and quality. In terms of quality it establishes inter alia the detailed composition and formulation of the medical product and the quality requirements for the product and its ingredients. It also includes details of the packaging, labelling, storage conditions, shelf-life and approved conditions of use.
Marketing authorization (6)		
	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	(product licence, registration certificate). A legal document issued by the competent medicines regulatory authority that authorizes the marketing or free distribution of a pharmaceutical product in the respective country after evaluation for safety, efficacy and quality. In terms of quality it establishes inter alia the detailed composition and formulation of the pharmaceutical product and the quality requirements for the product and its ingredients. It also includes details of packaging, labelling, storage conditions, shelf life and approved conditions of use.
Marketing authorization (product licence, registration certificate) (1)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
Marketing authorization (product licence, registration certificate) (2)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

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Term	Related reference(s)	Definition
Marketing authorization (product licence, registration certificate) (3)	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the pharmaceutical product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
Marketing authorization (product licence, registration certificate) (4)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A legal document issued by the competent medicines regulatory authority that authorizes the marketing or free distribution of a pharmaceutical product in the respective country after evaluation for safety, efficacy and quality. In terms of quality it establishes inter alia the detailed composition and formulation of the pharmaceutical product and the quality requirements for the product and its ingredients. It also includes details of packaging, labelling, storage conditions, shelf-life and approved conditions of use.
Marketing authorization (product licence, registration certificate) (5)	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
Marketing authorization (product licence, registration certificate) (6)	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A legal document issued by the competent regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself and includes details of packaging, labelling and shelf life.
Marketing authorization holder	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	An individual or a corporate entity being in possession of a marketing authorization of a pharmaceutical product.

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Term	Related reference(s)	Definition
Master data		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	A single source of business data used across multiple systems, applications and processes and subject to change control to ensure accuracy throughout the data life-cycle.
Master formula		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

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Term	Related reference(s)	Definition
Master record		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
Master seed		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A homogeneous suspension of the original cells, already transformed by the expression vector containing the desired gene, dispensed in aliquots into individual containers for storage. All containers are treated identically during storage and once removed from it are not returned to the seed stock.
Material (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.
	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.
Material (2)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A general term used to denote raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs and packaging and labelling materials.
Materials (3)		
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A term used to denote starting materials, process aids, intermediates, active pharmaceutical ingredients, packaging and labelling materials.

Term

Related reference(s)	Definition
Matrix approach or bracketing	
Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Bracketing is the assessment of a single parameter or variable by identifying the edge(s) of the range of conditions for the parameter or variable and assessing these during validation to span the possible range of that parameter or variable. For example, bracketing can be applied to process parameters, multiple pieces of identical equipment and/or different size considerations for the same product. The rationale for using this strategy should be justified, documented and approved. Matrixing involves the assessment of the effect of more than one parameter or variable by using a multidimensional matrix to identify the “worstcase” or “extreme” conditions for a combination of parameters or variables. These conditions are used during validation of the process, rather than validating all possible combinations. Matrixing is typically used when there are significant similarities between products in a product family (e.g. the same product with different strengths in the manufacturing stage or different products with a similar container-closure in the packaging stage). The rationale for using this strategy should be justified, documented and approved. The use of a matrix approach or bracketing design would not be considered appropriate if it is not possible to demonstrate that the extremes are limited to the batches, products, strengths, container sizes or fills. For those excluded from the exercise there should be no risk to process capability.
Non sterile process validation (Annex 3, 53rd report, 2019)	Bracketing is the assessment of a single parameter or variable by identifying the edge(s) of the range of conditions for the parameter or variable and assessing these during validation to span the possible range of that parameter or variable. For example, bracketing can be applied to process parameters, multiple pieces of identical equipment and/or different size considerations for the same product. The rationale for using this strategy should be justified, documented and approved. Matrixing involves the assessment of the effect of more than one parameter or variable by using a multidimensional matrix to identify the “worstcase” or “extreme” conditions for a combination of parameters or variables. These conditions are used during validation of the process, rather than validating all possible combinations. Matrixing is typically used when there are significant similarities between products in a product family (e.g. the same product with different strengths in the manufacturing stage or different products with a similar container-closure in the packaging stage). The rationale for using this strategy should be justified, documented and approved. The use of a matrix approach or bracketing design would not be considered appropriate if it is not possible to demonstrate that the extremes are limited to the batches, products, strengths, container sizes or fills. For those excluded from the exercise there should be no risk to process capability.

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Term	Related reference(s)	Definition
Matrixing		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations is tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations is tested. The design assumes that the stability of each subset of samples tested represents the stability of all samples at a given time point. The differences in the samples for the same finished pharmaceutical product should be identified as, for example, covering different batches, different strengths, different sizes of the same container-closure system, and, possibly in some cases, different container-closure systems (refer to ICH Q1D).
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations is tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations is tested. The design assumes that the stability of each subset of samples tested represents the stability of all samples at a given time point. The differences in the samples for the same finished pharmaceutical product should be identified as, for example, covering different batches, different strengths, different sizes of the same container-closure system, and, possibly in some cases, different container-closure systems (refer to ICH Q1D).
Maximum safe carryover (MSC)		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The maximum amount of carryover of a residual process residue (API, cleaning agent, degradant, and so forth) into the next product manufactured without presenting an appreciable health risk to patients.
Maximum safe surface residue (MSSR)		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The MSSR is the maximum amount of process residue that can remain on equipment surfaces and still be safe to patients. The MSSR is mathematically calculated by dividing the Maximum Safe Carryover (MSC) by the total area of shared contact (MSC/Total Product Contact Surface Area).
Maximum theoretical residual impurity		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A gaseous impurity coming from a possible backflow that remains after a cylinder's pretreatment before filling. The calculation of the maximum theoretical residual impurity is only relevant for compressed gases and supposes that these gases act as perfect gases.
Mean kinetic temperature		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The single test temperature for a drug product corresponding to the effects on chemical reaction kinetics of a given temperature-time distribution. A mean kinetic temperature is calculated for each of the four world climatic zones according to the formula developed by Haynes (Haynes JD. World wide virtual temperatures for product stability testing. Journal of pharmaceutical sciences, 1971, 60:927-929). It is normally higher than the arithmetic mean temperature.
Measurement uncertainty		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Non-negative parameter characterizing the dispersion of quantity values being attributed to a measurand (analyte), based on the information used.

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Term

Related reference(s)	Definition
Medical device	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: ■■ diagnosis, prevention, monitoring, treatment or alleviation of disease; ■■ diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or of a physiological process; ■■ supporting or sustaining life; ■■ control of conception; ■■ disinfection of medical devices; ■■ providing information by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (1).
Medical product (1)	
Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	Products including, but not limited to, finished pharmaceutical products, medical devices, vaccines and IVD products.
Medical product (2)	
WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	Refers to medicines, vaccines and in vitro diagnostics (and in the future may include medical devices).
Medical product (3)	
Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A term that includes medicines, vaccines, diagnostics and medical devices.
Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	A term that includes medicines, vaccines, diagnostics and medical devices.
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A term that includes medicines, vaccines, diagnostics and medical devices.
Medical product (4)	
WHO Guideline on data integrity (Annex 4, 55th report, 2021)	A term that includes medicines, vaccines, diagnostics and medical devices.
Medical product (5)	
Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	For the purpose of this document, the term includes medicines, vaccines, blood and blood products and medical devices, including in-vitro diagnostics.

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Term	Related reference(s)	Definition
Medical product (6)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	Medical products include a wide range of manufactured items, such as finished pharmaceutical products, medical devices, vaccines and ivd products.
Medical products	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Products including, but not limited to, finished pharmaceutical products, medical devices including in vitro diagnostic medical devices, and vaccines.
Medicinal gas	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	Any gas or mixture of gases classified as a medical product.
Medicinal plant (1)	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes. (In: Good Manufacturing Practices: supplementary guidelines for the manufacture of herbal medicinal products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth report. Geneva, World Health Organization, 1996:109-113, Annex 8 (WHO Technical Report Series, No. 863)).
Medicinal plant (2)	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (Annex 8, 34th report, 1996)	A plant (wild or cultivated) used for medicinal purposes.
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	A plant (wild or cultivated) used for medicinal purposes.
Medicinal plant (3)	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	see Herbal materials
Medicinal plant material (crude plant material, vegetable drug)	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (Annex 8, 34th report, 1996)	Medicinal plants or parts thereof collected for medicinal purposes.

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Term

Related reference(s)	Definition
Medicinal plant materials (1)	
Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	See herbal materials.
Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	See herbal materials.
Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	See herbal materials.
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	See herbal materials.
Medicinal plants	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes (1, 3, 4).
Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes (1, 3, 4).
WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes (1, 3, 4).
WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes (1, 3, 4).
Medicine (1)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	See drug.
Medicine (2)	
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms medicine and pharmaceutical product (see below) are used interchangeably.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Medicine (3)		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.
Medicines legislation		
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The legal conditions under which pharmaceutical activities should be organized (see also legislation above)
Medicines regulatory authority		
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A national body that administers the full spectrum of medicine regulatory activities, including at least all of the following functions in conformity with national medicine legislation: ■ marketing authorization of new products and variations of existing products; ■ quality control laboratory testing; ■ monitoring of adverse drug reactions; ■ provision of information on medicines and promotion of rational use of medicines; ■ good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels; ■ enforcement operations; ■ monitoring of drug utilization.
Memorandum of understanding (MoU)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	A formal agreement between two or more parties. Companies and organizations can use MoUs to establish official partnerships. MoUs are not legally binding but they carry a degree of seriousness and mutual respect, stronger than a gentlemen's agreement.
Metadata		
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	Metadata are data that provide the contextual information required to understand other data. These include structural and descriptive metadata, which describe the structure, data elements, interrelationships and other characteristics of data. They also permit data to be attributable to an individual. Metadata that are necessary to evaluate the meaning of data should be securely linked to the data and subject to adequate review. For example, in the measurement of weight, the number 8 is meaningless without metadata, such as, the unit, milligram, gram, kilogram, and so on. Other examples of metadata include the time or date stamp of an activity, the operator identification (ID) of the person who performed an activity, the instrument ID used, processing parameters, sequence files, audit trails and other data required to understand data and reconstruct activities.

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Term	Related reference(s)	Definition
Metadata (2)	Good chromatography practices (Annex 4, 54th report, 2020)	Data about data that provide the contextual information required to understand those data. Metadata necessary to evaluate the meaning of data should be securely linked to the data and subject to adequate review. Examples of metadata include the time/date stamp of an activity, the operator identification (ID) of the person who performed an activity, the instrument ID used, processing parameters, sequence files, audit trails and other data required to understand data and reconstruct activities.
Method validation/verification	Guidelines on pre-approval inspections. (Annex 7, 36th report, 2002)	Method validation is conducted where non-compendial analytical methods are included in the application to confirm that the applicants' proposed analytical methods are suitable for regulatory purposes. A side-by-side comparison with a compendial method, if available, should be included. Method verification is conducted where the methods are compendial, to confirm whether the product as compounded can be analysed satisfactorily by the official method.
Metrological traceability	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty
Microbiology	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A branch of science that refers to microbes of all of types, including bacteria, viruses, rickettsia, protozoa, fungi and prions. Derived words (such as microbiological) have a similar meaning.
Minimum pressure retention valve	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A cylinder valve that maintains a positive pressure above atmospheric pressure in a gas cylinder after use in order to prevent any internal contamination of the cylinder.
Mini-tablet	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	A tablet of no more than 4 mm diameter.
Mobile cryogenic vessel	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A mobile thermally insulated container designed to maintain the contents in a liquid state.
Mobile site	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A unit or site used for the collection of blood and/or blood components, operating temporarily or at movable locations off-site from a permanent collection site, under the responsibility of a blood establishment.

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Term	Related reference(s)	Definition
Model product	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (Annex 5, 35th report, 1999)	A product which simulates a group of similar products
Monitor (1)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.
Monitor (2)	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	A person appointed by, and responsible to, the sponsor for monitoring and reporting the progress of the trial and for the verification of data.
Monitor (3)	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A person appointed by, and responsible to, the sponsor or CRO for the monitoring and reporting of progress of the trial and for verification of data.
Monitor (4)	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	A person appointed by the sponsor who is responsible for monitoring and reporting the progress of the trial and for the verification of data.
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	A person appointed by the sponsor who is responsible for monitoring and reporting the progress of the trial and for the verification of data.
Mother liquor (1)	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (Annex 5, 35th report, 1999)	A concentrated solution from which the product is obtained by evaporation, freezing, and/or crystallization.
Mother liquor (2)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The residual liquid which remains after the crystallization or isolation processes. A mother liquor may contain unreacted materials,intermediates, levels of the API and/or impurities. It may be used for further processing.

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Term

Related reference(s)	Definition
Multisource (generic) pharmaceutical product(s) (1)	
Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource (generic) pharmaceutical product(s) (2)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.

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Term

Related reference(s)	Definition
Mutual recognition agreement	
Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	According to a definition issued by the Organisation for Economic Co-operation and Development (OECD), a mutual recognition agreement is: a principle of international law whereby states party to mutual recognition agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process which allows conformity assessments (of qualifications, product) carried out in one country to be recognized in another country
Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	This is defined as the reciprocal adoption or acceptance of regulatory decisions or outcomes in other partner states in form of a legal agreement. It is stronger than a gentlemen's agreement and is usually binding.
National list of essential pharmaceutical products	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The list of essential pharmaceutical products (see above) that has been defined, adopted and published at country level. It is normally used by all health facilities, including the main hospitals.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The list of essential pharmaceutical products (see above) that has been defined, adopted and published at country level. It is normally used by all health facilities, including the main hospitals.
National medicines regulatory authority (NMRA)	
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	The national authority responsible for the registration of and other regulatory activities concerning medical products, such as medicines, vaccines, blood products and medical devices.
National regulatory authority (1)	
Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	The national agency responsible for the marketing authorization of, and other regulatory activities concerning, medical products.
National regulatory authority (2)	
World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A regulatory body with authority in a specific country to control the importation and distribution of medical products. See also regulatory authority.
National regulatory authority (NRA)	
WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	WHO terminology for national medicines regulatory authorities. NRAs should promulgate and enforce medicines regulations.

Term	Related reference(s)	Definition
Near-miss event	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An incident that, if not detected in a timely manner, would have affected the safety of the recipients or donors.
Net storage capacity	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The total volume available for storing TTSPPs, taking account of the type of load support system employed (floor-standing pallets, adjustable pallet racking or shelving units), as modified by the utilization factor that can be achieved in the store.
New active pharmaceutical ingredient	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Active pharmaceutical ingredient that has not been previously authorized as a medicine for use in humans in the country in question.
New chemical (or biological) entities	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Actives that have not previously been authorized for marketing as a drug for use in humans in the country in question.
No-impact system (1)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	This is a system that will not have any impact, either directly or indirectly, on product quality. These systems are designed and commissioned according to GEP only.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	This is a system that will not have any impact, either directly or indirectly, on product quality. These systems are designed and commissioned according to GEP only.
No-impact system (2)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A system that will not have any impact, either directly or indirectly, on product quality. These systems are designed and commissioned according to good engineering practice only.
Non-biological	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Not involving or derived from biology or living organisms.
Non-critical defect	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A defect that might affect the acceptability of the product, causing the device to be rejected at the time of insertion, but is not expected to affect the safety or effectiveness of the device.

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Term	Related reference(s)	Definition
Non-critical parameter or component		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A processing parameter or component within a system where the operation, contact, data control, alarm or failure will have an indirect impact or no impact on the quality of the product.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A processing parameter or component within a system where the operation, contact, data control, alarm or failure will have an indirect impact or no impact on the quality of the product.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A processing parameter or component within a system where the operation, contact, data control, alarm or failure will have an indirect impact or no impact on the quality of the product.
Non-return valve		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A valve that permits flow in one direction only.
Normal operating range		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The range that the manufacturer selects as the acceptable values for a parameter during normal operations. This range must be within the operating range.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The range that the manufacturer selects as the acceptable values for a parameter during normal operations. This range must be within the operating range.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The range that the manufacturer selects as the acceptable values for a parameter during normal operations. This range must be within the operating range.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The range that the manufacturer selects as the acceptable values for a parameter during normal operations. This range must be within the operating range.
Normal storage conditions		
	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	Storage in dry, well-ventilated premises at temperature of 15-25 °C or,depending on climatic conditions, up to 30 °C. Extraneous odours, other indications of contamination, and intense light have to be excluded.
Nucleic acid amplification techniques (NAT)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A testing method to detect the presence of a targeted area of a defined microbial genome that uses amplification techniques such as polymerase chain reaction (PCR).

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Term	Related reference(s)	Definition
Nuclide	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	A species of atom characterized by its mass number, atomic number and nuclear energy state, provided that the mean life in that state is long enough to be observable.
Occupational exposure level (OEL)	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	Airborne concentration of substances that will not result in adverse effects to most healthy workers, exposed for 8 hours/day, 40 hours/week.
Occurrence	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Probability of negative events within a fixed time frame.
Officially recognized pharmacopoeia (or compendium) (1)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Those pharmacopoeias recognized in the WHO Prequalification of Medicines Programme (i.e. British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur.), The International Pharmacopoeia (Ph.Int.), Japanese Pharmacopoeia (JP) and United States Pharmacopeia (USP).
Officially recognized pharmacopoeia (or compendium) (2)	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	Those pharmacopoeias recognized in the WHO/PQP (i.e. The International Pharmacopoeia (Ph. Int.), the European Pharmacopoeia (Ph. Eur.), the British Pharmacopoeia (BP), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP)).
Officially recognized pharmacopoeia (or compendium) (3)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	Those pharmacopoeias whose standards are officially recognized by an NMRA. These may be national, regional or international pharmacopoeias, at the discretion of the NMRA.
Off-label use	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	Use of a medicine outside the scope of regulatory authorization.
Ongoing stability study (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected retest period (or shelf life) of the active harmaceutical ingredient, or confirm or extend the shelf life of the finished pharmaceutical product.

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Term	Related reference(s)	Definition
Ongoing stability study (2)		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected re-test period (or shelf-life) of the API, or confirm or extend the shelf-life of the FPP.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected re-test period (or shelf-life) of the API, or confirm or extend the shelf-life of the FPP.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The study carried out by the manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected re-test period (or shelf-life) of the API, or confirm or extend the shelf-life of the FPP.
Online		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Measurement where the sample is diverted from the manufacturing process, and may be returned to the process stream.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Measurement where the sample is diverted from the manufacturing process, and may be returned to the process stream.
Operating limits		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The minimum and/or maximum values that will ensure that product and safety requirements are met.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The minimum and/or maximum values that will ensure that product and safety requirements are met.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The minimum and/or maximum values that will ensure that product and safety requirements are met.
Operating range (1)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Operating range is the range of validated critical parameters within which acceptable products can be manufactured.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Operating range is the range of validated critical parameters within which acceptable products can be manufactured.

Term

Related reference(s)	Definition
Operating range (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The range of validated critical parameters within which acceptable products can be manufactured.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The range of validated critical parameters within which acceptable products can be manufactured.
Operational condition (1)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	This condition relates to carrying out room classification tests with the normal production process with equipment in operation, and the normal staff present in the room.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	This condition relates to carrying out room classification tests with the normal production process with equipment in operation, and the normal staff present in the room.
Operational condition (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	This condition relates to carrying out room classification tests with the normal production process with equipment in operation and the normal staff present in the specific room.
Operational qualification (1)	
Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
Guidelines on qualification (Annex 3, 53rd report, 2019)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.

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Term

Related reference(s)	Definition
Operational qualification (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	This is the documentary evidence to verify that the equipment operates in accordance with its design specifications within its normal operating range and performs as intended throughout all anticipated operating ranges.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	This is the documentary evidence to verify that the equipment operates in accordance with its design specifications within its normal operating range and performs as intended throughout all anticipated operating ranges.
Operational qualification (OQ) (3)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Operational qualification is the documentary evidence to verify that the equipment operates in accordance with its design specifications in its normal operating range and performs as intended throughout all anticipated operating ranges.
Operational qualification (OQ) (4)	
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Documented verification that the analytical equipment performs as intended over all anticipated operating ranges.
Operator	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Any individual participating in the processing operation, including line set-up, filling, maintenance or other personnel associated with manufacturing activities.
Oral solid dosage (OSD)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Usually refers to an OSD plant that manufactures medicinal products such as tablets, capsules and powders to be taken orally.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Usually refers to an OSD plant that manufactures medicinal products such as tablets, capsules and powders to be taken orally.
Oral solid dosage form	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Usually refers to solid dosage forms of medicinal products such as tablets, capsules and powders to be taken orally.
Order (1)	
Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	An instruction to process, package and/or ship a certain number of units of an investigational product.

Term	Related reference(s)	Definition
Order (2)	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	An instruction to process, package and ship a certain number of doses of an investigational radiopharmaceutical.
Order (3)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	An instruction to process, package and ship a certain number of units of an investigational product.
Original manufacturer	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.
Original sample	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample collected directly from the material.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample collected directly from the material.
Out-of-specification (OOS) result	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	All test results that fall outside the specifications or acceptance criteria established in product dossiers, drug master fi les, pharmacopoeias or by the manufacturer.
Overkill sterilization	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A process that is sufficient to provide at least a 12 log10 reduction of microorganisms having a minimum D-value of 1 minute.
Over-the-counter drugs	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	These are drugs that can be sold from licensed dealers without professional supervision and without prescriptions. These drugs are suitable for self-medication for minor diseases and symptoms.
Package (1)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The foil sachet in which the condom is sealed after manufacture.
Package (2)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The film–film or film–Tyvek peel pouch in which the IUD is sealed after manufacture and sterilization.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Packaging (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.
Packaging (2)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
Packaging material	
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Packaging material (1)	
Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Any material, including printed material, employed in the packaging of a medical product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary, according to whether or not they are intended to be in direct contact with the product.
Packaging material (2)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any material, including printed material, employed in the packaging of a pharmaceutical product, (but) excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	Any material, including printed material, employed in the packaging of a pharmaceutical product, (but) excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

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Term	Related reference(s)	Definition
Packaging material (3)		
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	Any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the product.(There is a reference to (should conform with) "Good manufacturing practices for pharmaceutical products")
Packaging material (4)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Packaging material (5)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Any material intended to protect an intermediate or API during storage and transport.
Packaging process		
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product.
Parison		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The “tube” of polymer extruded by the BFS machine from which containers are formed.

Term	Related reference(s)	Definition
Participating authority or participating national medicines regulatory authority	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	National regulatory authority (NRA) that voluntarily agrees to implement this collaborative procedure and accepts the task of processing applications for registration of medicines approved by reference SRAs in accordance with the terms of the Procedure. A list of participating authorities is posted on the WHO Prequalification Team (WHO PQT) website (http://www.who.int/prequal/).
Participating authority or participating national regulatory authority	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	A NRA that voluntarily agrees to implement this collaborative procedure and accept the task of processing applications for registration of WHO-prequalified pharmaceutical products and vaccines, in accordance with the terms of the Procedure. A list of participating authorities is posted on the WHO/PQT website, for pharmaceutical products (12) and for vaccines (13).
Participating manufacturer	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A manufacturer, which is a holder of a marketing authorization granted by a reference SRA for a medicine that is intended to be submitted, has been submitted or has been granted national registration by participating NRAs in line with principles of the Procedure.
Participating stringent regulatory authority	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A reference stringent regulatory authority that agrees to provide outcomes of its regulatory expertise (especially assessment and inspection reports) to applicants/authorization holders or inspected manufacturers, does not object to sharing of these documents with national medicines regulatory authorities and provides, under specified conditions in line with the principles of the Procedure, support to other parties involved in the Procedure.
Passive systems	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Systems which maintain a temperature-controlled environment inside an insulated enclosure, with or without thermostatic regulation, using a finite amount of pre-conditioned coolant in the form of chilled or frozen gel packs, phase change materials, dry ice or others.
Pass-through hatch	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Synonymous with airlock [refer to airlock definition] but typically smaller in size.
Pass-through hatch or pass box	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A cabinet with two or more doors for passing equipment, material or product while maintaining the pressure cascade and segregation between two controlled zones. A passive pass-through hatch (PTH) has no air supply or air extraction. A dynamic PTH has an air supply into the chamber.

Term	Related reference(s)	Definition
Pass-through-hatch (PTH) or pass box (PB)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A cabinet with two or more doors for passing equipment or product, whilst maintaining the pressure cascade and segregation between two controlled zones. A passive PTH has no air supply or extract. A dynamic PTH has an air supply into the chamber.
Patient	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Human or animal participant in a clinical trial.
Pedigree (1)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A complete record that traces the ownership of and transactions relating to a pharmaceutical product as it is distributed through the supply chain.
Pedigree (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A complete record that traces the ownership of, and transactions relating to, a medical product as it is distributed through the supply chain.
Performance qualification (1)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The documented verification that the process and/or the total process related to the system performs as intended throughout all anticipated operating ranges.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The documented verification that the process and/or the total process related to the system performs as intended throughout all anticipated operating ranges.
Performance qualification (2)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented verification that the equipment or system performs consistently and reproducibly within defined specifications and parameters in its normal operating environment (i.e. in the production environment).
Performance qualification (PQ) (3)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Performance qualification is the documented verification that the process and/or the total process related to the system performs as intended throughout all anticipated operating ranges.

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Term	Related reference(s)	Definition
Performance qualification (PQ) (4)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented verification that the equipment or system operates consistently and gives reproducibility within defined specifications and parameters for prolonged periods. (In the context of systems, the term “process validation” may also be used.)
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Documented verification that the equipment or system operates consistently and gives reproducibility within defined specifications and parameters for prolonged periods. (In the context of systems, the term “process validation” may also be used.)
Performance qualification (PQ) (5)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Documented verification that the analytical equipment operates consistently and gives reproducibility within the defined specifications and parameters for prolonged periods.
Performance qualification (PQ) (6)		
	Guidelines on qualification (Annex 3, 53rd report, 2019)	Documented verification that the equipment or system operates consistently and gives reproducibility within defined specifications and parameters, for prolonged periods.
Performance requirements		
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The critical tests of quality that all lots must pass in order to provide adequate consumer protection.
Permitted daily exposure (PDE)		
	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	PDE represents a substance-specific dose that is unlikely to cause an adverse effect if an individual is exposed at or below this dose every day for a lifetime.
Personal protective equipment (PPE)		
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The necessary garments and equipment required to protect the operator in the workplace.
Pests		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Includes birds, bats, rodents and insects whose uncontrolled presence affects hygiene and cleanliness.

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Term

Related reference(s)	Definition
Pharmaceutical alternatives (1)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Products are pharmaceutical alternative(s) if they contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product.
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Products are pharmaceutical alternative(s) if they contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product.
Pharmaceutical alternatives (2)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Products are pharmaceutical alternative(s) if they contain the same active pharmaceutical moiety or moieties but differ in dosage form (e.g. tablets versus capsules), strength, and/or chemical form (e.g. different salts or different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product.
Pharmaceutical equivalence (1)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	Products are pharmaceutical equivalents if they contain the same amount of the same active substance(s) in the same dosage form; if they meet the same comparable standards; and if they are intended to be administered by the same route. However, pharmaceutical equivalence does not necessarily imply therapeutic equivalence as differences in the excipients and/or the manufacturing process can lead to differences in product performance.
Pharmaceutical equivalence (2)	
Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Products are pharmaceutical equivalents if they contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance.
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Products are pharmaceutical equivalents if they contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance.

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Term	Related reference(s)	Definition
Pharmaceutical equivalence (3)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Products are pharmaceutical equivalents if they contain the same molar amount of the same APIs in the same dosage form, if they meet comparable standards and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the API solid state properties, the excipients and/or the manufacturing process and other variables can lead to differences in product performance.
Pharmaceutical equivalents		
	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Products are pharmaceutical equivalents if they contain the same amount of the same actives in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or manufacturing process and some other variables can lead to differences in product performance.
Pharmaceutical excipient (1)		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A substance, other than the active pharmaceutical ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to: — aid in the processing of the drug delivery system during its manufacture; — protect, support or enhance stability, bioavailability or patient acceptability; — assist in pharmaceutical product identification; or — enhance any other attribute of the overall safety and effectiveness of the drug during its storage or use.
Pharmaceutical excipient (2)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A substance, other than the active pharmaceutical ingredient (API), which has been appropriately evaluated for safety and is included in a medicines delivery system to: — aid in the processing of the medicines delivery system during its manufacture; — protect, support or enhance stability, bioavailability or patient acceptability; — assist in pharmaceutical product identification; or — enhance any other attribute of the overall safety and effectiveness of the medicine during its storage or use.
Pharmaceutical excipients		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (Annex 5, 35th report, 1999)	Substances, other than the active ingredient, which have been appropriately evaluated for safety and are included in a drug delivery system to:— aid in the processing of the drug delivery system during its manufacture; — protect, support or enhance stability, bioavailability or patient acceptability; — assist in product identification; or — enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.

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Term	Related reference(s)	Definition
Pharmaceutical Inspection Co-operation Scheme (PIC/S)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	This is a non-binding, informal cooperative arrangement between regulatory authorities in the field of good manufacturing practices of medical products for human or veterinary use.
Pharmaceutical product (1)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required; products that may be sold to patients without a prescription; biologicals; and vaccines. It does not, however, include medical devices.
Pharmaceutical product (2)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	Any material or product intended for human or veterinary use presented in its finished dosage form, or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state.
Pharmaceutical product (3)		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.
	Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.
	Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.

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Related reference(s)	Definition
Pharmaceutical product (4)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	See drug.
Pharmaceutical product (5)	
Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Any substance or combination of substances which has a therapeutic, prophylactic or diagnostic use, or is intended to modify physiological functions, and is presented in a dosage form suitable for administration to humans.
Pharmaceutical product (6)	
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices.
Pharmaceutical product (7)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
Pharmaceutical product (8)	
Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Any product intended for human use or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription,biologicals and vaccines. It does not, however, include medical devices.
Pharmaceutical product (9)	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	Any medicine intended for human use or administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

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Term	Related reference(s)	Definition
Pharmaceutical product (x10)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	For the purpose of this Annex, this term is defined in the same way as in the WHO guidelines on GCP (Guidelines for good clinical practice (GCP) for trials on pharmaceutical products. In: The use of essential drugs. Model List of Essential Drugs (Eighth List). Sixth report of the WHO Expert Committee. Geneva, World Health Organization, 1995:97 - 137(WHO Technical Report Series, No. 850)), i.e. as any substance or combination of substances which has a therapeutic, prophylactic or diagnostic purpose, or is intended to modify physiological functions, and is presented in a dosage form suitable for administration to humans.
Pharmaceutical product (x11)		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
	Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	Any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

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Term

Related reference(s)	Definition
Pharmaceutical product (x12)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * “Material” is used in the document for “pharmaceutical products and related materials” (WHO guidelines for sampling of pharmaceutical products and related materials.)
Pharmaceutical product (x13)	
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Any preparation for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.
Pharmaceutical product (x14)	
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Any material or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. (note: in this guidance, the term pharmaceutical product may include products for preclinical use.)

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Term	Related reference(s)	Definition
Pharmaceutical product (x15)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	For the purpose of this document, this term is defined in the same way as in the who handbook for good clinical research practices (4), that is, as any substance or combination of substances that has a therapeutic, prophylactic or diagnostic purpose, or is intended to modify physiological functions, and is presented in a dosage form suitable for administration to humans.
Pharmaceutical product (x16)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	Any material or product intended for human or veterinary use presented in its finished dosage form, or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state or the importing state.
Pharmaceutical product target profile (PPTP)	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A definition of the target properties of the FPP, including dosage form and strength(s), route of administration and relevant drug release and pharmacokinetic requirements.
Pharmaceutical quality system	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Management system to direct and control a pharmaceutical company with regard to quality.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Management system to direct and control a pharmaceutical company with regard to quality.
Pharmaceutical starting material (1)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A pharmaceutical starting material is an active pharmaceutical ingredient (API) or an excipient intended or designated for use in the production of a pharmaceutical product.
Pharmaceutical starting material (2)	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials. This includes active pharmaceutical ingredients (APIs) and pharmaceutical excipients.
Pharmaceutical substance	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	See Active pharmaceutical ingredient.
Pharmaceuticals	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	All products related to pharmacy, including starting materials (active pharmaceutical ingredients and excipients), finished dosage forms, and biological and other specific products.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Pharmacist	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A pharmacist is a holder of a degree or diploma in pharmacy from a recognized higher institution of learning and is registered or licensed to practise pharmacy.
Pharmacopoeial reference standards	General guidelines for the establishment, maintenance and distribution of chemical reference substances (Annex 3, 41st report, 2007)	The specificity of pharmacopoeial reference substances has been addressed in the introduction of ISO Guide: General requirements for the competence of reference material producers. “Pharmacopoeial standards and substances are established and distributed by pharmacopoeial authorities following the general principles of this Guide. It should be noted, however, that a different approach is used by the pharmacopoeial authorities to give the user the information provided by certificate of analysis and expiration dates” (*). *International Organization for Standardization. General requirements for the competence of reference material producers. 2006, ISO Guide 34.
Pharmacopoeial reference substances (standards)	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Pharmacopoeial reference substances (standards) are primary reference substances established and distributed by pharmacopoeial authorities following the general principles of the ISO Guide 34 (8). Note: a different approach is used by the pharmacopoeial authorities to give the user the information provided by certificate of analysis and expiration dates (7).
Pharmacy-only drugs	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	These are drugs authorized to be sold only in licensed pharmacies under the supervision of licensed or registered pharmacists; they may be sold without a prescription.
Pilot-scale batch (1)	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.
	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A batch of an API or FPP manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.

Term	Related reference(s)	Definition
Pilot-scale batch (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A batch of an active pharmaceutical ingredient or finished pharmaceutical product manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger, unless otherwise adequately justified.
Pilot-scale batch (3)	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A batch of an active pharmaceutical ingredient or finished pharmaceutical product manufactured by a procedure fully representative of and simulating that to be applied to a full production-scale batch. For example, for solid oral dosage forms, a pilot scale is generally, at a minimum, one-tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.
Pivotal clinical trials	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Those clinical studies that provide the significant evidence that is the basis for the decision as to the risk–benefit assessment for a particular FDC.
Placing on the market	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	All controls applied by the regulatory authority to the manufacturer and/or authorized representative at the stage of, and as a condition of, making available an individual medical device with a view to its distribution and/or use within the jurisdiction.
Planned risk assessment	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	An assessment that is conducted in advance of an activity, either before any work is conducted or before further work is conducted. This enables quality to be built into activities and risk to be reduced, e.g. design of high containment facilities for manufacture of cytotoxic products.
Plant preparations	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (Annex 8, 34th report, 1996)	Comminuted or powdered plant material, extracts, tinctures, fatty or essential oils, resins, gums, balsams, expressed juices, etc., prepared from plant material, and preparations whose production involves a fractionation, purification or concentration process, but excluding chemically defined isolated constituents. A plant preparation can be regarded as the active ingredient whether or not the constituents having therapeutic activities are known.
Plasma for fractionation	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The liquid part of human blood remaining after separation of the cellular elements from blood collected in a container containing an anticoagulant, or separated by continuous filtration and/or centrifugation of anticoagulated blood in an apheresis procedure, intended for further manufacturing.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Plasmid	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	An autonomously replicating, circular, extrachromosomal DNA element. It usually carries a few genes, some of which confer resistance to various antibiotics; such resistance is often used to discriminate between organisms that contain the plasmid and those that do not.
Platform technology	Development of paediatric medicines: points to consider in formulation (Annex 5, 46th report, 2012)	Technique, including formulation and related processes, which can be used to obtain different dosage forms, different strengths and/or accommodate different APIs.
Point extraction (1)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Air extraction to remove dust with the extraction point located as close as possible to the source of the dust.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Air extraction to remove dust with the extraction point located as close as possible to the source of the dust.
Point extraction (2)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Air extraction point located so that it effectively captures dust near its source.
Point of departure (of the HBEL calculation)	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	The dose-response point that marks the beginning of a low-dose extrapolation to derive an HBEL. This point can be a No Observed Adverse Effect Level (NOAEL) or No Observed Effect Level (NOEL), Lowest Observed Adverse Effect Level (LOAEL) or Lowest Observed Effect Level (LOEL), or Benchmark Dose Level (BMDL) for an observed effect [the highest dose at which no unwanted/adverse effect is observed (NOEL/NOAEL), or, if unavailable, the dose at which a significant adverse effect is first observed (LOEL/LOAEL)].
Poison	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A preparation or substance defined by a national drug law as a poison.
Pooled sample	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample resulting from the pooling of all or parts of two or more samples of the material.

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Term	Related reference(s)	Definition
Post-aseptic processing terminal heat treatment	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A terminal moist heat process employed after aseptic processing that has been demonstrated to provide a sterility assurance level of ≤ 10–6 but where the requirements of steam sterilization (for example, F0 ≥ 8 minutes) are not fulfilled. This may also be beneficial in the destruction of viruses that may not be removed through filtration.
Post-harvest processing	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	Post-harvest processing covers any treatment procedures performed on the herbs after harvest or collection when they are being processed into herbal materials. It includes processes such as inspection, sorting and various primary processing and drying. Often, well-defined combined or serial procedures are applied to herbs before they can be used in therapeutic treatment or as intermediates for manufacturing finished herbal products. These treatment processes are considered important pharmaceutical techniques in the herbal industry, through which purity and/or quality of raw herbs is assured (such as prevention of microbial and insect infection or infestation), and the therapeutic properties of raw herbs are altered (such as enhancement of effectiveness or reduction of toxicity). These primary processing procedures may vary from one herbal material to another, depending on its chemical and pharmacological characteristics, as well as the intended therapeutic purposes.
Postmarket controls	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	All controls applied by the regulatory authority to the manufacturer and/or authorized representative after a manufacturer's medical device has been placed on the market or put into service.
Postmarket surveillance	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The activities carried out and measures taken by a regulatory authority to ensure that medical devices placed on the market comply with regulations and do not endanger health, safety or any other aspect of public health (based on EU Council Directive 93/42/EEC of 14 JUNE 1993 concerning medical devices) (23).
Pre-approval batches	Guidelines on pre-approval inspections. (Annex 7, 36th report, 2002)	Pilot or laboratory-scale batches, upon which the application is based,e.g. batches used for pivotal clinical trials and/or those used for bioavailability, bioequivalence and stability studies, and scale-up batches.
Precision (1)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The degree of agreement among individual results when the procedure is applied repeatedly to multiple samplings of a homogeneous sample. Precision, usually expressed as relative standard deviation, may be considered at three levels: repeatability (precision under the same operating conditions over a short period of time), intermediate precision (within laboratory variations — different days, different analysts or different equipment) and reproducibility (precision between laboratories).

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Term	Related reference(s)	Definition
Precision (2)		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The degree of agreement among individual results.
Premarket controls		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	All controls applied by the regulatory authority to the manufacturer and/or the authorized representative before the manufacturer's medical device may be placed on the market or put into service.
Preparation or kit reconstitution.		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	For the purpose of this document, these terms are defined in the same way as in the IAEA/WHO guideline on good manufacturing practices for radiopharmaceutical products (3). They refer to all the procedures carried out as per instructions from marketing authorization holders that involve addition of radionuclide solution approved by regulatory authorities to an approved cold kit.
Prequalification (1)		
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The steps taken by the buyer to verify a manufacturer's suitability to provide condoms of the required quality. The WHO/UNFPA Prequalification Programme includes periodic assessment of manufacturing dossiers, testing of samples and factory inspection.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term

Related reference(s)	Definition
Prequalification (2)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the approval. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture or registration, but the amount and type of information requested from the supplier for use in the assessment by the procurement agency may differ.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the approval. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture or registration, but the amount and type of information requested from the supplier for use in the assessment by the procurement agency may differ.
WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the approval. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture or registration, but the amount and type of information requested from the supplier for use in the assessment by the procurement agency may differ.

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Term	Related reference(s)	Definition
Prequalification (3)		
	Procedure for prequalification of pharmaceutical Products. (Annex 3, 43rd report, 2009)	Standardized quality assessment procedure of WHO to evaluate the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies. Agencies using information resulting from the prequalification procedure should perform additional steps of qualification prior to purchasing, such as ensuring financial stability and standing of the supplier, ability to supply the required quantities, security of the supply chain, preshipment quality control and other related aspects.
	Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	Standardized quality assessment procedure of WHO to evaluate the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies. Agencies using information resulting from the prequalification procedure should perform additional steps of qualification prior to purchasing, such as ensuring financial stability and standing of the supplier, ability to supply the required quantities, security of the supply chain, preshipment quality control and other related aspects.
Prequalification (4)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The steps taken by the buyer to verify a manufacturer's suitability to provide iuds of the required quality. The WHO/UNFPA Prequalification Programme includes periodic assessment of manufacturing dossiers, testing of samples and manufacturer inspection.
Prescribed		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	Studies designed to increase the rate of chemical degradation and physical change of a drug by using exaggerated storage conditions as part of the formal stability testing programme. The data thus obtained, in addition to those derived from real-time stability studies, may be used to assess longer-term chemical effects under non-accelerated conditions and to evaluate the impact of short-term excursions outside the label storage conditions, as might occur during shipping. The results of accelerated testing studies are not always predictive of physical changes.
Prescription-only drugs		
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	These are drugs supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these drugs must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription drugs are further subdivided into controlled drugs (narcotic drugs and psychotropic substances) and non-controlled drugs.
Pre-shipment compliance testing		
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A regimen of compliance tests carried out before a shipment leaves the supplier's factory.

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Term

Related reference(s)	Definition
Pressure cascade (1)	
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A process whereby air flows from one area, which is maintained at a higher pressure, to another area at a lower pressure.
Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A process whereby air flows from one area, which is maintained at a higher pressure, to another area at a lower pressure.
WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A process whereby air flows from one area, which is maintained at a higher pressure, to another area at a lower pressure.
Pressure cascade (2)	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A process whereby air flows from one area, which is maintained at a higher pressure, to another area maintained at a lower pressure.
Pressurized container	
Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container suitable for compressed, liquefied or dissolved gas fitted with a device that, after its actuation, produces a controlled spontaneous release of the contents at atmospheric pressure and room temperature.
Primary batch (1)	
Guidelines on submission of documentation for a multisource (generic) finished product. General format: preparation of product dossiers in common technical document format. (Annex 15, 45th report, 2011)	A batch of an API or FPP used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a re-test period or shelf-life, as the case may be. A primary batch of an API should be at least a pilot-scale batch. For an FPP, two of the three batches should be at least pilot-scale batches, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch.
Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A batch of an API or FPP used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a re-test period or shelf-life, as the case may be. A primary batch of an API should be at least a pilot-scale batch. For an FPP, two of the three batches should be at least pilot-scale batches, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch.
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A batch of an API or FPP used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a re-test period or shelf-life, as the case may be. A primary batch of an API should be at least a pilot-scale batch. For an FPP, two of the three batches should be at least pilot-scale batches, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch.

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Term	Related reference(s)	Definition
Primary batch (2)	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A batch of an active pharmaceutical ingredient or finished pharmaceutical product used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a retest period or shelflife, as the case may be.
Primary batch (3)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A batch of an active pharmaceutical ingredient (API) or finished pharmaceutical product (FPP) used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a retest period or shelf life, as the case may be. Primary batch requirements are outlined in 2.1.3 and 2.2.3 for the API and FPP, respectively.
Primary chemical reference substance	General guidelines for the establishment, maintenance and distribution of chemical reference substances (Annex 3, 41st report, 2007)	A designated primary chemical reference substance is one that is widely acknowledged to have the appropriate qualities within a specified context, and whose assigned content when used as an assay standard is accepted without requiring comparison with another chemical substance.
Primary chemical reference substances	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Primary chemical reference substances are substances that are widely acknowledged to have the appropriate qualities within a specified context, and whose assigned content when used as a (mostly as an assay) standard is accepted without requiring comparison to another chemical substance (7).
Primary legislation	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A form of law, created by a legislative branch of government, consisting of statutes that set out broad outlines and principles and may delegate authority to an executive branch of government to issue secondary legislation.
Primary packaging	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	Any packaging material that comes into direct contact with the finished radiopharmaceutical product (i.e. an immediate container, such as a vial or a syringe).
Primary reference substance (or standard)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A substance that is widely acknowledged to possess the appropriate qualities within a specified context, and whose assigned content is accepted without requiring comparison with another chemical substance (8). Note: Pharmacopoeial chemical reference substances are considered to be primary reference substances. In the absence of a pharmacopoeial reference substance, a manufacturer should establish a primary reference substance.
Principal investigator	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	The investigator serving as coordinator for certain kinds or clinical trials, e.g. multicentre trials.

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Term	Related reference(s)	Definition
Principles (of a good review)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The important GRevP elements for Ras to implement in order to achieve successful review outcomes.
Procedure		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A documented description of the operations to be performed, the precautions to be taken and measures to be applied, directly or indirectly related to the manufacture of an intermediate or API.
Process		
	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	A set of interrelated or interacting activities that use inputs to deliver an intended result. In the context of NRAs, the production and service provision processes should coincide with basic regulatory functions.
Process aids		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Materials, excluding solvents, used as an aid in the manufacture of an intermediate or API that do not themselves participate in a chemical or biological reaction (e.g. filter aid or activated carbon).
Process average		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The percentage of nonconforming iuds over a defined time period or quantity of production. It is calculated for each requirement detailed in the WHO/UNFPA tcu380a IUD technical specification by dividing the number of nonconforming iuds by the total number of iuds tested. Ideally, the process average for a specific attribute should not be greater than half the specified AQL.
Process control		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	See In-process control.
Process qualification		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	Process qualification combines the actual facility, utilities, equipment (each now qualified) and the trained personnel with the commercial manufacturing process, control procedures and components to produce commercial batches; confirms the process design and demonstrates that the commercial manufacturing process performs as expected.
	Non sterile process validation (Annex 3, 53rd report, 2019)	Process qualification combines the actual facility, utilities, equipment (each now qualified) and the trained personnel with the commercial manufacturing process, control procedures and components to produce commercial batches; confirms the process design and demonstrates that the commercial manufacturing process performs as expected.

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Term	Related reference(s)	Definition
Process robustness		
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Ability of a process to tolerate variability of materials and changes of the process and equipment without negative impact on quality.
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Ability of a process to tolerate variability of materials and changes of the process and equipment without negative impact on quality.
Process validation (1)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Documented evidence which provides a high degree of assurance that a specific process will consistently result in a product that meets its pre-determined specifications and quality characteristics.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Documented evidence which provides a high degree of assurance that a specific process will consistently result in a product that meets its pre-determined specifications and quality characteristics.
Process validation (2)		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	The collection and evaluation of data, from the process design stage through to commercial production, which establishes scientific evidence that a process is capable of continuously delivering the finished pharmaceutical product meeting its predetermined specifications and quality attributes.
	Non sterile process validation (Annex 3, 53rd report, 2019)	The collection and evaluation of data, from the process design stage through to commercial production, which establishes scientific evidence that a process is capable of continuously delivering the finished pharmaceutical product meeting its predetermined specifications and quality attributes.
Process validation (3)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	The collection and evaluation of data, throughout the product life-cycle, which provides documented scientific evidence that a process is capable of consistently delivering quality products.
Process validation (4)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	The collection and evaluation of data, from the process design stage through to commercial production, that establish scientific evidence that a process is capable of consistently delivering the API or finished pharmaceutical product meeting its predetermined specifications and quality attributes.
Processing instructions		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	See master formula.

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Term

Related reference(s)	Definition
Procurement	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceuticals for human use. For the purpose of this document, procurement means the pre-selection of products and manufacturers through a procedure of qualification, including prequalification (see above) and continuous monitoring thereafter, purchase of the prequalified products from prequalified manufacturers (linked to the specific product) through defined purchasing mechanisms, storage and distribution.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceuticals for human use. For the purpose of this document, procurement means the pre-selection of products and manufacturers through a procedure of qualification, including prequalification (see above) and continuous monitoring thereafter, purchase of the prequalified products from prequalified manufacturers (linked to the specific product) through defined purchasing mechanisms, storage and distribution.
Procurement agency	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Any organization which is purchasing or otherwise acquiring any pharmaceutical product, vaccine or nutraceutical for human use. In the context of these guidelines it will normally be a not-for-profit organization, a non governmental organization (NGO) or a United Nations organization. A procurement agency in the context of this document is defined as any organization purchasing pharmaceutical products, vaccines, or other health sector goods or is otherwise involved in their prequalification (see above), purchasing, storage and distribution.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Any organization which is purchasing or otherwise acquiring any pharmaceutical product, vaccine or nutraceutical for human use. In the context of these guidelines it will normally be a not-for-profit organization, a non governmental organization (NGO) or a United Nations organization. A procurement agency in the context of this document is defined as any organization purchasing pharmaceutical products, vaccines, or other health sector goods or is otherwise involved in their prequalification (see above), purchasing, storage and distribution.
Product (1)	
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See pharmaceutical product.
Product (2)	
WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Output of an organization that can be produced without any transaction taking place between the organization and the customer. They are also called regulatory products in this guideline. Products of NRAs relate to the tangible items that the NRA produces for its customers. These items include regulatory guidelines; public health notices; guidance notes; alerts; databases; mobile phone applications; reports; and other materials that are intended to provide regulatory information and communications to customers. Before their production, some of these products may require lengthy consultations for designing them.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Product certificate	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	A document containing the information as set out in Appendix 1 of the guidelines that is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the competent authority in the importing country or - in the absence of such an authority - by the drug procurement authority (see also section 3.5 of the guidelines). Transmission of product certificate: see sections 3.8 and 4.9 of the guidelines. Validity of product certificate: see section 3.9 of the guidelines. When to request a product certificate: see section 3.5 of the guidelines.
Product information (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The approved product information referred to in section 4.7 of the guidelines and item 2A.5 of the Product Certificate. It normally consists of information for health professionals and the public (patient information leaflets), as approved in the exporting country and, when available, a data sheet or a Summary of Product Characteristics (SPC) approved by the regulatory authority.
Product information (2)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	The information provided by the supplier of an FPP that allows prescribers and consumers to ensure the safe and effective use of drugs. If it is written especially for prescribers, it may be termed prescribing information.
Product information (3)	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	In the context of this document, product information means information on pharmaceutical products submitted by manufacturers or suppliers in any of the formats specified in the procurement agency's guidelines (including product dossiers, product questionnaires or other formats) to obtain prequalification for the products.
Product information (4)	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Information on pharmaceutical products submitted by manufacturers or suppliers in any of the formats specified in the procurement agency's guidelines (including product dossiers, product questionnaires or other formats) to obtain prequalification for the products.
Product licence (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	An official document issued by the competent drug regulatory authority for the purpose of the marketing or free distribution of a product. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names or national generic names, where they exist), the shelf-life and storage conditions, and packaging characteristics. It also contains all the information approved for health professionals and the public (except promotional information), the sales category, the name and address of the licence holder, and the period of validity of the licence.

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Term	Related reference(s)	Definition
Product recall (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer/importer/ distributor or a responsible agency.
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer/importer/ distributor or a responsible agency.
Product recall (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A process for withdrawing or removing a medical product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be falsified. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.
Product recall (3)		
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.
Product specification file (2)		
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	The product specification file brings together and contains or refers to all of the essential reference documents to ensure that investigational products are manufactured according to good manufacturing practice for investigational products and the clinical trial authorization. It should be continually updated as development of the product proceeds, ensuring appropriate traceability to the previous versions.
Product specification file(s) (1)		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	Reference file(s) containing all the information necessary to draft the detailed written instructions on processing, packaging, labelling, quality control testing, batch release, storage conditions and shipping.
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	Reference file(s) containing all the information necessary to draft the detailed written instructions on processing, packaging, labelling, quality control testing, batch release, storage conditions and shipping.

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Term

Related reference(s)	Definition
Production (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.
Production (2)	
Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	All operations involved in the preparation of a pharmaceutical product, from receipt of the starting materials, through processing and packaging, to completion of the finished product.
Production (3)	
Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	All operations involved in the preparation of a pharmaceutical starting material, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished pharmaceutical starting materials.
Production (4)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
Production (5)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	All operations involved in the preparation of an API from receipt of materials through processing and packaging of the API.

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Term	Related reference(s)	Definition
Production (6)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	All operations involved in the preparation of blood components, from collection through processing to completion as a finished product (blood component).
Production (7)		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	All operations involved in the preparation of a product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	All operations involved in the preparation of a product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
Production (8)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	All operations involved in the preparation of a medical product, from receipt of materials through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product. quality assurance. A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that medical products are of the quality required for their intended use. quality risk management. A systematic process for the assessment, control, communication and review of risks to the quality of medical products in the supply chain. quality system. An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. quarantine. The status of medical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Production at finite passage		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A cultivation method involving a limited number of passages or population doublings which must not be exceeded during production.
Production batch (1)		
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A batch of an active pharmaceutical ingredient or finished pharmaceutical product manufactured at production scale by using production equipment in a production facility as specified in the application.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A batch of an active pharmaceutical ingredient or finished pharmaceutical product manufactured at production scale by using production equipment in a production facility as specified in the application.

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Term	Related reference(s)	Definition
Production batch (2)		
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.
	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6, 48th report, 2014)	A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.
	WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A batch of an API or FPP manufactured at production scale by using production equipment in a production facility as specified in the application.
Production environment		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	For regulated computerized systems, the production environment is the business and computing operating environment in which the computerized system is being used for GMP-regulated purposes.
Product-licence holder		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See licence holder.
Prohibited drugs		
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	These are drugs with toxicity or side-effects that outweigh their therapeutic usefulness, so that public health and welfare are protected by prohibiting their production, manufacture, export, import, trade, distribution, supply, possession or use, except in amounts required for medical or scientific research. Prohibited drugs are normally determined by the national or supranational registration/licensing authority.
Project management (for the review process)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The planning, organization and resources to achieve a complete and high quality review of an application within a specified time frame.

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Term	Related reference(s)	Definition
Prospective validation		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Validation carried out during the development stage on the basis of a risk analysis of the production process, which is broken down into individual steps; these are then evaluated on the basis of past experience to determine whether they may lead to critical situations.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Validation carried out during the development stage on the basis of a risk analysis of the production process, which is broken down into individual steps; these are then evaluated on the basis of past experience to determine whether they may lead to critical situations.
Protocol (1)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	A document which gives the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. It should be dated and signed by the investigator/institution involved and the sponsor, and can, in addition, function as a contract.
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	A document which gives the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. It should be dated and signed by the investigator/institution involved and the sponsor, and can, in addition, function as a contract.
Protocol (2)		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	A document that gives the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator or institution involved and the sponsor, and can, in addition, function as a contract.
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	A document that gives the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator or institution involved and the sponsor, and can, in addition, function as a contract.
Provisional (tentative) shelf-life		
	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	The provisional shelf-life is determined by projecting results from accelerated stability studies.
Provisional shelf life (1)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A provisional expiry date that is based on acceptable accelerated and available long-term data for the finished pharmaceutical product to be marketed in the proposed container-closure system.
Provisional shelf-life (2)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A provisional expiry date which is based on acceptable accelerated and available long-term data for the FPP to be marketed in the proposed container closure system.

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Term	Related reference(s)	Definition
Public health emergency	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	The condition that requires a governor to declare a state of public health emergency, defined as an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability. The declaration of a state of public health emergency permits a governor to suspend state regulations and change the functions of state agencies
Purge	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	To remove the residual gas from a container or system by first venting the residual gas from the container or system, then pressurizing the container or system to 2 bar and thereafter venting the gas used for purging to 1.013 bar.
Purity	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	The degree to which other chemical or biological entities are present in any substance.
Pyrogen	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A substance that induces a febrile reaction in patients receiving injections.
Qualification (1)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.
Qualification (2)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Qualification is the planning, carrying out and recording of tests on equipment and a system, which forms part of the validated process, to demonstrate that it will perform as intended.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Qualification is the planning, carrying out and recording of tests on equipment and a system, which forms part of the validated process, to demonstrate that it will perform as intended.

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Term	Related reference(s)	Definition
Qualification (3)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The planning, carrying out and recording of tests on equipment and a system, which forms part of the validated process, to demonstrate that it will perform as intended.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The planning, carrying out and recording of tests on equipment and a system, which forms part of the validated process, to demonstrate that it will perform as intended.
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The action of proving and documenting that any premises, systems and equipment are properly installed and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.
Qualification (4)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.
Qualification (5)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A set of actions used to provide documented evidence that any piece of equipment, critical material or reagent used to produce the final product and that might affect the quality or safety of a product works reliably as intended or specified and leads to the expected results.
Qualification (6)		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Documented testing that demonstrates, with a high degree of assurance, that a specific process will meet its predetermined acceptance criteria.
Qualification (7)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Documented evidence that premises, systems or equipment are able to achieve the predetermined specifications when properly installed, and/or work correctly and lead to the expected results.

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Term	Related reference(s)	Definition
Qualification (8)		
	Good chromatography practices (Annex 4, 54th report, 2020)	Documented evidence that premises, systems or equipment are able to achieve the predetermined specifications, are properly installed, and/or work correctly, and lead to the expected results.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Documented evidence that premises, systems or equipment are able to achieve the predetermined specifications, are properly installed, and/or work correctly, and lead to the expected results.
Qualification (9)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Documented evidence that premises, systems or equipment are able to achieve the predetermined specifications when properly installed and working correctly, and lead to the expected results.
Qualification batches		
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Those batches produced by the receiving unit (RU) to demonstrate its ability to reproduce the product
Qualification of equipment (1)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The act of planning, carrying out and recording the results of the tests on equipment to demonstrate that it will perform as intended.Measuring instruments and systems must be calibrated.
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	The act of planning, carrying out and recording the results of the tests on equipment to demonstrate that it will perform as intended.Measuring instruments and systems must be calibrated.
Qualification of equipment (2)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Action of proving and documenting that any analytical equipment complies with the required specifications and performs suitably for its intended purpose (see Part two, section 12).
Quality (1)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The total set of characteristics of an entity that affect its ability to satisfy stated and implied needs, and the consistent and reliable performance of services or products in conformity with specified requirements. Implied needs include safety and quality attributes of products intended both for therapeutic use and as starting materials for further manufacturing.
Quality (2)		
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	The suitability of either an active pharmaceutical ingredient or a pharmaceutical product for its intended use. This term includes such attributes as the identity, strength and purity.

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Term	Related reference(s)	Definition
Quality (3)		
	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	The total set of characteristics of an entity that affect its ability to satisfy stated and implied needs and to ensure the consistent and reliable performance of services or products in conformity with specified requirements.

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Term

Related reference(s)	Definition
Quality assurance (1)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.
WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.

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Term

Related reference(s)	Definition
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.

Quality assurance (2)

Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality assurance (3)

Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product, including pharmaceutical starting materials. It is the totality of the arrangements made with the object of ensuring that pharmaceutical starting materials and pharmaceutical products are of the quality required for their intended use.

Quality assurance (4)

WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A part of quality management focused on providing confidence that quality requirements will be met.

Quality assurance (5)

WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	See Part One. Good manufacturing practices for pharmaceutical products, In:WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report. Geneva, World Health Organization, 1992,Annex 1 (WHO Technical Report Series, No. 823); and in: Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume 2, Second updated edition. Good manufacturing practices and Inspection. Geneva, World Health Organization, 2007; and in: Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Geneva, World Health Organization, 2010 (CD-ROM).

Quality assurance (7)

Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that medical products are of the quality required for their intended use.

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Term	Related reference(s)	Definition
Quality assurance (QA)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The sum total of the organized arrangements made with the object of ensuring that all APIs are of the quality required for their intended use and that quality systems are maintained.
Quality assurance relating to clinical trials		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Systems and quality control procedures that are established to ensure that the trial is performed and the data are generated in compliance with GCP and GLP. These include procedures to be followed which apply to ethical and professional conduct, standard operating procedures (SOPs), reporting, and professional qualifications or skills of personnel .
Quality audit		
	Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	An examination and assessment of all or part of a quality system with the specific purpose of improving it. A quality audit is usually conducted by outside or independent specialists or a team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	An examination and assessment of all or part of a quality system with the specific purpose of improving it. A quality audit is usually conducted by outside or independent specialists or a team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors.
Quality control (1)		
	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	All measures designed to ensure the uniform output of batches of drugs that conform to established specifications of identity, strength, purity and other characteristics.
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	All measures designed to ensure the uniform output of batches of drugs that conform to established specifications of identity, strength, purity and other characteristics.
Quality control (2)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Quality control is the part of GMP concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, no products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

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Term	Related reference(s)	Definition
Quality control (3)		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Quality control (4)		
	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	Embraces all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other pharmaceutical characteristics.
Quality control (5)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Online - See Part One (pp. 7–35). Pinted version - See Page 47.
Quality control (6)		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Quality control (7)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

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Term

Related reference(s)	Definition
Quality control (8)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Quality control is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Quality control is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.
Quality control (9)	
International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products (Annex 2, 54th report, 2020)	
Quality control (QC) (x10)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Checking or testing that specifications are met.
Quality control (QC) (x11)	
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	See Part One. Good manufacturing practices for pharmaceutical products, In:WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report. Geneva, World Health Organization, 1992,Annex 1 (WHO Technical Report Series, No. 823); and in: Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume 2, Second updated edition. Good manufacturing practices and Inspection. Geneva, World Health Organization, 2007; and in: Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Geneva, World Health Organization, 2010 (CD-ROM).
Quality control (x12)	
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Quality critical process parameter	
Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A process parameter which could have an impact on the critical quality attribute.
WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A process parameter which could have an impact on the critical quality attribute.

Quality Assurance of Medicines Terminology Database - List of Terms and related guideline

Term	Related reference(s)	Definition
Quality critical process parameter (CPP)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	A process parameter which could have an impact on the critical quality attribute.
Quality indicators	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	Selected data intended to be monitored and used in assessing trends in performance.
Quality management (1)	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The coordinated activities that direct and control an organization with regard to quality.
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The coordinated activities that direct and control an organization with regard to quality.
Quality management (2)	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
Quality management system	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	An appropriate infrastructure comprising the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
Quality management system (1)	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
Quality management system (2)	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A management system that directs and controls an organization with respect to quality and that ensures that steps, processes, procedures and policies related to quality activities are being followed.

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Term	Related reference(s)	Definition
Quality management system (3)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Quality management system. The organizational structure, responsibilities, procedures, processes and resources for implementing quality management. For the purpose of these guidelines “implementing quality management” is taken to include both the establishment and maintenance of the system (24).
Quality management system (4)	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
Quality management system (5)	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
Quality manager	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A member of staff who has a defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times (see Part one, section 1.3(j)).
Quality manual (1)	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A handbook that describes the various elements of the system for assuring the quality of the test results generated by a laboratory.
	Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	A handbook that describes the various elements of the system for assuring the quality of the test results generated by a laboratory.
Quality manual (2)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A handbook that describes the various elements of the quality management system for assuring the quality of the test results generated by a laboratory (see Part one, sections 2.1–2.2).
Quality manual (3)	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	A document that includes the quality policy and objectives and describes the various elements of the QMS.
Quality planning (1)	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives.

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Term	Related reference(s)	Definition
Quality planning (2)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Part of quality management, quality planning entails setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives.
Quality policy (1)		
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Overall intentions and direction of an organization related to quality as formally expressed by senior management.
Quality policy (2)		
	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	A brief statement that describes the organization's purpose, overall intentions and strategic direction; provides a framework for quality objectives; and includes a commitment to meet applicable requirements.
Quality policy (3)		
	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	A brief statement that describes the organization's purpose, overall intentions and strategic direction; provides a framework for quality objectives; and includes a commitment to meet applicable requirements.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A brief statement that describes the organization's purpose, overall intentions and strategic direction; provides a framework for quality objectives; and includes a commitment to meet applicable requirements.
Quality risk management (1)		
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A systematic process for the assessment, control communication, and review of risks to the quality of the pharmaceutical product across the product life-cycle.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A systematic process for the assessment, control communication, and review of risks to the quality of the pharmaceutical product across the product life-cycle.
Quality risk management (2)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A systematic process for the assessment, control, communication and review of risks to the quality of medical products in the supply chain.
Quality risk management (3)		
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A systematic process for the assessment, control, communication and review of risks.
Quality risk management (QRM) (1)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A systematic process for the assessment, control, communication and review of risks to the quality of the product across the product's life cycle.

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Term	Related reference(s)	Definition
Quality risk management (QRM) (2)		
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the pharmaceutical product throughout the product life-cycle.
Quality specification		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Explicit written test procedures and requirements that must be met.
Quality system (1)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. (see Part One, sections 2.1 and 3.1).
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. (see Part One, sections 2.1 and 3.1).
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. (see Part One, sections 2.1 and 3.1).
Quality system (2)		
	Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality.
Quality system (3)		
	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions (Annex 9, 52nd report, 2018)	The sum of all features that are necessary to implement an organization's quality policy and meet quality objectives. It includes organizational structure, responsibilities, procedures, systems, processes and resources. Typically these features will be addressed in different kinds of documents, such as the quality manual and documented procedures.
Quality system (4)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.
Quality target product profile (QTPP) (1)		
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	A prospective summary of the quality characteristics of a finished pharmaceutical product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the finished pharmaceutical product.

Term	Related reference(s)	Definition
Quality target product profile (QTPP) (2)		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	A prospectively documented summary of the quality characteristics of a finished pharmaceutical product (FPP) that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the FPP. The QTPP forms the basis of design for the development of the product and typically would include: — intended use in clinical setting, route of administration, dosage form, delivery systems; — dosage strength(s); — container-closure system; — therapeutic moiety release or delivery and attributes affecting pharmacokinetic characteristics (e.g. dissolution, aerodynamic performance) appropriate to the FPP dosage form being developed; — FPP quality criteria (e.g. sterility, purity, stability and drug release) appropriate for the intended marketed product.
	Non sterile process validation (Annex 3, 53rd report, 2019)	A prospectively documented summary of the quality characteristics of a finished pharmaceutical product (FPP) that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the FPP. The QTPP forms the basis of design for the development of the product and typically would include: — intended use in clinical setting, route of administration, dosage form, delivery systems; — dosage strength(s); — container-closure system; — therapeutic moiety release or delivery and attributes affecting pharmacokinetic characteristics (e.g. dissolution, aerodynamic performance) appropriate to the FPP dosage form being developed; — FPP quality criteria (e.g. sterility, purity, stability and drug release) appropriate for the intended marketed product.
Quality unit(s) (1)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	An organizational unit, independent of production, which fulfils both quality assurance and quality control responsibilities. This can be in the form of separate quality assurance and quality control or a single individual or group, depending on the size and structure of the organization.
Quality unit(s) (2)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	An organizational unit independent of production which fulfils both quality assurance (QA) and quality control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	An organizational unit independent of production which fulfils both quality assurance (QA) and quality control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	An organizational unit independent of production which fulfils both quality assurance (QA) and quality control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.

Term	Related reference(s)	Definition
Quantitation limit (limit of quantitation)		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Applied to quantitative microbiological tests. The lowest number of microorganisms within a defined variability that may be counted under the experimental conditions of the method under evaluation.
Quantitatively similar amounts (concentrations) of exipients		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	The relative amount of excipient present in two solid oral FPPs is considered to be quantitatively similar if the differences in amount fall within the limits shown in Table A7.1. If an excipient serves multiple functions (e.g. microcrystalline cellulose as a filler and as a disintegrant) then the most conservative recommended range should be applied (e.g. ± 1.0% for microcrystalline cellulose should be applied in this example). The relative concentration of an excipient present in two aqueous solution FPPs is considered to be similar if the difference is ≤ 10%.
Quarantine (1)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Quarantine (2)		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection.
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection.

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Term	Related reference(s)	Definition
Quarantine (3)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Quarantine (4)		
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	The status of a material that is kept in isolation and that is not available for use until released.
Quarantine (5)		
	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	The status of a material that is set apart and that is not available for use until released.
	Good practice in the manufacture and quality control of drugs. (Annex 2, 24th report,1972)	The status of a material that is set apart and that is not available for use until released.
Quarantine (6)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	The status of starting or packaging materials, intermediate, bulk or finished products that are isolated physically or by other means while a decision is awaited on their release for use or rejection.
Quarantine (7)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The status of medical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Radioactive concentration		
	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The radioactive concentration of a solution refers to the radioactivity in a unit volume of the solution. As with all statements involving radioactivity, it is necessary to include a reference date of the standardization. For radionuclides with a half-life of less than 30 days, the time of standardization should be expressed to the nearest hour. For radionuclides with a half-life of less than one day, a more precise statement of the reference time is required.
Radioactivity		
	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The property of certain nuclides of emitting radiation by the spontaneous transformation of their nuclei into those of other nuclides.
Radiochemical purity		
	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The radiochemical purity of a preparation is that percentage of the stated radionuclide that is present in the stated chemical form.
Radionuclide		
	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	A nuclide that is radioactive.

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Term	Related reference(s)	Definition
Radionuclidic purity		
	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The rationuclidic purity of a preparation is that percentage of the total radioactivity which is present in the form of the stated radionuclide.
Radiopharmaceutical product		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	For the purpose of this document, this term is defined in the same way as in the IAEA/WHO guideline on good manufacturing practices for radiopharmaceutical products (3), as any pharmaceutical product that, when ready for use, contains one or more radionuclides (radioactive isotopes) included for medicinal purposes.
Random sample (1)		
	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample in which the different fractions of the material have an equal probability of being represented.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample in which the different fractions of the material have an equal probability of being represented.
Random sample (2)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A sample of iuds drawn randomly from a lot for testing purposes.
Rapid alert		
	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	An urgent notification submitted by an NRA participating in the rapid alert system concerning measures taken against a product placed on the market that poses a risk to consumers' health and/or safety.
Rapid transfer system or port		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A system used for the transfer of items into RABS or isolators that minimizes the risk to the critical zone. An example would be a rapid transfer container with an alpha/beta port.
Raw data		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	All records or certified copies of original observations, clinical findings or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Such material includes laboratory notes, memoranda, calculations and documents, as well as all records of data from automated instruments or exact, verified copies, e.g. in the form of photocopies or microfiches. Raw data can also include photographic negatives, microfilm or magnetic media (e.g. computer diskettes) and optical media (CD-ROMs).
	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	The original record (data) which can be described as the firstcapture of information, whether recorded on paper or electronically. Raw data is synonymous with source data.
Raw material (1)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A general term used to denote starting materials, reagents and solvents intended for use in the production of intermediates or APIs.

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Term	Related reference(s)	Definition
Raw material (2)		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Any ingredient intended for use in the manufacture of a sterile product, including those that may not appear in the final drug product.
Real-time (long-term) stability studies		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	Experiments on the physical, chemical, biological, biopharmaceutical and microbiological characteristics of a drug, during and beyond the expected shelf-life and storage periods of samples under the storage conditions expected in the intended market. The results are used to establish the shelf-life, to confirm the projected shelf-life, and to recommend storage conditions.
Real-time release testing		
	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	The ability to evaluate and ensure the quality of in-process and/or final product based on process data, which typically include a valid combination of measured material attributes and process controls.
	Non sterile process validation (Annex 3, 53rd report, 2019)	The ability to evaluate and ensure the quality of in-process and/or final product based on process data, which typically include a valid combination of measured material attributes and process controls.
Recall (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Recall (2)		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Any measure aimed at achieving the return of a product that has already been made available to the end-user (based on EU Council Directive EC No 756/2008 of 9 JULY 2008 concerning the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93) (21).
Receiving unit (RU)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	The involved disciplines at an organization where a designated product, process or method is expected to be transferred.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The involved disciplines at an organization where a designated product, process or method is expected to be transferred.

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Term

Related reference(s)	Definition
Recognition	
Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	Acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.
Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.
Recognition (1)	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The routine acceptance by the regulatory authority in one jurisdiction of the regulatory decision of another regulatory authority or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition may be unilateral or multilateral, and may be the subject of a mutual recognition agreement (25).
Recognition (2)	
Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	The routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B.
Reconciliation (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A comparison, making due allowance for normal variation, between the amount of product or materials theoretically produced or used and the amount actually produced or used.
Reconciliation (2)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A comparison between the theoretical quantity and the actual quantity.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A comparison between the theoretical quantity and the actual quantity.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A comparison between the theoretical quantity and the actual quantity.

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Term	Related reference(s)	Definition
Recovery (1)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use.
Recovery (2)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Room recovery or clean-up tests are performed to determine whether the installation is capable of returning to a specified cleanliness level within a finite time, after being exposed briefly to a source of airborne particulate challenge.
Recovery (or blending)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture.
Reference authority		
	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	A regulatory authority that agrees to provide outcomes of its regulatory expertise (especially assessment and inspection reports) to applicants/authorization holders or inspected manufacturers; agrees to sharing of these documents with national regulatory authorities; and provides, under specified conditions in line with the principles of the Procedure, support to other parties involved in the Procedure.
Reference cultures		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Collective term for reference strain and reference stocks.
Reference material		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Material sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Material sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

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Term	Related reference(s)	Definition
Reference materials		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Reference materials refer to materials other than substances appropriate for intended uses in standardization or quality control of herbs and herbal materials. Reference materials include, among others, herbarium samples, authentic specimens of herbal materials (such as extracts and their fractions), herbal reference preparations and authentic spectra or fingerprints.
Reference method		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	A method which has been validated as being fit for purpose, with which an alternative method may be compared.
Reference product		
	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A reference product is a pharmaceutical product with which the new product is intended to be interchangeable in clinical practice. The reference product will normally be the innovator product for which efficacy, safety and quality have been established. Where the innovator product is not available, the product which is the market leader may be used as a reference product, provided that it has been authorized for marketing and its efficacy, safety and quality have been established and documented.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	A reference product is a pharmaceutical product with which the new product is intended to be interchangeable in clinical practice. The reference product will normally be the innovator product for which efficacy, safety and quality have been established. Where the innovator product is not available, the product which is the market leader may be used as a reference product, provided that it has been authorized for marketing and its efficacy, safety and quality have been established and documented.
Reference regulatory authority		
	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	For the purpose of this document, a national or regional authority or a trusted institution such as WHO prequalification (WHO PQ) whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions.
Reference sample		
	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	A sample of a batch of starting material, packaging material, product contained in its primary packaging, or finished product that is stored for the purpose of being analysed, should the need arise. This may include storage in a suitable bulk container.
Reference standard, primary		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A substance that has been shown by an extensive set of analytical tests to be authentic material that should be of high purity. This standard can be: — obtained from an officially recognized source; — prepared by independent synthesis; — obtained from existing production material of high purity; or — prepared by further purification of existing production material.

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Term	Related reference(s)	Definition
Reference standard, secondary	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A substance of established quality and purity, as shown by comparison to a primary reference standard, used as a reference standard for routine laboratory analysis.
Reference stocks	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	A set of separate identical cultures obtained by a single subculture from the reference strain.
Reference strains	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Microorganisms defined at least to the genus and species level, catalogued and described according to its characteristics and preferably stating its origin. Normally obtained from a recognized national or international collection.
Reference substance (or standard)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	An authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use.
Reference substances	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Reference substances are chemically defined molecular entities (appropriate for intended uses in standardization or quality control of herbs and herbal materials).
Refrigeration equipment	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The term “refrigeration” or “refrigeration equipment” means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.
Refurbishing	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A systematic process of rebuilding or restoring that ensures safety and effectiveness of the medical equipment without significantly changing the equipment’s or system’s performance safety specifications and/or changing intended use as in its original registration (26).
Regional regulatory system	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	A system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework but not necessarily under a common legal framework. The common framework must at least ensure equivalence among the members in terms of regulatory requirements, practices and quality assurance policies. The system or regional body may have enforcement powers to ensure compliance with the common regulatory framework.

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Term	Related reference(s)	Definition
Registration (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	Any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on to the market.
Registration (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The process by which a party submits information to the regulatory authority in a jurisdiction, regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the market in that jurisdiction (20).
Registration certificate (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See product licence.
Regression analysis and testing	Validation of computerized systems (Annex 3, 53rd report, 2019)	A documented software verification and validation task to determine the extent of verification and validation analysis and testing that must be repeated when changes are made to any previously examined software component or system.
Regular donor	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A person who routinely donates blood, blood components or plasma in the same blood establishment in accordance with the minimum time intervals.
Regulation	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A written instrument containing rules having the force of law.
Regulations	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The second stage of the legislative process (the first stage being legislation, see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The second stage of the legislative process (the first stage being legislation, see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.
Regulatory authority (1)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements (8).

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Term	Related reference(s)	Definition
Regulatory authority (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A national or international body set up to oversee the safety, efficacy and quality of medical devices, including condoms, imported and distributed within a country or region.
Regulatory Authority (RA)	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The agency responsible for the registration of and other regulatory activities concerning medical products.
Regulatory convergence	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	A voluntary process whereby the regulatory requirements in different countries or regions become more similar or “aligned” over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices.
Regulatory cooperation	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	A practice among regulatory authorities for efficient and effective regulation of medical products. May be practised by an agency, an institution or a government. The formal mechanisms include creation of joint institutions, treaties and conventions such as mutual recognition agreements, while less formal mechanisms include sharing information, scientific collaboration, common risk assessment, joint reviews and inspections and joint development of standards. May also include work with international counterparts to build regulatory capacity or provide technical assistance, thus contributing to improvement of international regulatory governance practices.
Regulatory harmonization	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	A process whereby the technical guidelines of participating authorities in several countries are made uniform.
Regulatory impact analysis	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	Process of examining the probable impacts of a proposed regulation and of alternative policies to assist the policy development process.
Regulatory stock	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	Collection or inventory of accumulated regulations.

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Term	Related reference(s)	Definition
Regulatory system		
	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	The combination of institutions, processes and the regulatory framework with which a government controls particular aspects of an activity.
Relabelling		
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The process of putting a new label on the material (see also labelling).
Relative humidity		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The ratio of the actual water vapour pressure of the air to the saturated water vapour pressure of the air at the same temperature expressed as a percentage. More simply put, it is the ratio of the mass of moisture in the air, relative to the mass at 100% moisture saturation, at a given temperature.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The ratio of the actual water vapour pressure of the air to the saturated water vapour pressure of the air at the same temperature expressed as a percentage. More simply put, it is the ratio of the mass of moisture in the air, relative to the mass at 100% moisture saturation, at a given temperature.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The ratio of the actual water vapour pressure of the air to the saturated water vapour pressure of the air at the same temperature expressed as a percentage. More simply put, it is the ratio of the mass of moisture in the air, relative to the mass at 100% moisture saturation, at a given temperature.
Release specification (1)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of an API or FPP at the time of its release.
Release specification (2)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of an active pharmaceutical ingredient or finished pharmaceutical product at the time of its release.
Reliability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	An expression of the degree to which a measurement performed by difference people at different times and under different circumstances produces the same results (see also validity).
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	An expression of the degree to which a measurement performed by difference people at different times and under different circumstances produces the same results (see also validity).

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Term	Related reference(s)	Definition
Reliable quantification of drug needs	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A careful evaluation of the quantities needed of each drug, based on either adjusted past consumption or anticipated pattern of diseases and standard treatment, which can be expected to match actual needs reasonably well.
Reliable quantification of medicines needs	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A careful evaluation of the quantities needed of each medicine, based on either adjusted past consumption or anticipated pattern of diseases and standard treatment, which can be expected to match actual needs reasonably well.
Reliance	Good regulatory practices in the regulation of medical products (Annex 11, 55th report, 2021)	The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.
	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.
Reliance (1)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others (25).
Reliance (2)	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	An act whereby a regulatory authority in one jurisdiction may take into account or give significant weight to work performed by another regulator, or other trusted institution, in reaching its own decision.
Remaining shelf-life (1)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	Defined as the period remaining, from the date upon delivery, to the expiry date, retest date, install by date or other use before date established by the manufacturer.
Remaining shelf-life (2)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The period remaining from the date of delivery to the expiry date, retest date, install-by date or other use-before date established by the manufacturer.

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Term	Related reference(s)	Definition
Repackaging	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The action of changing the packaging of the material.
Repeat donor	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A person who has donated before in the same establishment but not within the period of time considered as regular donation.
Repeatability	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Closeness of the agreement between the results of successive measurements of the same measure and under the same conditions of measurement (adapted from ISO).
Repeatedly reactive	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	A donation is considered to be repeatedly reactive if it is found reactive in a screening test, is retested in duplicate using the same assay, and at least one of the repeat tests is also reactive.
Representative sample	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or the different properties of a non-uniform material are proportionately represented.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or the different properties of a non-uniform material are proportionately represented.
Reprocessing (1)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.
Reprocessing (2)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Subjecting all or part of a batch or lot of an in-process drug, bulk process intermediate (final biological bulk intermediate) or bulk product of a single batch/lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary for biological drugs and, in such cases, are validated and pre-approved as part of the marketing authorization.
Reprocessing (3)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g. distillation, filtration, chromatography or milling) that are part of the established manufacturing process. Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process and not to be reprocessing.

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Term

Related reference(s)	Definition
Reprocessing (4)	
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Subjecting all or part of a batch or lot of an in-process medicine, bulk process intermediate (final biological bulk intermediate) or bulk product of a single batch/lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary for biological medicines and, in such cases, are validated and pre-approved as part of the marketing authorization.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Subjecting all or part of a batch or lot of an in-process medicine, bulk process intermediate (final biological bulk intermediate) or bulk product of a single batch/lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary for biological medicines and, in such cases, are validated and pre-approved as part of the marketing authorization.
Reprocessing (5)	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The process carried out on a used medical device in order to allow its safe reuse including, where appropriate, cleaning, disinfection, sterilization and related procedures, repackaging, relabelling, as well as testing and restoration of the technical and functional safety of the used device based on proposal for amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 of 26 September 2012 concerning medical devices (27).
Reproducibility	
WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Reproducibility expresses precision between laboratories.
Reservoir	
World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.
Restricted access barrier system (RABS)	
WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A system that provides an enclosed, but not fully sealed, environment meeting defined air quality conditions (for aseptic processing grade A) and using a rigid wall enclosure and integrated gloves to separate its interior from the surrounding cleanroom environment. The inner surfaces of the RABS are disinfected and decontaminated with a sporicidal agent. Operators use gloves, half suits, rapid transfer systems or ports, and other integrated transfer ports to perform manipulations or convey materials to the interior of the RABS. Depending on the design, doors are rarely opened and only under strictly predefined conditions.
Retention sample (1)	
Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample collected and reserved for future controls. The size of a retention sample should be sufficient to allow at least two confirmatory analyses. In some cases statutory regulations may require one or more retention samples, each of which should be separately identified, packaged and sealed.

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Term	Related reference(s)	Definition
Retention sample (2)	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample collected as part of the original sampling process and reserved for future testing. The size of a retention sample should be sufficient to allow for at least two confirmatory analyses. In some cases statutory regulations may require one or more retention samples, each of which should be separately identified, packaged and sealed.
Retention sample (3)	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	An additional sample of the final drug product that is collected and stored for the purpose of being analysed, should the need arise.
Retention sample (4)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	A sample of a packaged unit from a batch of finished product for each packaging run or trial period. It is stored for identification purposes – for example, presentation, packaging, labelling, leaflet, batch number and expiry date – should the need arise.
Re-test date	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The date after which an active API should be re-examined to ensure that the material is still in compliance with the specification and thus is still suitable for use in the manufacture of an FPP.
Retest date (1)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The date when a material should be re-examined to ensure that it is still suitable for use.
	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	The date when a material should be re-examined to ensure that it is still suitable for use.
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The date when a material should be re-examined to ensure that it is still suitable for use.
Retest date (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The date after which an active pharmaceutical ingredient should be re-examined to ensure that the material is still in compliance with the specification and thus is still suitable for use in the manufacture of a finished pharmaceutical product.
Retest date (3)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The date when a material should be re-examined to ensure that it is still suitable for use.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The date when a material should be re-examined to ensure that it is still suitable for use.

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Term	Related reference(s)	Definition
Retest date (4)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The date when a material should be re-examined to ensure that it is still suitable for use.
Retest period		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The period of time during which the active pharmaceutical ingredient (API) is expected to remain within its specification and, therefore, can be used in the manufacture of a given finished pharmaceutical product (FPP), provided that the API has been stored under the defined conditions. After this period, a batch of API destined for use in the manufacture of an FPP should be retested for compliance with the specification and then used immediately. A batch of API can be retested multiple times and a different portion of the batch used after each retest, as long as it continues to comply with the specification. For most substances known to be labile, it is more appropriate to establish a shelf life than a retest period. The same may be true for certain antibiotics.
Re-test period		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The period of time during which the API is expected to remain within its specification and, therefore, can be used in the manufacture of a given FPP, provided that the API has been stored under the defined conditions. After this period a batch of API destined for use in the manufacture of an FPP should be re-tested for compliance with the specification and then used immediately. A batch of API can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification. For most substances known to be labile, it is more appropriate to establish a shelf-life than a re-test period. The same may be true for certain antibiotics.
Retrospective validation		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Involves the evaluation of past experience of production on the condition that composition, procedures, and equipment remain unchanged.
Returned product		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Finished product sent back to the manufacturer.
Revalidation (1)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements.
Revalidation (2)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Repeated validation of a previously validated system (or a part thereof), to ensure continued compliance with established requirements. part thereof), to ensure continued compliance with established requirements.

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Term	Related reference(s)	Definition
Review	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	A highly complex, multidisciplinary assessment of medical product applications to assess whether they meet scientific and evidentiary standards for safety, efficacy and quality. It forms the scientific foundation for regulatory decisions. The first stage of the review process, validation (sometimes referred to as screening), occurs before the scientific review with the aim of ensuring completeness of the application in order to subsequently facilitate the scientific review.
Review strategy	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	The approach or plan of action that a reviewer or review team uses to review a medical product application.
Reworking (1)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Subjecting an in-process or bulk process intermediate (final biological bulk intermediate) or final product of a single batch to an alternate manufacturing process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and is not pre-approved as part of the marketing authorization.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Subjecting an in-process or bulk process intermediate (final biological bulk intermediate) or final product of a single batch to an alternate manufacturing process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and is not pre-approved as part of the marketing authorization.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Subjecting an in-process or bulk process intermediate (final biological bulk intermediate) or final product of a single batch to an alternate manufacturing process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and is not pre-approved as part of the marketing authorization.
Reworking (2)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	Subjecting an intermediate or API that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or API (e.g. recrystallizing with a different solvent).
Risk (1)	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Combination of the probability of occurrence of harm and severity of the harm.
Risk (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The combination of the probability of occurrence of harm and the severity of that harm (15).
Risk analysis	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The estimation of the risk associated with the identified hazards.

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Term	Related reference(s)	Definition
Risk assessment	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the evaluation of risk associated with exposure to those hazards.
Risk control	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The sharing of information about risk and risk management between the decisionmaker and other stakeholders.
Risk evaluation	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
Risk identification	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.
risk management	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	The systematic application of quality management policies, procedures and practices to the tasks of assessing, controlling, communicating and reviewing risk.
Risk priority number (RPN)	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	A numeric assessment of risk assigned to a process, or steps in a process, as part of failure mode effects analysis (FMEA). Each failure mode gets a numeric score that quantifies likelihood of occurrence, likelihood of detection and severity of impact. The product of these three scores is the RPN for that failure mode. RPN = severity rating × occurrence rating × detection rating.
Risk review	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Review or monitoring of output or results of the risk management process considering (if appropriate) new knowledge and experience about the risk.
Robustness (or ruggedness)	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The ability of the procedure to provide analytical results of acceptable accuracy and precision under a variety of conditions.

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Term	Related reference(s)	Definition
Sameness of product	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	For the purpose of this document, sameness of product means that two products have identical essential characteristics (i.e. the product being submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same). All relevant aspects of drugs, medical devices and in vitro diagnostics, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g. same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredients, same quality of all excipients). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same. The impact of potential, justified differences should be assessed by the manufacturer (for the purpose of this document, manufacturer also means marketing authorization holder) and the relying national regulatory authority (NRA) in determining the possibility of using foreign regulatory assessments or decisions
Sample set	Good chromatography practices (Annex 4, 54th report, 2020)	The combination of samples, standards and blanks prepared for analysis, which includes the specified sequence to be injected or analysed.
Sample(s) (1)	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	A portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to carry out all anticipated test procedures, including all repetitions. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector must record that the sampled material is the available sample (see Available sample) and the evaluation of the results must take account of the limitations deriving from the insufficient sample size. Sample should be stored in accordance with storage instructions for the respective drug; closures and labels should be of such a kind that unauthorized opening can be detected.
Sample(s) (2)	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	A portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to allow all anticipated test procedures to be carried out, including all repetitions and retention samples. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector should record that the sampled material is the available sample (see Sampling record) and the evaluation of the results should take account of the limitations that arise from the insufficient sample size.
Sampler	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Person responsible for performing the sampling operations.
Sampling (1)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Operations designed to obtain a representative portion of a pharmaceutical starting material based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release, etc.

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Term	Related reference(s)	Definition
Sampling (2)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.
Sampling (3)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Operations designed to obtain a representative portion of a medical product, based on an appropriate statistical procedure, for a defined purpose, for example, acceptance of consignments or batch release.
Sampling inspector		
	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Person responsible for performing the sampling operations. The sampling inspector need not be a qualified analyst. However, everyone called upon to take samples should be trained in the practical aspects of sampling and should have sufficient knowledge of pharmaceutical substances to execute the work effectively and safely. A conscientious approach, with meticulous attention to detail and cleanliness, is essential. The sampling inspector must remain alert to any signs of contamination, deterioration or tampering. Any suspicious signs should be recorded in detail in the sampling record.
Sampling method (1)		
	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Section of the sampling procedure dealing with the method prescribed for withdrawing samples.
Sampling method (2)		
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	That part of the sampling procedure dealing with the method prescribed for withdrawing samples.
Sampling plan (1)		
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Description of the location, number of units and/or quantity of material that should be collected, and associated acceptance criteria.
Sampling plan (2)		
	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Description of the number of units or quantity of material that must be collected.
Sampling plan (3)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A specific plan that indicates the number of units (iuds) from each lot that are to be inspected (sample size) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers).

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Term	Related reference(s)	Definition
Sampling procedure (1)	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	The complete sampling operations to be performed on a defined material for a specific purpose. A detailed written description of the sampling procedure is provided in the sampling protocol.
Sampling procedure (2)	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	The complete sampling operations to be applied to a defined material for a specific purpose. A detailed written description of the sampling procedure is provided as the sampling protocol.
Sampling record (1)	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Written record of the sampling operations carried out on a particular material for a defined purpose. The sampling record must contain the date and place of sampling, a reference to the sampling protocol used, a description of the containers and of the materials sampled, notes on possible abnormalities, together with any other relevant observations, and the name and signature of the inspector.
Sampling record (2)	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Written record of the sampling operations carried out on a particular material for a defined purpose. The sampling record should contain the batch number, date and place of sampling, reference to the sampling protocol used, a description of the containers and of the materials sampled, notes on possible abnormalities, together with any other relevant observations, and the name and signature of the inspector.
Sampling unit	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Discrete part of a consignment such as an individual package, drum or container.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Discrete part of a consignment such as an individual package, drum or container.
Screening technologies (1)	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	The qualitative and/or semiquantitative technologies that can rapidly acquire the information or analytical data for preliminary identification of suspect medical products in the field.
Screening technologies (2)	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	The qualitative and/or semi-quantitative technologies that could rapidly acquire the analytical information or data for preliminary identification of suspect medical products in the field.

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Term	Related reference(s)	Definition
Secondary chemical reference substance	General guidelines for the establishment, maintenance and distribution of chemical reference substances (Annex 3, 41st report, 2007)	A secondary chemical reference substance is a substance whose characteristics are assigned and/or calibrated by comparison with a primary chemical reference substance. The extent of characterization and testing of a secondary chemical reference substance may be less than for a primary chemical reference substance. Although this definition may apply inter alia to some substances termed “working standards”, part B of these guidelines is intended to apply to secondary reference substances supplied as “official”, e.g. regional/national standards, and not to manufacturers’ or other laboratories’ working standards.
Secondary chemical reference substances	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Secondary chemical reference substances (also called working standards) are substances whose characteristics are assigned and/or calibrated by comparison with a primary chemical reference substance. The extent of characterization and testing of a secondary chemical reference substance may be less than for a primary chemical reference substance (7).
Secondary legislation	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A form of law, issued by an executive branch of government, specifying substantive regulations and procedures for implementing them. The power to pass delegated legislation is defined and limited by the primary legislation that delegated those powers.
Secondary reference substance (or standard)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A substance whose characteristics are assigned and/or calibrated by comparison with a primary reference substance. The extent of characterization and testing of a secondary reference substance may be less than for a primary reference substance. Note: Often referred to as an “in-house” working standard.
Selected sample	Sampling procedure for industrially manufactured pharmaceuticals. (Annex 2, 31st report,1990)	Sample obtained according to a sampling procedure designed to select a fraction of the material that is likely to have special properties. A selected sample that is likely to contain deteriorated, contaminated, adulterated or otherwise unacceptable material is known as an extreme sample.
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	Sample obtained according to a sampling procedure designed to select a fraction of the material that is likely to have special properties. A selected sample that is likely to contain deteriorated, contaminated, adulterated or otherwise unacceptable material is known as an extreme sample.

Term	Related reference(s)	Definition
Self-contained area		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings.
Self-inspection		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	An internal procedure followed to evaluate the entity's compliance with GSP and GDP, as well as GXP in all areas of activities, designed to detect any shortcomings and to recommend and implement necessary corrective actions.
Semi-permeable containers		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Containers that allow the passage of solvent, usually water, while preventing solute loss. The mechanism for solvent transport occurs by adsorption onto one container surface, diffusion through the bulk of the container material, and desorption from the other surface. Transport is driven by a partial-pressure gradient. Examples of semi-permeable containers include plastic bags and semi-rigid, low-density polyethylene (LDPE) pouches for large-volume parenterals and LDPE and high-density polyethylene (HDPE) ampoules, bottles and vials.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Containers that allow the passage of solvent, usually water, while preventing solute loss. The mechanism for solvent transport occurs by adsorption onto one container surface, diffusion through the bulk of the container material, and desorption from the other surface. Transport is driven by a partial-pressure gradient. Examples of semi-permeable containers include plastic bags and semi-rigid, low-density polyethylene (LDPE) pouches for large-volume parenterals and LDPE and high-density polyethylene (HDPE) ampoules, bottles and vials.
Sending unit (SU)		
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	The involved disciplines at an organization from where a designated product, process or method is expected to be transferred.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The involved disciplines at an organization from where a designated product, process or method is expected to be transferred.

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Term	Related reference(s)	Definition
Senior (top) management	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Person(s) who direct and control an organization at the highest levels and who have the authority and responsibility to mobilize resources within the organization. In NRAs, the terms “senior management” or “top management” can be used interchangeably.
Sensitivity	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The fraction of the total number of positive cultures or colonies correctly assigned in the presumptive inspection.
Serious adverse event (1)	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	An event that is associated with death, admission to hospital, prolongation of a hospital stay, persistent or significant disability or incapacity, or is otherwise life threatening in connection with a clinical trial.
Serious adverse event (2)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Adverse event that: a) led to a death; b) led to a serious deterioration in the health of the subject that either 1) resulted in a life-threatening illness or injury; 2) resulted in a permanent impairment of a body structure or a body function; 3) required inpatient hospitalization or prolongation of existing hospitalization; 4) resulted in medical or surgical intervention to prevent lifethreatening illness or injury or permanent impairment to a body structure or a body function; c) led to fetal distress, fetal death or a congenital abnormality or birth defect (3).
Serious injury	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Serious injury (also known as serious deterioration in state of health) is either: — life-threatening illness or injury; — permanent impairment of a body function or permanent damage to a body; — a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure (28).
Service level agreement	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes.
Services	WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13, 54th report, 2020)	Output of an organization with at least one activity necessarily performed between the organization and the customer. Services of NRAs are also called regulatory services in this guideline. This includes, for example, activities such as evaluation of applications for market authorizations, inspections of facilities, testing of health product samples, etc.

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Term	Related reference(s)	Definition
Shelf life	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The period of time during which an active pharmaceutical ingredient (API) or finished pharmaceutical product (FPP), if stored under the conditions in which stability was established, is expected to comply with the specification as determined by stability studies on a number of batches of the API or FPP. The shelf life is used to establish the expiry date of each batch.
Shelf-life (1)	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The period of time during which a drug product, if stored correctly, is expected to comply with the specification* as determined by stability studies on a number of batches of the product. The shelf-life used to establish the expiry date of each batch. * "Shelf-life specification" means the requirements to be met throughout the shelf-life of the drug product (should not be confused with "release specification").
Shelf-life (2)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.
Shelf-life (3)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The period of time during which an API or FPP, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the API or FPP. The shelf-life is used to establish the expiry date of each batch.
Shelf-life (4)	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions.
Shelf-life (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The period of time during which a medical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.
Shelf-life (6)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The period of time after manufacture that the product is considered acceptable for use.

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Term	Related reference(s)	Definition
Shelf-life (7)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	The period of time after manufacture that the product is considered suitable for insertion, stated as the insert before date (previously, latest insertion date) on the pack.
Shelf-life (expiration dating period or validity period)	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	The period of time during which a drug product is expected, if stored correctly, to remain within specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.
Shelf-life specification (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	The combination of physical, chemical, biological and microbiological tests and acceptance criteria that an active pharmaceutical ingredient or finished pharmaceutical product should meet throughout its retest period or shelf life.
Shelf-life specification (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	The combination of physical, chemical, biological, and microbiological tests and acceptance criteria that an FPP should meet throughout its shelf life. In certain exceptional cases an unstable API might have a shelf-life specification (see section 1.3).
Shipping/dispatch (1)	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	The assembly, packing for shipment, and sending of ordered medicinal products for clinical trials.
Shipping/dispatch (2)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	The packing for shipment and sending of ordered products for clinical trials.
Signature (signed) (1)	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Record of the individual who performed a particular action or review. The record can be initials, full handwritten signature, personal seal or authenticated and secure electronic signature.
Signature (signed) (2)	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The record of the individual who performed a particular action or review. This record can be in the form of initials, full handwritten signature, personal seal or an authenticated and secure electronic signature.

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Term

Related reference(s)	Definition
Significant change (1)	
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	(See section 2.2.6.1.) In general “significant change” for an FPP is defined as: 1. A 5% or more change in assay from its initial content of API(s), or failure to meet the acceptance criteria for potency when using biological or immunological procedures. (Note: other values may be applied, if justified, to certain products, such as multivitamins and herbal preparations.) 2. Any degradation product exceeding its acceptance criterion. 3. Failure to meet the acceptance criteria for appearance, physical attributes and functionality test (e.g. colour, phase separation, resuspendability,caking, hardness, dose delivery per actuation). However, some changes in physical attributes (e.g. softening of suppositories, melting of creams or partial loss of adhesion for transdermal products) may be expected under accelerated conditions. Also, as appropriate for the dosage form: 4. Failure to meet the acceptance criterion for pH. Or 5. Failure to meet the acceptance criteria for dissolution for 12 dosage units.
Significant change (2)	
Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	(See sections 2.1.7 and 2.2.7.) “Significant change” for an active pharmaceutical ingredient (API) is defined as failure to meet its specification. In general “significant change” for a finished pharmaceutical product is defined as: a 5% or more change in assay from its initial content of API(s), or failure to meet the acceptance criteria for potency when using biological or immunological procedures. Any degradation product exceeding its acceptance criterion. 1. Failure to meet the acceptance criteria for appearance, physical attributes and functionality test (e.g. colour, phase separation, resuspendability, caking, hardness, dose delivery per actuation). However, some changes in physical attributes (e.g. softening of suppositories, melting of creams or partial loss of adhesion for transdermal products) may be expected under accelerated conditions. Also, as appropriate for the dosage form: 2. failure to meet the acceptance criterion for pH; or 3. failure to meet the acceptance criteria for dissolution for 12 dosage units
Single-dose container	
Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container for single doses of solid, semi-solid or liquid preparations.
Single-use medical device	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Single-use medical device. A medical device intended by the manufacturer to be used on an individual patient during a single procedure and then disposed of (17).

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Term	Related reference(s)	Definition
Single-use system (SUS)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A system in which product contact components are used only once to replace reusable equipment such as stainless steel transfer lines or bulk containers. Single-use systems covered in this document are those that are used in manufacturing processes of sterile products and are typically made up of disposable components such as bags, filters, tubing, connectors, storage bottles and sensors.
Site acceptance test	Guidelines on qualification (Annex 3, 53rd report, 2019)	A test conducted at the manufacturer's site of use, to verify that the system, equipment or utility, as assembled or partially assembled, meets approved specifications.
Skip lot (periodic) testing	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The performance of specified tests at release on preselected batches and/or at predetermined intervals, rather than on a batch-to-batch basis, with the understanding that those batches not tested must still meet all the acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified, presented to, and approved by, the regulatory authority before implementation. When tested, any failure of the starting material to meet the acceptance criteria established for the periodic (skip lot) test should be handled by proper notification of the appropriate regulatory authority (authorities). If these data demonstrate a need to restore routine testing, then batch-by-batch release testing should be reinstated.
Social marketing	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The use of commercial marketing techniques to distribute, promote and sell products and services of social importance, often at a subsidized price.
Solvent	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	An inorganic or organic liquid used as a vehicle for the preparation of solutions or suspensions in the manufacture of an intermediate or API.
Source data	Good chromatography practices (Annex 4, 54th report, 2020)	Original data obtained as the first-capture of information, whether recorded on paper or electronically.
Specific radioactivity (or specific activity)	Specification for radiopharmaceuticals. (Annex 2, 25th report, 1975)	The specific radioactivity of a preparation of a radioactive material is the radioactivity per unit mass of the element or of the compound concerned.
Specification (1)	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Term	Related reference(s)	Definition
Specification (2)		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	A document describing in detail the requirements with which the pharmaceutical products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.
Specification (3)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
Specification (4)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges or other criteria for the tests described. It establishes the set of criteria to which an API or FPP should conform to be considered acceptable for its intended use.
Specification (5)		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A list of detailed requirements (acceptance criteria for the prescribed test procedures) with which the substance or pharmaceutical product has to conform to ensure suitable quality.
Specification (6)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See Appendix 3, explanatory note 7.
Specification (7)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A list of tests, references to analytical procedures and appropriate acceptance criteria that are numerical limits, ranges or other criteria for the test described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. “Conformance to specification” means that the material, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.
Specification (8)		
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	A list of defined requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

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Term	Related reference(s)	Definition
Specification (9)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A list of tests, references to analytical procedures and appropriate acceptance criteria, which are numerical limits, ranges or other criteria for the tests described. It establishes the set of criteria to which an active pharmaceutical ingredient or finished pharmaceutical product should conform to be considered acceptable for its intended use. See Release specification and Shelf-life specification.
Specification (x10)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A detailed statement of a product's requirements as established by the buyer. Usually, a specification is based on an established standard.
	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A detailed statement of a product's requirements as established by the buyer. Usually, a specification is based on an established standard.
Specifications archive		
	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	An up-to-date collection of all quality specifications and related documents (see Part Two, section 9).
Specificity (selectivity)		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The ability of the method to detect the required range of microorganisms that might be present in the test sample.
Spiking		
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	The addition of a known amount of a compound to a standard, sample or placebo, typically for the purpose of confirming the performance of an analytical procedure.
Sponsor (1)		
	IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products (Annex 3, 56th report, 2022)	An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (Annex 7, 34th report, 1996)	An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.

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Term	Related reference(s)	Definition
Sponsor (2)	WHO good manufacturing practices for investigational products (Annex 7, 56th report, 2022)	An individual, company, institution or organization that takes responsibility for the initiation, management and financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, the investigator also then assumes the role of the sponsor.
Sporicidal agent	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Stability (1)	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	The ability of a drug to retain its properties within specified limits throughout its shelf-life. The following aspects of stability are to be considered: chemical, physical, microbiological and biopharmaceutical.
Stability (2)	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The ability of a pharmaceutical product to retain its chemical, physical, microbiological and biopharmaceutical properties within specified limits throughout its shelf-life.
Stability indicating methods	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Validated analytical procedures that can detect the changes with time in the chemical, physical or microbiological properties of the API or FPP, and that are specific so that the content of the API, degradation products, and other components of interest can be accurately measured without interference.
Stability studies (stability testing) (1)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Long-term and accelerated (and intermediate) studies undertaken on primary and/or commitment batches according to a prescribed stability protocol to establish or confirm the re-test period (or shelf-life) of an API or the shelf-life of an FPP.
Stability studies (stability testing) (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Long-term and accelerated (and intermediate) studies undertaken on primary and/or commitment batches according to a prescribed stability protocol to establish or confirm the retest period (or shelf life) of an active pharmaceutical ingredient or the shelf life of a finished pharmaceutical product.
Stability tests (1)	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	The purpose of stability tests is to obtain information in order to define the shelf-life of the pharmaceutical product in its original container and to specify storage conditions.

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Term	Related reference(s)	Definition
Stability tests (2)	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	A series of tests designed to obtain information on the stability of a pharmaceutical product in order to define its shelf-life and utilization period under specified packaging and storage conditions.
Stability-indicating methods	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Validated analytical procedures that can detect the changes with time in the chemical, physical or microbiological properties of the active pharmaceutical ingredient (API) or finished pharmaceutical product, and that are specific so that the content of the API, degradation products and other components of interest can be accurately measured without interference.
Stakeholder	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	Any individual, group or organization that can affect, be affected by, or perceive itself to be affected by a risk. Primary stakeholders are the patient, health-care professional, MRAs and the pharmaceutical industry.
Standard (1)	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (29).
Standard (2)	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority.
Standard (3)	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory body.

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Term

Related reference(s)	Definition
Standard operating procedure (SOP) (1)	
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g.equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g.equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g.equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g.equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

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Term

Related reference(s)	Definition
Standard operating procedure (SOP) (2)	
Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control;sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control;sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control;sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control;sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Quality systems requirements for national good manufacturing practice inspectorates. (Annex 8, 36th report, 2002)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control;sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

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Term	Related reference(s)	Definition
Standard operating procedure (SOP) (3)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (e.g. operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (e.g. operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (e.g. operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (e.g. operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Standard operating procedure (SOP) (4)		
	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	An authorized written procedure giving instructions for performing operations both general and specific.
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	An authorized written procedure giving instructions for performing operations both general and specific.
Standard operating procedure (SOP) (5)		
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).
Standard operating procedure (SOP) (6)		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness.
standard operating procedure (SOP) (7)		
	Quality management system requirements for national inspectorates (Annex 5, 54th report, 2020)	An authorized written procedure giving detailed instructions for performing a task or following a process in accordance with legislation, official guidance or internal standards.

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Term	Related reference(s)	Definition
standard operating procedure (SOP) (8)		
	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	An authorized written procedure giving instructions for performing operations that are not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises, environmental control, sampling and inspection).
Standard operating procedure (x10)		
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (for example operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain standard operating procedures may be used to supplement product-specific master and batch production documentation.
Standard operating procedure (x11)		
	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	An authorized written procedure giving instructions for performing standardized operations both general and specific.
	WHO guidance on testing of “suspect” falsified medicines (Annex 5, 52nd report, 2018)	An authorized written procedure giving instructions for performing standardized operations both general and specific.
Standard operating procedure (x9)		
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (for example, equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	WHO guidelines on good herbal processing practices for herbal medicines (Annex 1, 52nd report, 2018)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (for example, equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Standard operating procedures (SOPs)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Standard, detailed, written instructions for the management of clinical trials. They provide a general framework enabling the efficient implementation and performance of all the functions and activities for a particular trial as described in this document.
Standard uncertainty		
	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Uncertainty of the result of a measurement expressed as a standard deviation.

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Term	Related reference(s)	Definition
Starting material (1)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	Guidelines on import procedures for pharmaceutical products. (Annex 12, 34th report, 1996)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
Starting material (2)		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (Annex 3, 38th report, 2004)	See pharmaceutical starting material.
Starting material (3)		
	Good practices in the manufacture and quality control of drugs (Annex 2, 22nd report, 1969)	All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed solely for the manufacture of drugs.
Starting material (4)		
	Good practice in the manufacture and quality control of drugs. (Annex 1, 25th report,1975)	All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs.
	Good practice in the manufacture and quality control of drugs. (Annex 2, 24th report,1972)	All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs.
Starting material (5)		
	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	Any substance of defined quality used in the production of a medical product, but excluding packaging materials.

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Term	Related reference(s)	Definition
Starting materials for synthesis	Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part (Annex 4, 46th report, 2012)	Materials that mark the beginning of the manufacturing process as described in an application or in an API master file (APIMF). A starting material for a synthetic API is a chemical compound of defined molecular structure that contributes to the structure of the API. See also API starting material.
State	Good pharmacopoeial practices: Chapter on monographs on herbal medicines (Annex 7, 52nd report, 2018)	of the herbal material means whole, fragmented, peeled, cut, fresh or dried.
State of control	Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation (Annex 3, 49th report, 2015)	A condition in which the set of controls consistently provides assurance of continued process performance and product quality.
	Non sterile process validation (Annex 3, 53rd report, 2019)	A condition in which the set of controls consistently provides assurance of continued process performance and product quality.
Statement of licensing status	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 3.13 of the guidelines and Appendix 2.
Static data	WHO Guideline on data integrity (Annex 4, 55th report, 2021)	A static record format, such as a paper or electronic record, that is fixed and allows little or no interaction between the user and the record content. For example, once printed or converted to static electronic format chromatography records lose the capability of being reprocessed or enabling more detailed viewing of baseline.
Sterile product	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	For the purpose of this guidance, sterile product refers to one or more of the sterilized elements exposed to aseptic conditions and, ultimately, making up the sterile active substance or finished sterile product. These elements include the containers, closures and components of the finished drug product. Or, a product that is rendered sterile by a terminal sterilization process.
Sterilizing grade filter	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A filter that, when appropriately validated, will remove a defined microbial challenge from a fluid or gas producing a sterile effluent. Usually such filters have a pore size equal to or less than 0.22 micrometres (µm).
Storage (1)	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	The storing of pharmaceutical products and materials up to their point of use.

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Term	Related reference(s)	Definition
Storage (2)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	The storing of pharmaceutical products up to the point of use.
	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The storing of pharmaceutical products up to the point of use.
Storage (3)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The storing of medical products up to the point of use.
Storage temperature	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The temperature range listed on the TTSPP label, and within the regulatory documentation, for long-term storage.
Storage unit temperature/humidity distribution	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The range and pattern of temperatures and/or humidity within a temperature controlled storage unit during normal operation.
Stress testing (of the active pharmaceutical ingredient (API))	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Studies undertaken to elucidate the intrinsic stability of an API. Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated testing.
Stress testing (of the API)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Studies undertaken to elucidate the intrinsic stability of API. Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated testing.
Stress testing (of the finished pharmaceutical product (FPP))	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Studies undertaken to assess the effect of severe conditions on the FPP. Such studies include photostability testing and specific testing on certain products (e.g. metered-dose inhalers, creams, emulsions, refrigerated aqueous liquid products).
Stress testing (of the FPP)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Studies undertaken to assess the effect of severe conditions on the FPP. Such studies include photostability testing and specific testing on certain products (e.g. metered dose inhalers, creams, emulsions, refrigerated aqueous liquid products).

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Term

Related reference(s)	Definition
Stringent regulatory authority	
Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	A regulatory authority which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015)
Stringent regulatory authority (SRA) (1)	
WHO Expert Committee on Specifications for Pharmaceutical Preparations, TRS 1003 – Fifty-first report, 2017	The interim definition adopted by the 51st ECSPP of a stringent regulatory authority (SRA) includes the same elements as the current definition, each qualified by the wording “as before 23 October 2015”, as follows: A regulatory authority which is: a. a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or b. an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or c. a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015). The Expert Committee adopted the interim definition and noted the work being done towards developing a new approach to the assessment of national regulatory authorities, based on the various existing systems currently in place such as that used by the Pan American Health Organization and that applied by WHO with respect to vaccines. The Committee requested that an update on this work be provided at its fifty-second meeting.
Stringent regulatory authority (SRA) (2)	
Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A regulatory authority which is: a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015)); or b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

Term

Related reference(s)	Definition
Stringent regulatory authority (SRA) (3)	
Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	For the purpose of this document, a stringent regulatory authority (SRA) is the medicines regulatory authority in a country which is: ■ (a) a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (European Union, Japan and the United States of America); or (b) an ICH Observer, being the European Free Trade Association as represented by SwissMedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time); ■ only in relation to good manufacturing practices inspections: a medicines regulatory authority that is a member of the Pharmaceutical Inspection Co-operation Scheme as specified at http://www.Picscheme.org.
Procedure for prequalification of pharmaceutical Products.(Annex 10, 45th report, 2011)	For the purpose of this document, a stringent regulatory authority (SRA) is the medicines regulatory authority in a country which is: ■ (a) a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (European Union, Japan and the United States of America); or (b) an ICH Observer, being the European Free Trade Association as represented by SwissMedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time); ■ only in relation to good manufacturing practices inspections: a medicines regulatory authority that is a member of the Pharmaceutical Inspection Co-operation Scheme as specified at http://www.Picscheme.org.
Stringent regulatory authority (SRA) (4)	
WHO guidelines on variations to a prequalified product (Annex 3, 47th report, 2013)	A stringent regulatory authority is: the medicines regulatory authority in a country which is: (a) a member of the International Conference on Harmonisation (ICH) (European Union (EU), Japan and the United States of America); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by SwissMedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time); ■ only in relation to good manufacturing practices (GMP) inspections: a medicines regulatory authority that is a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as specified at http://www.picscheme.org
Stringent regulatory authority (SRA) (5)	
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A regulatory authority which is: a. a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (as specified on www.ich.org); or b. an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or c. a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

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Term	Related reference(s)	Definition
Stringent regulatory authority (SRA) (6)	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	The authority as defined by the interim definition in 2017 (10) and updated in 2018 (11).
Strip	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A multi-dose container consisting of two layers, usually provided with perforations, suitable for containing single doses of solid or semi-solid preparations. Blisters are excluded.
Study director	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	According to the Organisation for Economic Co-operation and Development (OECD) Principles of good laboratory practice: the individual responsible for the overall conduct of the nonclinical health and environmental safety study. In a bioequivalence trial, the individual responsible for the conduct of the bioanalytical part of the study.
Study product	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	See invistigational product
Substandard medicines	WHO Technical Report Series 961 (45th report, 2011)	Substandard medicines are pharmaceutical products that fail to meet either their quality standards or their specifications, or both. Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifi cations, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifi cations are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing.
Substandard product	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	An authorized product that fails to meet either its quality standards or its specifications, or
Substandard products	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	“Substandard” medical products (also called “out of specification”) are authorized by NRAs but fail to meet either national or international quality standards or specifications – or, in some cases, both.

Term	Related reference(s)	Definition
Substandard/spurious/falsely-labelled/falsified/counterfeit medical products	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	Substandard/spurious/falsely-labelled/falsified/counterfeit medical products. There is currently no universally agreed definition of what used to be widely known as “counterfeit medicine”. Pending negotiation among Member States, WHO will continue to use the term substandard/spurious/falsely-labelled/ falsified/counterfeit medical products (30).
Substitute	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Substitute is a herbal material or herbal preparation that is replaced by another, appropriately labelled herbal material, or herbal preparation consistent with the national pharmacopoeia, or traditional (or complementary and alternative) medicine practice.
Summary Basis of Approval	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	The document prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.7 of the guidelines and explanatory note 9 of the Product Certificate contained in Appendix 1).
Summary of Product Characteristics (SPC) (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	Product information as approved by the regulatory authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising (see also Product information).
Summary of product characteristics (SPC) (2)	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	A term used in the European Union. Product information or data sheets in the European Union should be based on the approved SPC.
Summary of technical information	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	New document format introduced to replace the product dossier and site master file.
Supplier (1)	Guide to good storage practices for pharmaceuticals. (Annex 9, 37th report, 2003)	A person providing pharmaceutical products and materials on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where possible, suppliers should be authorized by a competent authority.
Supplier (2)	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc.

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Term	Related reference(s)	Definition
Supplier (3)	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Persons or company providing pharmaceutical products on request. Suppliers include distributors, manufacturers or traders.
Supplier (4)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	A person or entity engaged in the activity of providing products and/or services.
Supplier (5)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	A person or entity engaged in the activity of providing products and/or services.
Supporting stability data (1)	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	Supplementary data, such as stability data on small-scale batches, related formulations, and products presented in containers other than those proposed for marketing, and scientific rationales that support the analytical procedures, the proposed retest period or the shelf-life and storage conditions.
Supporting stability data (2)	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	Supplementary data, such as stability data on small-scale batches, related formulations, and products presented in containers not necessarily the same as those proposed for marketing, and scientific rationales that support the analytical procedures, the proposed retest period or the shelf life and storage conditions.
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	Supplementary data, such as stability data on small-scale batches, related formulations, and products presented in containers not necessarily the same as those proposed for marketing, and scientific rationales that support the analytical procedures, the proposed retest period or the shelf life and storage conditions.
Suspect product	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	A time- and temperature-sensitive pharmaceutical product (TTSPP) whose presentation and/or pharmacological formulation indicates that it has not been manufactured by the company named on the packaging. A TTSPP that shows visible or pharmacological evidence of tampering.
System	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	A regulated pattern of interacting activities and techniques that are united to form an organized whole.
System life-cycle	Validation of computerized systems (Annex 3, 53rd report, 2019)	The period of time that starts when a computerized system is conceived and ends when the system is retired and decommissioned, taking into consideration regulatory requirements. The system life-cycle typically includes a planning phase; a development phase that includes a design phase and a programming and testing phase; a qualification and release phase that includes a system integration and testing phase; a validation phase; a release phase; an operation and maintenance phase; and, finally, a system retirement phase.

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Term	Related reference(s)	Definition
System suitability test	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	A test which is performed to ensure that the analytical procedure fulfils the acceptance criteria which had been established during the validation of the procedure. This test is performed before starting the analytical procedure and is to be repeated regularly, as appropriate, throughout the analytical run to ensure that the system's performance is acceptable at the time of the test.
Tank	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A static thermally insulated container designed for the storage of liquefied or cryogenic gas (also called a fixed cryogenic vessel).
Tanker	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A thermally insulated container fixed on a vehicle for the transport of liquefied or cryogenic gas.
Technical documentation	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The documented evidence, normally an output of the quality management system that demonstrates the medical device complies with the relevant principles of safety, performance and labelling specified through legislation (32).
Technology transfer protocol (master plan)	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A document that describes the intended sequential phases and activities of the transfer, and serves as a plan for the execution and management of the transfer.
Technology transfer report (1)	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A documented summary of a specific technology transfer project listing procedures, acceptance criteria, results achieved and conclusions. Any deviation should be discussed and justified.
Technology transfer report (2)	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A documented summary of a specific technology transfer project listing procedures, acceptance criteria, results achieved and conclusions.
Technology transfer, transfer of technology	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A logical procedure that controls the transfer of any product or process, including product or process knowledge, together with its documentation and professional expertise. Technology transfer may involve development, manufacturing or testing sites.
Temperature excursion	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	An excursion event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

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Term	Related reference(s)	Definition
Temperature-controlled	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.
Temperature-modified	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Includes any environment in which the temperature is predictably maintained at a level different from that of the surrounding environment, but is not actively or passively controlled within precise predefined limits.
Tenders and brokers	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 4.6 of the guidelines.
Terminal sterilization	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The application of a lethal sterilizing agent or conditions to a product in its final container to achieve a predetermined sterility assurance level of 10^{-6} or better (that is, the theoretical probability of there being a single viable microorganism present on or in a sterilized unit is equal to or less than 1 x 10–6, or 1 in a million).
Test procedure	Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Analytical procedure
Test report	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	The report of the results, including the final conclusion of the analysis of a sample which has been submitted by a laboratory in another country or in the field not having appropriate facilities to perform certain tests, and issued by the official pharmaceutical control laboratory that performed the test. This is often in the same style as a certificate of analysis. (see Part Three, section 17.3).
Therapeutic activity (1)	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (Annex 3, 40th report, 2006)	Therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and mental illnesses; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body and development of a sense of general well-being. (In: General guidelines for methodologies on research and evaluation of traditional medi-cine, Geneva, World Health Organization, 2000).
Therapeutic activity (2)	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and mental illnesses. Treatment includes beneficial alteration or regulation of the physical and mental status of the body and development of a sense of general well-being as well as improvement of symptoms.

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Term	Related reference(s)	Definition
Therapeutic activity (3)		
	Guidelines on good manufacturing practices for the manufacture of herbal medicines (Annex 2, 52nd report, 2018)	Successful prevention, diagnosis and treatment of physical and mental illnesses, improvement of symptoms of illnesses, as well as beneficial alteration or regulation of the physical and mental status of the body and development of a sense of general well-being.
Therapeutic equivalence (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 9, 34th report, 1996)	Two pharmaceutical products are therapeutically equivalent if they are pharmaceutically equivalent and after administration in the same moral dose their effects, with respect to both efficacy and safety, will be essentially the same, as determined from appropriate studies (bioequivalence, pharmacodynamic, clinical or in vitro studies).
Therapeutic equivalence (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (Annex 7, 49th report, 2015)	Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Annex 7, 40th report, 2006)	Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies.
	Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider (Annex 3, 46th report, 2012)	Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies.
Time- and temperature-sensitive pharmaceutical product (TTSPP)		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.
Toxic constituent		
	WHO Guidelines for selecting marker substances of herbal origin for quality control of herbal medicines (Annex 1, 51st report, 2017)	Toxic constituents are substances or group(s) of substances that are chemically defined and their toxic property is predominant, although they may contribute to the therapeutic activities of the herbal material or herbal preparation.

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Term	Related reference(s)	Definition
Traceability	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Traceability aims at ensuring that the results of laboratory measurements using procedures of lower metrological order are reproducible and scientifically acceptable by referring to an internationally agreed denominator by means of a reference procedure of highest metrological order and/or a primary reference material (see Part Two, section 13).
Transit (1)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	The period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.
Transit (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	The period during which medical products are in the process of being carried, conveyed or transported across, over or through a passage or route to reach their destination.
Transparency (1)	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	The term transparency means: — defining policies and procedures in writing and publishing the written documentations; and — giving reasons for decisions to the public (see also accountability above).
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	The term transparency means: — defining policies and procedures in writing and publishing the written documentations; and — giving reasons for decisions to the public (see also accountability above).
Transparency (2)	Good review practices: guidelines for national and regional regulatory authorities (Annex 9, 49th report, 2015)	Defining policies and procedures in writing and publishing the written documentation, and giving reasons for decisions to the public.
Transport temperature	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Anticipated ambient temperature variation and duration to which a TTSPP may be exposed during transport.
Trial subject	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	An individual who participates in a clinical trial, either as a recipient of the pharmaceutical product under investigation or as a control The individual may be: –a healthy person who volunteers to participate in a trial; –a person with a condition unrelated to the use of the investigational product; –a person (usually a patient) whose condition is relevant to the use of the investigational product.
Tube	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A container for multi-dose semi-solid pharmaceutical forms consisting of collapsible material; the contents are released via a nozzle by squeezing the package.

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Term	Related reference(s)	Definition
Turbulent airflow (1)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	Turbulent flow, or non-unidirectional airflow, is air distribution that is introduced into the controlled space and then mixes with room air by means of induction.
Turbulent airflow (2)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	Air that is not unidirectional. Turbulent air in cleanrooms should flush the cleanroom via a mixed flow dilution and ensure maintenance of acceptable air quality.
Turbulent flow	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Turbulent flow, or non-unidirectional airflow, is air distribution that is introduced into the controlled space and then mixes with room air by means of induction.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Turbulent flow, or non-unidirectional airflow, is air distribution that is introduced into the controlled space and then mixes with room air by means of induction.
Unauthorized market (in some countries called parallel market)	Guidelines for inspection of drug distribution channels. (Annex 6, 35th report, 1999)	The unauthorized market consists of wholesale establishments and retail outlets distributing or selling drugs without authorization from a competent authority.
Unidirectional airflow (2)	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (see also turbulent air flow). (Modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow.)
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	A rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (see also turbulent air flow). (Modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow.)
Unidirectional airflow (3)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

Term	Related reference(s)	Definition
Unidirectional airflow (UDAF) (1)		
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	Unidirectional airflow is a rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (see also turbulent flow). (Modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow.)
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Unidirectional airflow is a rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (see also turbulent flow). (Modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow.)
Unidirectional airflow unit		
	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A cabinet supplied with filtered unidirectional airflow (previously referred to as a laminar airflow unit).
Unified numbering system (UNS)		
	WHO/UNFPA technical specification for TCu380A intrauterine device (Annex 10, 56th report, 2022)	An alloy designation of the National Bureau of Standards.
Uniformity		
	WHO guidelines for sampling of pharmaceutical products and related materials. (Annex 4, 39th report, 2005)	A starting material may be considered uniform when samples drawn from different layers do not show significant differences in the quality control tests which would result in non-conformity with specifications. The following materials may be considered uniform unless there are signs to the contrary: organic and inorganic chemicals; purified natural products; various processed natural products such as fatty oils and essential oils; and plant extracts. The assumption of uniformity is strengthened by homogeneity, i.e. when the consignment is derived from a single batch.
Unplanned risk assessment		
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	An assessment that is conducted to assess the impact of a situation that has already occurred, e.g. impact of a deviation from normal ways of working.
Unregistered product		
	Guidelines on import procedures for medical products (Annex 5, 53rd report, 2019)	A medical product that has not undergone evaluation and/or approval by the NRA for the market in which it is marketed/ distributed or used, subject to permitted conditions under national or regional regulation and legislation. This medical product may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

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Term	Related reference(s)	Definition
Upon delivery		
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 54th report, 2020)	The date a medical product is delivered as specified, for example at the port, at the point in-country after customs clearance, or at the end user, and as defined in the agreement between relevant parties.
	Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8, 56th report, 2022)	The date a medical product is delivered as specified, for example at the port, at the point in-country after customs clearance, or at the end user, and as defined in the agreement between relevant parties.
User		
	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The person, either professional or lay, who uses a medical device. The patient may be the user (17).
User acceptance testing		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	Verification of the fully configured computerized system installed in the production environment (or in a test environment equivalent to the production environment) to perform, as intended, in the business process when operated by end-users trained in end-user SOPs that define system use and control. User acceptance testing (UAT) may be a component of the performance qualification (PQ) or a validation step separate from the PQ.
User requirements specification (1)		
	Guidelines on qualification (Annex 3, 53rd report, 2019)	An authorized document that defines the requirements for use of the system, equipment or utility in its intended production environment.
User requirements specification (2)		
	Validation of computerized systems (Annex 3, 53rd report, 2019)	The user requirements specification (URS), if prepared as a separate document, is a formal document that defines the requirements for use of the computerized system in its intended production environment.
Utilization factor		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	The percentage of the total volume available for storing temperature-sensitive pharmaceutical products (TTSPPS) that can reliably be achieved in practice, taking account of the types of stock-keeping unit (SKU), the types of load support system and the stock management systems used in the store.
Utilization period (1)		
	Stability of drug dosage forms.(Annex 1, 31st report, 1990)	A period of time during which a reconstituted preparation or the preparation in an opened multidose container can be used.
Utilization period (2)		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (Annex 5, 34th report, 1996)	The period of time during which a reconstituted preparation or finished dosage form in an opened multidose container can be used.

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Term	Related reference(s)	Definition
Utilization period (3)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. (Annex 2, 43rd report, 2009)	A period of time during which a reconstituted preparation of the finished dosage form in an unopened multidose container can be used.
Utilization period (4)		
	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	See in-use period.
Vaccine		
	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, one of its surface proteins or genetically-engineered material. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.
Validation (1)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	Good trade and distribution practices for pharmaceutical starting materials. (Annex 2, 38th report, 2003)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	WHO good manufacturing practices for pharmaceutical products containing hazardous substances. (Annex 3, 44th report, 2010)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

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Term	Related reference(s)	Definition
Validation (2)		
	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	Action of proving, in accordance with the principles of GCP and GLP, that any procedure, process, equipment (including the software or hardware used), material, activity or system actually and consistently leads to the expected results.
Validation (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	Action of proving and documenting, in accordance with the principles of good manufacturing practice, that any procedure, process, or method actually and consistently leads to the expected results (see also qualification above).
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Action of proving and documenting, in accordance with the principles of good manufacturing practice, that any procedure, process, or method actually and consistently leads to the expected results (see also qualification above).
Validation (4)		
	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A documented programme that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criteria.
Validation (5)		
	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	Action of proving, in accordance with the principles of good practice quality guidelines and regulations (GxP), that any procedure, process, equipment (including the software or hardware used), material, activity or system actually and consistently leads to the expected results.
Validation (6)		
	WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	Actions for proving that any operational procedure, process, activity or system leads to the expected results. Validation work is normally performed in advance according to a defined and approved protocol that describes tests and acceptance criteria.
Validation (7)		
	Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. (Annex 9, 45th report, 2011)	Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.

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Term	Related reference(s)	Definition
Validation (8)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The collection and evaluation of data, beginning at the process development stage and continuing through the production phase, which ensure that the manufacturing processes — including equipment, buildings, personnel and materials — are capable of achieving the intended results on a consistent and continuous basis. Validation is the establishment of documented evidence that a system does what it is supposed to do.
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	The collection and evaluation of data, beginning at the process development stage and continuing through the production phase, which ensure that the manufacturing processes — including equipment, buildings, personnel and materials — are capable of achieving the intended results on a consistent and continuous basis. Validation is the establishment of documented evidence that a system does what it is supposed to do.
Validation (9)		
	Good manufacturing practices for pharmaceutical products. (Annex 1, 32nd report, 1992)	Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).
	WHO good manufacturing practices for pharmaceutical products: main principles. (Annex 3, 45th report, 2011)	Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).
	WHO good manufacturing practices for pharmaceutical products: main principles1 (Annex 2, 48th report, 2014)	Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).
Validation (x10)		
	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
Validation (x11)		
	Good chromatography practices (Annex 4, 54th report, 2020)	The action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results

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Term	Related reference(s)	Definition
Validation (x12)	WHO good practices for research and development facilities of pharmaceutical products (Annex 6, 56th report, 2022)	The action of proving, in accordance with the principles of gmp, that any procedure, process, equipment, material, activity or system actually leads to the expected results.
Validation batches	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	Those batches produced by the receiving unit (RU) to demonstrate its ability to manufacture the transferred product in compliance with its predetermined specifications, or as part of process performance qualification.
Validation master plan	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8, 52nd report, 2018)	A high-level document that establishes an umbrella validation plan for the entire project and is used as guidance by the project team for resource and technical planning (also referred to as a master qualification plan).
	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (Annex 2, 40th report, 2006)	A high-level document that establishes an umbrella validation plan for the entire project and is used as guidance by the project team for resource and technical planning (also referred to as a master qualification plan).
Validation master plan (VMP) (1)	Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. (Annex 5, 45th report, 2011)	Validation master plan is a high-level document which establishes an umbrella validation plan for the entire project, and is used as guidance by the project team for resource and technical planning (also referred to as master qualification plan).
Validation master plan (VMP) (2)	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	The VMP is a high-level document that establishes an umbrella validation plan for the entire project and summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's validation work programme and defines details of and timescales for the validation work to be performed, including a statement of the responsibilities of those implementing the plan.
Validation master plan (VMP) (3)	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A high-level document that establishes an umbrella validation plan for the entire project and summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's validation work programme and defines details of and timescales for the validation work to be performed, including a statement of the responsibilities of those implementing the plan.

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Term

Related reference(s)	Definition
Validation master plan (VMP) (4)	
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A high-level document that summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's qualification and validation work programme and defines details of and timelines for the work to be performed, including a statement of the responsibilities of those implementing the plan.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A high-level document that summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's qualification and validation work programme and defines details of and timelines for the work to be performed, including a statement of the responsibilities of those implementing the plan.
Validation of an analytical procedure	
WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	The documented process by which an analytical procedure (or method) is demonstrated to be suitable for its intended use.
Validation of analytical	
Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	The documented evidence that analytical procedures or methods are suitable for their intended purpose.
Validation protocol (1)	
Guidance on variations to a prequalified product dossier (Annex 6, 41st report, 2007)	Validation scheme, validation plan.
Validation protocol (2)	
WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	A written plan stating how validation will be conducted and defining acceptance criteria. For example, the protocol for a manufacturing process identifies processing equipment, critical process parameters and operating ranges, product characteristics, sampling, test data to be collected, number of validation runs and acceptable test results.
Validation protocol (3)	
Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A document describing the activities to be performed during validation, including the acceptance criteria.
WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A document describing the activities to be performed during validation, including the acceptance criteria.

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Term	Related reference(s)	Definition
Validation protocol (or plan) (VP)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process - or a part thereof - for routine use.
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process - or a part thereof - for routine use.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process - or a part thereof - for routine use.
Validation report (1)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Annex 6, 34th report, 1996)	A document in which the records, results and evaluation of a completed validation programmed are assembled. It may also contain proposals for the improvement of processes and/or equipment.
Validation report (2)		
	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	A document in which the records, results and evaluation of a completed validation programme are assembled and summarised. It may also contain proposals for the improvement of processes and/or equipment.
	WHO guidelines on transfer of technology in pharmaceutical manufacturing. (Annex 7, 45th report, 2011)	A document in which the records, results and evaluation of a completed validation programme are assembled and summarised. It may also contain proposals for the improvement of processes and/or equipment.
Validation report (3)		
	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A document in which the records, results and evaluation of validation are documented and summarized. It should also contain a conclusion of the outcome of the validation.
	WHO guidelines on technology transfer in pharmaceutical manufacturing (Annex 4, 56th report, 2022)	A document in which the records, results and evaluation of validation are documented and summarized. It should also contain a conclusion of the outcome of the validation.
Validity		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	An expression of the degree to which a measurement performed actually measures the characteristic which the investigator wishes to measure (see also reliability above).
	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	An expression of the degree to which a measurement performed actually measures the characteristic which the investigator wishes to measure (see also reliability above).
Valve		
	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	A device for opening and closing containers.

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Term	Related reference(s)	Definition
Variation (1)	Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	Variation to an approved product questionnaire or product dossier that includes, for example, changes in formulation, specifications, or manufacturing process.
Variation (2)	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (Annex 11, 52nd report, 2018)	A change to any aspect of a medicine, including but not limited to, the change of use of a starting material, a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.
Variations	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 10, 52nd report, 2018)	A change to any aspect of a pharmaceutical product, including but not limited to, the change of use of a starting material, a change to formulation, method or site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.
Vector	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Annex 4, 32nd report, 1992)	A piece of DNA that can direct its own replication within a host cell and to which other DNA molecules can be attached and thus amplified. Many vectors are bacterial plasmids, but in other instances a vector may be integrated into the host-cell chromosome following its introduction into the cell and is maintained in this form during the growth and multiplication of the host organism.
Vehicle	Good distribution practices for pharmaceutical products. (Annex 5, 40th report, 2006)	Vehicle refers to trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.
Vehicles (1)	WHO good distribution practices for pharmaceutical products. (Annex 5, 44th report, 2010)	Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.
Vehicles (2)	Good storage and distribution practices for medical products (Annex 7, 54th report, 2020)	Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means that are used to convey medical products.
Vent	WHO good manufacturing practices for medicinal gases (Annex 5, 56th report, 2022)	To remove the residual gas from a container or system down to 1.013 bar by opening the container or system to the atmosphere.
Verification	Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation (Annex 2, 54th report, 2021)	Evidence that the equipment is clean (i.e. that residues are reduced from prior operations to levels no higher than those that are predetermined and specified as acceptable). Appropriate methods should be used and, depending upon the circumstances, may include visual inspection, analytical and microbial (as applicable) testing of swab and/or rinse samples.

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Term	Related reference(s)	Definition
Verification (1)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (Annex 7, 37th report, 2003)	The application of methods, procedures, tests and other evaluations,in addition to monitoring, to determine compliance with the HACCP plan.
Verification (2)	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the GMP principles.
Verification (3)	WHO guidelines on quality risk management (Annex 2, 47th report, 2013)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the quality risk management activities.
Verification (4)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with established requirements and specifications..
Verification (5)	Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Annex 6, 53rd report, 2019)	The procedure by which a regulatory authority only validates the product or submission, and ensures that the product for local marketing is equal or similar to that approved by the reference authority or trusted institution. Verification may be on the basis of assessment reports, GMP inspection reports and/or a certificate of pharmaceutical product of a reference authority
Verification (validation) of data	Additional guidance for organizations performing in vivo bioequivalence studies. (Annex 9, 40th report, 2006)	The procedures carried out to ensure that the data contained in the final report match original observations. These procedures may apply to raw data, data in case-report forms (in hard copy or electronic form), computer printouts and statistical analysis and tables.
Verification of an analytical procedure	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Process by which a pharmacopoeial method or validated analytical procedure is demonstrated to be suitable for the analysis to be performed.
Verification of methods	Good practices for national pharmaceutical control laboratories. (Annex 3, 36th report, 2002)	Verification is conducted where the methods are compendial to confirm whether the pharmaceutical product as compounded can be analysed satisfactorily by the official method.
Verification of performance	WHO good practices for pharmaceutical quality control laboratories. (Annex 1, 44th report, 2010)	Test procedure regularly applied to a system (e.g. liquid chromatographic system) to demonstrate consistency of response.
Verification specified	WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with GxP principles.

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Term	Related reference(s)	Definition
Vial	Guidelines on packaging for pharmaceutical products. (Annex 9, 36th report, 2002)	A small container for parenteral medicinal products, with a stopper and overseal; the contents are removed after piercing the stopper. Both single-dose and multi-dose types exist.
Vigilance	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	A process whereby a manufacturer records and investigates any adverse event report it receives, taking field safety corrective action where necessary, and informing the regulatory authority of those that meet criteria specified through legislation. The regulatory authority may monitor the investigation.
Viscosity	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The resistance to flow of a fluid.
Wall thickness	World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The thickness of the latex film.
Water system	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A system for producing, storing and distributing water, usually compliant with a specific pharmacopoeia grade (for example, purified water and water for injection).
Well-established drugs	Guidelines for registration of fixed-dose combination medicinal products. (Annex 5, 39th report, 2005)	Actives that: — have been marketed for at least 5 years in countries that undertake active postmarket monitoring; — have been widely used in a sufficiently large number of subjects to permit the assumption that safety and efficacy are well known; and — have the same route of administration and strength and the same or similar indications as in those countries.
WHO responsibility	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (Annex 10, 34th report, 1996)	See section 5.4 of the guidelines.

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Term

Related reference(s)	Definition
WHO-type certificate	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers,purchasing,storage and distribution of pharmaceutical products) (Annex 6,40th report, 2006)	A certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce* . *World Health Organization. WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva, World Health Organization, 2000 WHO/EDM/QSM/2000.2. (http://www.who.int/medicines/organization/qsm/activities/drugregul/certification/certifschemes.html).
Model quality assurance system for procurement agencies (Annex 3, 48th report, 2014)	A certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce* . *World Health Organization. WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva, World Health Organization, 2000 WHO/EDM/QSM/2000.2. (http://www.who.int/medicines/organization/qsm/activities/drugregul/certification/certifschemes.html).
Width	
World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10, 54th report, 2020)	The mean lay-flat width of 13 condoms measured in accordance with the relevant annex of ISO 4074 at a point 75 ± 5 mm from the closed end, rounded to the nearest 0.5 mm.
WNV, West Nile Virus	
WHO guidelines on good manufacturing practices for blood establishments. (Annex 4, 45th report, 2011)	An enveloped single-stranded RNA virus that is the causative agent of West Nile fever.
Working culture	
WHO good practices for pharmaceutical microbiology laboratories. (Annex 2, 45th report, 2011)	A primary subculture from a reference stock.

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Term	Related reference(s)	Definition
Work-sharing	Good reliance practices in the regulation of medical products: high level principles and considerations (Annex 10, 55th report, 2021)	A process by which NRAs of two or more jurisdictions share activities to accomplish a specific regulatory task. The opportunities for worksharing include joint assessment of applications for authorization of clinical trials or marketing authorizations, joint inspections for good practices, joint post marketing surveillance of the quality and safety of medical products, joint development of technical guidelines or regulatory standards and collaboration on information platforms and technology. Work-sharing also entails exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other NRAs. A joint activity is a form of work-sharing whereby a regulatory task is conducted by two or more NRAs in collaboration in order to share their assessments, benefit from each other's expertise and discuss any shortcomings of the data evaluated. For example, a joint assessment is a procedure in which the same application is submitted simultaneously to two or more NRAs so that they conduct their evaluations in parallel and share their scientific assessments (e.g. the different modules for quality, nonclinical and clinical data can be assigned to different NRAs for review). The NRAs participating in a joint assessment can combine their lists of questions or deficiencies to the manufacturer and base their respective independent regulatory decisions on the outcome of these assessments. Similarly, a joint inspection is one in which two or more NRAs share the activities and assessments performed during an inspection
World Health Assembly	WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. (Annex 4, 51st report, 2017)	The forum through which the World Health Organization is governed by its 194 Member States.
Worst case (1)	Supplementary guidelines on good manufacturing practices: validation. (Annex 4, 40th report, 2006)	A condition or set of conditions encompassing upper and lower processing limits for operating parameters and circumstances, within SOPs, which pose the greatest chance of product or process failure when compared to ideal conditions. Such conditions do not necessarily include product or process failure.
Worst case (2)	Good manufacturing practices: guidelines on validation (Annex 3, 53rd report, 2019)	A condition or set of conditions encompassing the upper and lower processing limits for operating parameters and circumstances, within standard operating procedures, which pose the greatest chance of product or process failure when compared to ideal conditions. Such conditions do not necessarily include product or processfailure.
Worst case (3)	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	A set of conditions encompassing processing limits and circumstances, including those within standard operating procedures, that pose the greatest chance of process or product failure (when compared with ideal conditions). Such conditions have the highest potential to, but do not necessarily always, result in product or process failure.

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Term	Related reference(s)	Definition
Yield, expected	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The quantity of material or the percentage of theoretical yield anticipated at any appropriate phase of production based on previous laboratory, pilot-scale or manufacturing data.
Yield, theoretical	WHO good manufacturing practices for active pharmaceutical ingredients. (Annex 2, 44th report, 2010)	The quantity that would be produced at any appropriate phase of production, based upon the quantity of material to be used, in the absence of any loss or error in actual production.
Z-value	WHO good manufacturing practices for sterile pharmaceutical products (Annex 2 56th report, 2022)	The temperature difference that leads to a 10-fold change in the D-value of the biological indicator.