WORLD HEALTH ORGANIZATION

REGULATION AND PREQUALIFICATION DEPARTMENT

Quality Manual

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1.0 Introduction

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. WHO is responsible for providing leadership in global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based options, providing technical support to countries and monitoring and assessing health trends.

The WHO Constitution, adopted in 1946 and entered into force in 1948, provides the mandate for WHO’s work. The World Health Assembly (WHA) is the decision-making body of the WHO, attended by delegations from all WHO Member States.

WHO’s Access to Medicines and Health Products (MHP) Division comprises of the Health Products Policy and Standards (HPS) and Regulation and Prequalification (RPQ) departments.

RPQ implements functions and activities on strengthening sustainable local production, promoting effective and efficient regulatory systems, and improving access to quality assured and affordable health products in collaboration with the WHO member states and other stakeholders.

To deliver these activities, RPQ consists of three units: Regulation and Safety (REG), Local Production and Assistance (LPA) and Prequalification (PQT) as shown on the WHO Intranet organization charts. The core functions of these three units are described on the WHO website at: REG, LPA and PQT.

1.1 Mandates

RPQ’s three units have mandates based on the WHO Constitution and World Health Assembly resolutions. An overview of mandates is provided in Table 1.

Table 1: overview of mandates for RPQ

<table>
<thead>
<tr>
<th>Mandate source</th>
<th>REG</th>
<th>LPA</th>
<th>PQT</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Constitution: Article 2, which calls for WHO: c) ‘to assist Governments, upon request, in strengthening health services’ d) ‘to furnish appropriate technical assistance and, in emergencies, necessary aid upon request or acceptance of Governments’</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
### Mandate source

<table>
<thead>
<tr>
<th>Mandate source</th>
<th>REG</th>
<th>LPA</th>
<th>PQT</th>
</tr>
</thead>
<tbody>
<tr>
<td>u) ‘to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products’, and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO Constitution: Article 21, which states that the World Health Assembly shall have authority to adopt regulations concerning:</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>b) ‘nomenclatures with respect to diseases, causes of death and public health practices’</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>d) ‘standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce’</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>e) ‘advertising and labelling of biological, pharmaceutical and similar products moving in international commerce’</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Resolution WHA 74.6 - Strengthening local production of medicines and other health technologies to improve access</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Resolution WHA73.8 - Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005)</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Resolution WHA70.17 - Global vector control response: an integrated approach for the control of vector-borne diseases</td>
<td>✓ FPI</td>
<td>x</td>
<td>✓ VCP</td>
</tr>
<tr>
<td>Resolutions WHA69.20 and WHA60.20 Better medicines for children</td>
<td>✓ RCN</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Resolution WHA67.20 - Regulatory system strengthening for medical products – including Section 2(6) call for “the Director general to strengthen WHO’s prequalification programme</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Resolution WHA67.21 - Access to biotherapeutic products, including similar biotherapeutic products and ensuring their quality, safety and efficacy</td>
<td>x</td>
<td>✓</td>
<td>✓ VAX MED</td>
</tr>
<tr>
<td>Resolution WHA65.19 – Substandard and falsified medical products</td>
<td>✓ ISF</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
Mandate source

<table>
<thead>
<tr>
<th>Mandate Source</th>
<th>REG</th>
<th>LPA</th>
<th>PQT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution WHA57.14 Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS - Section 3 (4) requires the publication of prequalification review process and the results of inspection and assessment reports of the listed products, aside from proprietary and confidential information.</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Resolution WHA45.17 - Immunization and vaccine quality</td>
<td>✓ LNS</td>
<td>✓</td>
<td>✓ VAX</td>
</tr>
<tr>
<td>Resolution WHA16.36 - Pharmacovigilance</td>
<td>✓ PVC</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

1.2 Reference documents used

To fulfil the mandates, RPQ uses a range of standards and guidelines. This includes technical documents published by WHO as well as standards and guidelines from other sources like the International Organization for Standardization (ISO), Pharmaceutical Inspection Co-operation Scheme (PIC/S), International Medical Devices Regulators Forum (IMDRF), Clinical and Laboratory Standards Institute (CLSI) and International Electrotechnical Commission (IEC).

A selection of relevant technical documents published by WHO is provided in Table 2.

Table 2: Selection of WHO-published reference documents used within RPQ

<table>
<thead>
<tr>
<th>Reference document</th>
<th>REG</th>
<th>LPA</th>
<th>PQT</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO’s 13th General Programme of Work (GPW13)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>WHO’s Roadmap for Access to Medicines, Vaccines and other Health Products 2019-2023</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Reference document</td>
<td>REG</td>
<td>LPA</td>
<td>PQT</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>-----</td>
<td>-----</td>
<td>----------------</td>
</tr>
<tr>
<td>The International Pharmacopoeia (Ph. Int.)</td>
<td>X</td>
<td>X</td>
<td>√ MED</td>
</tr>
<tr>
<td>WHO TRS 1033 – Annex 11 Good regulatory practices in the regulation of medical products</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>WHO TRS 1030 – Annex 4: Collaborative procedure in the assessment and accelerated national registration of WHO prequalified in vitro diagnostics</td>
<td>√</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>WHO TRS 1025 – Annex 5: Quality management systems for national inspectorates</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>WHO TRS 1010 – Annex 11: Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>WHO TRS 1003 - Annex 6: Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products International pharmacopoeia</td>
<td>√ FPI</td>
<td>X</td>
<td>√ MED</td>
</tr>
<tr>
<td>WHO TRS 999 – Annex 1: Good Manufacturing Practices for biological products</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>WHO TRS 986 - Annex 5: Guidance on good data and record management practices</td>
<td>X</td>
<td>X</td>
<td>√ MED</td>
</tr>
<tr>
<td>WHO TRS 978 – Annex 6: Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies</td>
<td>√ LNS</td>
<td>X</td>
<td>√ VAX</td>
</tr>
</tbody>
</table>
2.0 Regulation and Prequalification Department

2.1 Context of the constituent entities

2.1.1 Office of the Director

The Office fulfils general and overarching activities of the Department, such as:

- Overall coordination
- Ensure WHO’s regulatory support capacity
- Drive the development of key performance indicators (KPIs) for RPQ processes
- Collaborate with WHO Regional and Country Offices to improve targeted and aligned WHO regulatory support activities
- Monitor RPQ’s impact on regulation of and access to medical products
- Establish, coordinate, implement and maintain the Quality Management System; the staff tasked with this are referred to as Quality Assurance staff (QA)
- Assist with grant management and reporting according to WHO rules
- Administrative planning
- Management of external experts

2.1.2 Regulation and Safety Unit (REG)

REG provides guidance and support to WHO Member States to enhance effectiveness and efficiency of regulatory systems. REG also facilitates collaboration among stakeholders regarding the regulation of medical products across their lifecycle.

REG comprises of the following teams:
- Regulatory Systems Strengthening (RSS):
  - building regulatory capacity in Member States in accordance with good regulatory practices,
  - developing and implementing the Global Benchmarking Tool to allow assessment of regulatory systems,
  - formulating institutional development plans to assist countries in implementing effective regulatory oversight,
  - supporting countries in the implementation of the established institutional development plans.
- Regulatory Convergence and Networks (RCN):
  - promoting regulatory cooperation, harmonization, convergence and transparency through networking, work-sharing, and reliance,
  - supporting Member States in their activities to regulatory convergence, regional or international regulatory networks and harmonization initiatives,
  - working with a range of harmonization initiatives and regulatory networks to strengthen the capacity for regulatory oversight.
- Facilitated Product Introduction (FPI):
  - supporting Member States with collaborative registration of prequalified medical products,
  - supporting Member States with collaborative registrations of medical products according to WHO procedures.
- Incidents and Substandard and Falsified medical products (ISF):
  - receiving, assessing and coordinating the response to health incidents on a range of issues,
  - addressing issues on substandard and falsified medical products (SF),
- Pharmacovigilance (PVG):
  - developing guidelines on the pharmacovigilance of priority medicines and vaccines in public health programmes in low- and middle- income countries
  - developing innovative methods and tools for the collection, analysis and communication of safety signals for medicinal products,
  - providing technical support and training to countries to establish and develop good pharmacovigilance systems and practice
  - coordinating networks and platforms for information exchange on safety and regulatory aspects of medicines and vaccines
  - convening global advisory committees of experts on the safety of medicines and vaccines,
- Laboratory Networks and Services (LNS):
• assessing compliance of laboratories with required standards,
• assisting national laboratories to achieve technical maturity and/or prequalification through direct technical assistance or other collaborations including audits,
• building and supporting regional and global collaboration and networks of laboratories.
• organizing and coordinating laboratory testing,
• providing training, feasibility, collaborative and proficiency testing studies.

2.1.3 Local Production and Assistance Unit (LPA)
LPA supports Member States in strengthening sustainable local production and technology transfer to improve access to quality-assured health products in a holistic manner. This involves, for example:

• providing guidance and support to countries to strengthen coherent policies
• create a conducive business environment for sustainable local production of quality-assured health products
• promoting the global partnership and cooperation
• providing capacity building and technical assistance for quality production and sustainability
• facilitating and supporting technology transfer
• providing specialized technical assistance to help speed up attainment of WHO PQ/EUL.

2.1.4 Prequalification Unit (PQT)
The mission of PQT is to work in close cooperation with NRAs and other partner organizations to make quality priority health products available for those who urgently need them.
PQT comprises of the following teams:

• Medicines assessment (MED):
  ▪ supporting prequalification of finished pharmaceutical products and/or the active pharmaceutical ingredients (APIs)
  ▪ assessing product dossiers of finished pharmaceutical products,
  ▪ assessing master files of active pharmaceutical ingredients,
2.1.5 Cross-cutting activities between units within RPQ

There are various activities that involve input from more than one team. These are termed “cross-cutting” activities. Cross-cutting SOPs should not be confused with general SOPs, which describe managerial and supportive rather than operational processes.

Cross-cutting SOPs can involve various teams within one unit, or within several units. An example of cross-cutting SOPs within one unit are most prequalification SOPs, where the PQT application is a core activity of the relevant assessment team and the process requires input from the PQT-INS team.

An example of cross-cutting SOPs that require input from teams across units within RPQ is the assessment of reported incidents. The reporting is a core activity of the
incidents team and may require input across units, depending on the nature of the product as well as the problem. For cross-cutting processes across units, RPQ assigns ‘process ownership’ to one team, with the other teams considered contributors.

Table 3 provides an overview of cross-cutting activities that involve teams from different units.

**Table 3: cross-cutting activities between units within RPQ**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Process owner</th>
<th>Contributing team(s) / unit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity building for Member States</td>
<td>REG</td>
<td>All teams</td>
</tr>
<tr>
<td>Incidents that are about PQT outcomes</td>
<td>REG/ISF</td>
<td>PQT</td>
</tr>
<tr>
<td>Coalition of Interested Parties</td>
<td>REG/RSS</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Regulatory Preparedness and Readiness</td>
<td>REG/RSS</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Regulatory Systems Strengthening</td>
<td>REG/RSS</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Designation of WHO listed authorities (WLA)</td>
<td>REG/RSS</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Harmonization initiatives</td>
<td>REG/RCN</td>
<td>Any</td>
</tr>
<tr>
<td>ICDRA</td>
<td>REG/RCN</td>
<td>Any</td>
</tr>
<tr>
<td>Collaborative Registration Procedures</td>
<td>REG/FPI</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Other collaboration initiatives</td>
<td>REG/FPI</td>
<td>PQT, LPA</td>
</tr>
<tr>
<td>Vaccine Safety Net</td>
<td>REG/PVG</td>
<td>VAX</td>
</tr>
<tr>
<td>Technical assistance to laboratories for prequalification</td>
<td>REG/LNS</td>
<td>INS</td>
</tr>
<tr>
<td>QCL prequalification</td>
<td>REG/LNS</td>
<td>INS</td>
</tr>
<tr>
<td>Situational analysis and readiness, for example feasibility study for local production</td>
<td>LPA</td>
<td>RSS and RCN</td>
</tr>
</tbody>
</table>
Activity | Process owner | Contributing team(s) / unit(s)
--- | --- | ---
Technology transfer facilitation | LPA | REG but not PQT due to potential conflict of interest
Capacity building for manufacturers involved in local production in initiatives | LPA | RSS, RCN and LNS but not PQT due to potential conflict of interest
Technical assistance to manufacturers for prequalification / EUL | LPA | REG
Emergency Use Listing | PQT | REG
Capacity building for manufacturers interested in prequalification | PQT | REG
Vaccine prequalification | PQT/VAX | LNS

### 2.2 Interested parties and stakeholders

RPQ has internal (= within WHO) interested parties and external stakeholders. The most important internal interested parties are the Health Products and Policy Standards Department within the Access to Medicines and Health Products Division (MHP) and WHO’s various disease programmes departments that decide on invitations for Expression of Interest (EOI) for prequalification.

External stakeholders are a variety of entities including:

- those that directly use the services of RPQ, particularly:
  - Ministries of Member States using the services of LPA
  - NRAs and National Control Laboratories using the services of REG and LPA
  - Manufacturers using the services of PQT, REG and LPA
- those that use the outcomes of services of RPQ, like procurement agencies and NRAs looking to register a product based on its prequalification
- those that contribute to the funding of RPQ programmes

Note that manufacturers using the services of PQT are usually referred to as ‘customers’.

A specific category of external stakeholders are donors. They support RPQ directly in the funding of its processes. These stakeholders will communicate their needs to RPQ through
official WHO grant management procedures. The management of donor stakeholders largely occurs according to WHO procedures, hence outside the scope of RPQ’s QMS.

Expectations of donor stakeholders are discussed and agreed by both parties and they constitute part of the deliverables and/or performance indicators of the grant agreements. RPQ’s QMS describes key performance indicators (KPIs) in a general SOP or policy and refers to individual performance indicators in the relevant SOPs.

Engagement of other stakeholders is entirely within the scope of RPQ’s QMS and is described in the relevant SOP or policy.

### 2.3 Quality Management System scope

RPQ’s Quality Management System (QMS) is developed in accordance with ISO 9001: 2015 and is intended to continue compliance with future ISO 9001 editions.

The scope of the RPQ QMS includes all processes and activities undertaken by RPQ, except for the following. RPQ is part of WHO’s wider organization. A range of activities is covered by other entities within WHO. Examples include GSM approvals, PMDS activities, procurement of products and services, IT hardware and software and human resource management. These activities are centrally managed under the respective WHO Department and RPQ staff are required to use their procedures. Where relevant RPQ’s QMS has connecting provisions in place.

### 2.4 Quality Management System background

When RPQ was established in 2020, the quality management systems and arrangements of its constituent units were combined into one department-wide QMS. RPQ is working to harmonize these arrangements whilst allowing and supporting the different teams to apply a tailored approach to their team-specific QMS documents.

RPQ has an increasing number of processes that require input from multiple units or teams. To accommodate these “cross-cutting” processes, RPQ needs a Quality Management System (QMS) that is highly integrated.

Amongst others, RPQ uses the relevant parts of Technical Report Series (TRS) 1025 - Annex 13: WHO Guideline on the implementation of QMSs for National Regulatory Authorities (NRAs) as guidance in this respect.
The environment that RPQ operates in is very dynamic, hence RPQ’s QMS should be light, flexible and adaptable to accommodate future organizational and other changes.

The processes within PQT are largely of a repetitive nature and consistency on how different applications of the same type are processed is a major factor in how stakeholders perceive PQT’s performance. Therefore, the part of the QMS that relates to PQT is relatively detailed and prescriptive, to ensure consistency at all times.

The processes within LPA and REG on the other hand are often tailored to the individual stakeholder’s needs. Each request is different and its handling will depend on how these needs are best met. Essentially, the requesting entity may influence the way LPA or REG works together with them to achieve the best possible outcome. Consequently, the part of the QMS that relates to LPA and REG is of a ‘higher level’, i.e. much less prescriptive and leaving space to find ways to aim for that best possible outcome.

The processes within the RPQ’s administrative section are focused on facilitating and supporting the various units’ processes to proceed as efficiently as possible. Therefore, the level of detail of the relevant part of the QMS may be in-between that of PQT and that of LPA and REG.

2.5 Quality Management System concepts

RPQ wants to ensure that the QMS meets its needs without making it unnecessarily complex. Therefore, the QMS has been designed according to the following leading concepts:

- The QMS is based on the principles provided by ISO 9001:2015:
  - Stakeholder focus (to meet stakeholder requirements and to strive to exceed stakeholder expectations)
  - Leadership at all levels (to establish unity of purpose and direction)
  - Engagement of people at all levels of the organization
  - Process approach
  - Continuous improvement
  - Evidence-based decision-making
  - Relationship management with relevant interested parties

- Wherever possible, continuous improvement of RPQ’s services, products and of the effectiveness of the QMS applies the Plan-Do-Check-Act cycle:
RPQ applies a range of conduct improvement mechanisms within its QMS in which the Plan-Do-Check-Act cycle is applied, particularly:

- Change management
- Internal audit
- Management review
- Periodic document review
- Handling of complaints and appeals

- Wherever applicable, processes are risk-based. They include some form of risk-assessment to set priorities in planning as well as conducting a process. Therefore, the PDCA cycle and risk-based approach are intertwined.
- Processes are kept simple and the associated process description in the QMS is kept short, sharp and succinct.
- Process descriptions in QMS documents like SOPs and WIs are preferably written in an active “who, verb, what” style, thus identifying the responsibility as well as the action.
- At all times, documents are written in plain English, avoiding complex language to ensure that all staff, regardless of their level of proficiency, will have the same understanding of content.
3.0 Leadership

3.1 Management and leadership commitment

3.1.1 Quality Management System commitment

RPQ management consists of the Director RPQ, the three Unit Heads (LPA, REG and PQT) and the Team Leads. RPQ management provides evidence of its leadership and commitment to the development and implementation of the QMS and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the QMS;

b) ensuring that the Quality Policy and quality objectives are established for the QMS and are aligned with the strategic plan and the context of RPQ;

c) ensuring that the quality policy is communicated, understood and applied within RPQ;

d) ensuring that the content of the quality policy is communicated to stakeholders;

e) ensuring the integration of the QMS and its requirements into the processes:
   i. within teams,
   ii. between teams in the same unit,
   iii. between units within RPQ;

Noting that other business processes, for example accounting, employee benefits management and legal activities, follow WHO general procedures and are out of scope of the QMS;

f) promoting awareness of the plan-do-check-act approach and risk-based thinking;

g) ensuring that the resources needed for the QMS are available;

h) communicating the importance of effective quality management and of conforming to the QMS requirements;

i) engaging, directing and supporting persons to contribute to the effectiveness of the QMS;

j) promoting continuous improvement; and

k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
3.1.2 Stakeholder focus

RPQ works with a range of stakeholders as outlined on section 2.2. RPQ's applies WHO's Framework for Engaging with non-State Actors (FENSA) to its stakeholder engagement.

RPQ acknowledges that the interests of these stakeholders are very diverse. Therefore, RPQ management adopted a broad stakeholder focused approach that ensures that stakeholder needs and expectations are determined, converted into requirements and are met with the aim of enhancing stakeholder satisfaction. This is because the service needs and expectations of stakeholders are related to the quality, safety and efficacy of the medicines and other health products that are handled and managed by stakeholders.

3.2 Quality policy

The Quality policy is provided in RPQ/POL/1.

The quality policy is a compass by providing the direction and framework for establishing key performance measures, as well as related objectives and targets. RPQ management ensures that the quality policy is established and documented, and that it is available to all interested parties. The Quality Policy Statement includes RPQ's quality policy and management commitment to implement processes and activities. The policy statement and the quality manual are part of documented information of the QMS.

The RPQ director has the authority to appoint Quality Assurance staff responsible to ensure that defining, documenting, implementing and reviewing of the quality policy is done in consultation with the RQP management and other personnel, or their representatives. The policy statement is reviewed every two years or earlier if required, as part of the management review programme or at a frequency determined by:

- the changing needs and expectations of stakeholders;
- the risks and opportunities that are presented through the risk management process.

The quality policy is communicated to all staff at all levels throughout RPQ via quality awareness meetings, training, regular internal communications and reinforcement during annual staff performance reviews. Employees’ understanding of the quality policy and objectives is determined during documented internal audits and other
methods deemed appropriate. The quality policy may be available to stakeholders through appropriate means with the approval from RPQ Director or Unit Heads as appropriate.

3.3 Roles, responsibility and authorities

RPQ management assigns roles and responsibilities within the Department, units and teams. Job descriptions are available, defining the responsibilities and authorities of each position. These job descriptions are currently not considered part of the QMS, but may be included in the QMS at a later stage as required.

The job roles, responsibilities, authorities and organizational structure are defined to ensure meeting the needs and expectations of the stakeholders. This is achieved through planning and resource management done with the support of an effective risk management process.

RPQ management has responsibility for the following:

- Planning and resource management of RPQ processes
- Development and communication of policies
- Establishing and implementation of quality objectives
- Continuous improvement of the quality management system

The RPQ director assigns the responsibility and authority to Quality Assurance staff to:

- Ensure that QMS processes are delivering their intended outcomes;
- Report on the operation of the QMS and identifying any opportunities;
- Ensure that continuous improvement mechanisms occur;
- Ensure that stakeholder focus is promoted throughout the organization;
- Ensure that whenever changes to the QMS are planned and implemented, the integrity of the system is maintained;
- Ensure that responsibilities and authorities relating to the QMS are communicated and understood.

Unit Heads (UHs) and Team Leads (TLs) are responsible for drafting and execution of the units’ annual operational plans and the implementation of the quality policy, processes and systems described in this manual. TLs are responsible for planning and controlling the QMS processes within their team /area of responsibility, including the establishment and implementation of operational level objectives and facilitating the acquisition of resources needed to implement and improve these processes.
All staff are responsible for the quality of their work and implementation of the policies and procedures applicable to processes they perform. Employees are motivated and empowered to identify and report any known or potential problems and to recommend related solutions to aid the corrective action and risk management processes as part of process approach and risk-based thinking. This includes the QMS focal points within each team that facilitates the implementation, review and monitoring of the quality management system.

4.0 Planning

4.1 Controlling risks and opportunities

RPQ manages risks and opportunities in accordance with WHO’s Corporate Risk Management Policy and the associated Risk Management Tool. The policy describes risk management as ‘a process of identifying, prioritizing and responding to risks across an organization. Risk management includes activities to realize opportunities while mitigating threats’.

PQT processes provide a largely standardized service to customers (manufacturers) and stakeholders (users of prequalification decisions) and risks are associated with the failure to achieve PQT’s objectives in relation to these services. PQT has addressed this in a procedure that is based on the WHO’s Corporate Risk Management Policy.

LPA and REG processes are largely tailored to the individual needs of the requesting stakeholder. This includes any adjustments during the process, including adjustments to address risks or opportunities. Consequently, risks and opportunities are controlled in-process rather than in a unit-level SOP.

Opportunities management is an important input in determining the RPQ areas of improvement and development in the service provision. Opportunities are assessed on the feasibility of their undertaking and the impact they may have on the continuous quality improvement.

Management of risks and opportunities involve periodic monitoring and assessment of the controls to mitigate the risks and implementation of the opportunities.

4.2 Quality objectives

The objectives of RPQ’s QMS are provided in the Quality policy:

- to promote and assure consistency across RPQ;
- to increase effectiveness, transparency and efficiency;
• to better facilitate cross-cutting processes between units and teams within RPQ;
• to strengthen collaboration and coordination with WHO entities outside RPQ.

RPQ aims to build quality into its processes. This involves designing its processes to assure consistent quality of the process outcomes.

5.0 Support

This section provides information on the resources that are required to support the QMS.

5.1 Resources

RPQ uses a range of resources that are provided at Division or higher levels. Therefore, management of these resources remains outside the scope of RPQ’s QMS. Examples are: building management and security, human resources, information technology hard- and software, financial and other infrastructure.

However, where RPQ can influence resources provided; if applicable this will be managed in accordance with the QMS.

5.1.1 Personnel

The WHO Human Resources (HR) Department has the lead in personnel matters. RPQ follows the relevant HR procedures and requires its staff to follow all HR procedures, instructions and related training.

RPQ management ensures that the required technical competences are available and managed appropriately. In addition, TLs ensure that potential and/or known conflicts of interest for members of staff and consultants are addressed before allocation of work duties.

5.1.2 Infrastructure

RPQ management determines the use of infrastructure required to conduct operational processes, including:

• workspace and associated facilities;
• process equipment, hardware and software;
• information and communication technologies.
Where equipment is used for critical processing activities the WHO IT Department provides the technical assistance with regards to the system qualification and validation as well as periodic system maintenance to ensure consistent system performance.

5.1.3 Monitoring resources
RPQ management monitors the quality of services that it offers to its stakeholders. The quality requirements as well as quality performance indicators are provided in the relevant mandates and tools.

RPQ does not retain the associated documented information as they are managed by other WHO Departments and institutions that have working relations with RPQ.

RPQ generally does not use any measuring devices in its processes that require any measurement traceability, calibration or maintenance.

5.1.4 Knowledge management
RPQ management determines the knowledge necessary for the operation of its functions and to achieve the objectives. The knowledge and information is obtained from:

- internal sources, such as trainings, workshops, non-conformities, corrective actions, and the results of improvement; and
- external sources such as standards, academia, conferences, and/or information gathered from different stakeholders.

This knowledge is documented, maintained, and may be accessed for reference to the extent necessary whenever needed.

When addressing the changing needs, trends and expectations of stakeholders, RPQ considers its current knowledge and determines how to acquire or access the necessary additional knowledge.

5.2 Competence
Staff competency is critical to successful, effective and efficient operations. RPQ determines competency on the basis of education, training and experience in the area of duty and function. RPQ management regularly identifies emerging competency
needs during management reviews. Emergent competency needs are converted into job descriptions for the type and number of positions that need to be filled through internal or external recruitment.

Where possible, competency training is conducted in-house, although for more specialist skills, external courses are utilized. The effectiveness of training is evaluated and recorded. Future competency training needs are identified as part of the management review.

5.3 Awareness

Members of staff are regularly reminded of the relevance and importance of their activities and how they contribute to achieving the strategic priorities and quality objectives. RPQ holds regular meetings on unit and / or team level, where progress on implementation, benefits of improved performance and implications non-conformities with the QMS requirements are reviewed and discussed.

5.4 Communication

RPQ recognizes that good internal and external communication is important to ensure efficiency and effectiveness. There are measures in place to ensure that effective communication channels and coordination exist between the units and the teams as well as with other WHO Departments. There are similar measures to ensure the effective communication between RPQ and relevant international, regional and national institutions, external experts, UN agencies, national regulatory authorities and other stakeholders. External communication is conducted in a range of ways, including:

- WHO website, including MVP’s workplan
- Letters
- Memos
- Emails
- Reports and minutes of meetings and activities
- Newsletters
- Forms
5.5 Documented information

5.5.1 QMS documentation structure

The QMS documentation includes both documents and records, defined as follows:

A *document* is a compilation of authorised information describing how an activity is done.

A *record* is captured evidence of an activity being done or having been done.

Documents and records undergo different controls.

The basic structure of the QMS aligns with that recommended in ISO 9001:2015:

- The *Quality Policy* (RPQ/POL/1) is on top of the pyramid and defines the high level policy of RPQ management. It defines the **WHY**?
- This *Quality Manual* (RPQ/MAN/1) comes underneath the policy and contains guidance on how processes are conducted to achieve the quality objectives of the QMS. It provides further detail on the **WHY**? and defines the **WHO**? and the **WHEN**?

![ISO 9001:2015 Documentation](image-url)
• On several overarching topics, like stakeholder engagement and knowledge management, **Policies (POL)** provide overarching high-level information that is applied across RPQ. They define the high-level **WHO?** and **WHY?**

• **Procedures (SOPs)** provide further detail about the **WHO?** and provide the **HOW?** SOPs provide a process description to be followed to perform designated operations.

• Where deemed useful, **Work Instructions** may provide further detail on the **WHO?** as well as the **HOW?** and include step-by-step detailed instructions under an SOP, compiled to help execute routine operations.

• **Records** and **forms** are templates that have to be completed to become records: either as an output (letter, report etc.) or as a form. They record **WHAT has been done**.

• Documents may have **Annexes**: an extension of the document to provide detailed illustration and demonstration of the section or subject.

### 5.5.2 Document generation and review

The generation of QMS-documents is initiated by the user/staff that identifies the need for a process or activity to be guided by a standardized document. However, the initiated or proposed document undergoes stages of review by the immediate supervisor to determine the fitness and necessity of the document. QA staff facilitate this drafting and review process, ensuring that the proposed document is in line with QMS quality policy and the quality objectives. The validity of different documents is described in the SOP for management of QMS documents.

All QMS documents are made available electronically only.

### 5.5.3 Document management and records control

Documents required for the management system are made available and controlled in accordance with the document management SOP. The purpose of document management is to ensure that personnel have access to the latest, approved document and to avoid the use of obsolete information. This includes assurance that QMS documents are protected from any loss of confidentiality and loss of integrity.

All documented procedures are established, documented, implemented and maintained.

The document management SOP defines the controls needed for the identification,
Once printed or copied from the Master, this document is no longer controlled and only valid on the day of printing or copying.

storage, retrieval, protection, retention time, and disposition of QMS records. This procedure also defines the methods for controlling records that are created by and/or retained by other stakeholders.
6.0 **Operation**

6.1 **Operational planning and control**

RPQ management plans and implements the activities that are needed to provide the services to the stakeholders. Planning occurs at unit and team level, in accordance with WHO procedures on work planning and depending on operational requirements. Planning of the activities is consistent with the requirements of the other processes of the management system.

The planning of activities is done considering:

- availability of resources,
- ability to deliver services consistently in accordance with relevant mandates, standards and guidelines,
- needs and expectations of the stakeholders,
- risks and related opportunities as per the risks and opportunities management procedure.

6.2 **Stakeholder requirements**

6.2.1 **Stakeholder management**

In accordance with the quality policy commitment to aim at exceeding our stakeholders’ expectations, RPQ highlights effective communication as an essential element of delivering stakeholder satisfaction. Stakeholder communication includes the management of stakeholder expectation. Early and clear communication are crucial in this respect. Methods of stakeholder communication include:

1. Website publications
2. Expression of Interests, brochures, bulletins, specifications or technical data sheets relating to our services;
3. Meetings, letters, memos, enquiries, invoices, reports, E-mails and general correspondence;
4. Customer feedback and complaints management process.
6.2.2 Determining stakeholder requirements

The various categories of stakeholders are described in 2.2. These categories of stakeholders have different needs and expectations of RPQ and may share some general ones:

- UN procurement agencies and some donor agencies largely depend on RPQ’s prequalification services to provide evidence of quality assurance of the health products they procure.
- NRAs and regional regulatory entities and networks may depend on RPQ’s regulatory support services to strengthen their regulatory frameworks.
- NRAs in countries that have weak or inexistent regulatory systems and regional regulatory entities and networks may depend on RPQ’s prequalification services to support registration.
- Member States, particularly low and middle income countries (LMICs), may rely on RPQ’s support on policy coherence and strategy setting.
- Manufacturers, particularly in LMICs, may depend on capacity building and technical assistance to improve understanding of and compliance with regulatory standards and requirements to produce quality health products.

RPQ management ensures that the requirements are clearly articulated, captured and understood before the acceptance of the work/processes to be done. Factors considered to determine stakeholder requirements include:

1. Previous stakeholders’ requirements on the same activities;
2. Key Performance Indicators (KPIs) set by donors;
3. WHA resolutions, guidelines, guidance documents and international regulatory requirements related to the services or product(s) and
4. Any other additional requirements that may be important to be considered depending on the nature and type of services to be delivered or products to be assessed.

6.2.3 Reviewing stakeholder requirements

RPQ management ensures and confirms the capacity, available resources and feasibility to meet the stakeholder requirements of the requested services and activities. Pre-agreement/contract reviews and/or meetings with stakeholders may be conducted.

Stakeholder requirements and expected deliverables are discussed and confirmed by both parties before being accepted. The discussion is done through the prior exchange
of contracts, agreements, memoranda or purchase orders via appropriate electronic or hard copy formats that allow traceability and retrieval of changes.

6.2.4 Changes to requirements
RPQ management ensures that any changes in stakeholders’ requirements are communicated internally and relevant documents are amended authorized as applicable.

Stakeholder related matters and feedback are described in detail in RPQ/003 and RPQ/007.

6.3 Design and development of services
RPQ services are based on mandates, standards and guidelines and the associated design and development is typically limited to finetuning within these contexts. Where relevant, design and development of processes is conducted in accordance with the change management procedure and in consultation with stakeholders. This includes an internal assessment whether existing resources and requirements are applicable to the (re) developed process(es).

6.4 Management of externally provided products and services

6.4.1 Types of external suppliers
RPQ engages individuals and institutions to provide products and services, typically as part of a process where other parts are conducted internally. Types of external suppliers used include:

- External assessors: Engaged to assist with the product dossier assessments for PQ applications,
- External inspectors: Engaged to assist with the GXP inspections for the PQ applications,
- Evaluating sites: WHO collaborating centres and other laboratories involved in the prequalification performance evaluations and testing,
6.4.2 External supplier control

RPQ management has established a process for the initial assessment of external suppliers’ technical competence, their ability to provide an effective and timely service and to ensure that the suppliers are free from conflicts of interest that would preclude their participation in their specific duties. RPQ controls the service delivery by the external supplier as part of its operational process.

6.4.3 External supplier information

RPQ management communicates in various ways with external suppliers to convey information and ensure understanding of RPQ’s requirements of the products and services to be provided. This may include information regarding the review and approval of the supplier’s methodology and delivery processes as well as the resources to be used. The information communicated to the supplier also provides room for interaction and understanding of the extent of control and monitoring of the supplier’s performance.
6.5 Production and service provision

6.5.1 Control of production and service provision
RPQ operates various processes to ensure production and service provision, such as controlling availability of appropriate QMS documents, monitoring of resources for the performance indicators and implementing the resources at appropriate stages as input data for periodic performance evaluations. Where relevant, RPQ management ensures control of its processes through effective risk management process. All the processes are conducted using documented information such as procedures and work instructions.

6.5.2 Identification and traceability of services
RPQ services may be concluded with an output report. For prequalification activities this is standard practice whereas for activities by LPA and REG this is not applicable.

Prequalification reports may be released to the stakeholder and are identified by name and a unique code, which is verified during the internal process of approval / release of the report. Information may also be communicated to the public and stakeholders through public reports that are published on the WHO website.

6.5.3 Handling stakeholder and suppliers’ property
RPQ management exercises extreme care when handling property that belongs to stakeholders and external suppliers. In events of loss and/or damage, RPQ reports this to the owner through a report of the incident which is retained for reference and use internally within WHO.

6.5.4 Service integrity
RPQ management preserves the quality and integrity of its services. Prequalification reports are preserved for legibility, loss and damage once published. This is to ensure that the reports remain useful to the customer and other stakeholders for the entire validity of the report.
6.5.5 After-delivery services
RPQ ensures that service provision reports, if applicable, remain valid throughout their validity term.

The availability of a Prequalification report provides assurance that the associated product consistently meets the applicable regulatory requirements on safety, quality and efficacy/performance. The QMS requirements provide for monitoring of prequalified products but do not apply to withdrawn and cancelled products. PQT provides post-prequalification services of monitoring the quality, safety and efficacy/performance compliance through GXP inspections and assessments of changes/amendments and variations to the evaluated product dossier information of the prequalified products.

6.5.6 Change control of services
Whenever changes to prequalification reports are made, this is communicated to relevant stakeholders.

6.6 Service release
Completed services and activities of the RPQ processes are released through internal reports that undergo approvals by the respective TL, UH and/or the Director. Public reports are prepared from the approved final reports and may be published on the website. The review and approval process is done within IT systems that have records retention and traceability functionality. Other technical activities and services are approved by the respective TL, UH and authorized by the Director to the stakeholder as applicable.

6.7 Non-conforming services control
Where relevant, non-conforming RPQ processes and activities are reported and controlled. Any non-conformances that are identified and controlled after a report has been released/published may result in a change made to the report and a change to
any associated decision, for example a decision to prequalify. RPQ management is responsible for controlling non-conformances.
7.0 Performance monitoring and evaluation

7.1 Performance monitoring

7.1.1 Performance evaluation planning

RPQ management is responsible for ensuring that the objectives and targets that are set in the operational plan are achieved. These targets provide a measure of performance at the time of evaluation. Indicators that are measured are described in the policy or procedure for process performance management. This SOP provides methodologies and resources for monitoring and evaluation of the results. Outputs and indicators also include performance-indicating parameters of the QMS to evaluate its effectiveness.

7.1.2 Customer satisfaction

RPQ management considers the customers’ and stakeholders’ satisfaction an important aspect of maintaining working relationships and identifying room for opportunities. Therefore, RPQ conducts stakeholder surveys and feedback from time to time, in order to determine the degree of the stakeholders’ perceptions with regard to the fulfilment of their needs and expectations.

7.2 Performance evaluation

Process monitoring data is analysed and evaluated at the required level of detail. Considerable parameters are:

- Stakeholder feedback and satisfaction
- Performance and progress on QMS implementation
- Implementation and effectiveness of the annual operational plan
- Corrective actions, risk and opportunities management process effectiveness
- Performance of external assessors, consultants, experts and other suppliers of products and services
- Customer complaints management effectiveness
- Areas of improvements to the QMS
The above-mentioned processes are captured in the performance evaluation report for the period under review.

8.0 Improvement

8.1 Change management

RPQ provides its services in line with MHP’s strategic direction while conforming to its mandates and tools. As RPQ’s operational environment is very dynamic, the need for change is continuous.

Changes to the procedures for RPQ functions and activities are managed as per the SOP on change management.

Substantial changes require change management whilst minor changes can be made without.

Change management involves planning, evaluation and agreement before the change is made. This includes an assessment of the potential impact of the proposed change against criteria that are defined in the change management SOP or policy. It also includes implementation requirements for example the need for training is evaluated and agreed. Substantial changes are reviewed and authorized before being implemented and communicated to the affected parties. This information is retained and tracked.

8.2 Internal audit

RPQ has arrangements in place to ensure that regular reviews are conducted to assess whether the QMS is implemented and applied as intended and whether it achieves its intended objectives. RPQ management periodically issues an internal audit plan that involves all teams and includes at least one process of each team.

The reviews are conducted by allocated staff and focus on specific activities within the respective processes, looking at availability, content and compliance of the required QMS documents and records.
8.3 Quality management system review

Review of the operation and effectiveness of the QMS is conducted periodically as per the relevant SOP. RPQ staff prepare the input for the management review and RPQ management, together with relevant staff participate in the review. The management review includes but is not limited to the following agenda items;

- the status of recommended actions from the previous management review;
- changes in external and internal issues that are relevant to the quality management system;
- information on the performance and effectiveness of the quality management system, including trend analysis in:
  1) satisfaction degree and feedback from stakeholders;
  2) the extent to which quality objectives and targets have been met;
  3) conformity of services and activities to QMS requirements;
  4) nonconformities and implemented corrective actions;
  5) monitoring and measurement results of the key performance indicators;
  6) internal and external audit results;
  7) the performance of external assessors, inspectors, consultants, experts and other suppliers of products and services;
- the availability of required and planned resources;
- the effectiveness of risk and opportunities management;
- opportunities for improvement in processes and the QMS

The outputs of the management review include decisions and action points on:

- process improvement
- proposed changes to the QMS
- required resources and its availability

The management review meeting minutes are documented and retained.
9.0 Abbreviations

- **ERP**: Expert Review Panel
- **GXP**: Good Practices (X: C=Clinical, L=Laboratory, M=Manufacturing)
- **ISO**: International Organization for Standardization
- **IT**: Information Technology
- **FPP**: Finished Pharmaceutical Product
- **MHP**: WHO’s Access to Medicines and Health Products Division
- **LPA**: Local Production and Assistance Unit
- **MS**: Member State
- **NRA**: National Regulatory Authority
- **POL**: Policy document
- **PQ**: Prequalification
- **PQT**: Prequalification Unit
- **QM**: Quality Manual
- **QMS**: Quality Management System
- **REG**: Regulation and Safety Unit
- **RPQ**: WHO’s Regulation and Prequalification Department
- **SOP**: Standard Operating Procedure
- **TL**: Team Lead
- **TRS**: WHO’s Technical Report Series
- **UH**: Unit Head
- **WHA**: World Health Assembly
- **WHO**: World Health Organization
- **WI**: Work Instruction
10.0 Revision History

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<th>Rev.</th>
<th>Reason for revision</th>
<th>Author</th>
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<tbody>
<tr>
<td>01</td>
<td>First issue</td>
<td>John Taylor</td>
<td>15/10/2014</td>
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| 02   | 1) Document identification number included in the header  
2) Header repeated on all Quality Manual pages  
3) Table of contents revised with change and realignment of Quality Manual sections  
4) Context of PQT revised to provide only the general product streams of PQ and removal of activities that no longer fall within the scope of current PQT  
5) Scope of PQT-QMS revised to group the major processes into PQT product streams and removal of the activities that no longer fall under PQT  
6) Specific sections of the Quality Manual revised to provide PQT processes and activities that fall under each respective ISO clause  
7) Inclusion of the annexes for attachments on figures and process flows  
8) Inclusion of the appendix to cross reference the ISO standard with the Quality Manual  
9) Appendices 1 – 4 have been turned into annex documents of revised manual  
10) Inclusion of annex documents to support the manual | Mario Musonda | 12/02/2019 |
| RPQ/MAN/01 | 1) Organizational structural changes and new titles (Dept, units and teams)  
2) Rewrite to expand from PQT to RPQ  
3) Reshuffle of paragraphs to align with the chapters of ISO9001:2015  
4) Customer replaced with stakeholder  
5) Addition of mandates, standards and guidelines  
6) Addition of cross-cutting SOPs between units | Anton Norder | Jan 2022 |
### 7) Merging of previous sections 6.0 and 9.2, both on Quality Policy, into one new section 3.2

### 8) Shortening of content

### 9) Addition of ISO9001:2015 diagram to describe QMS structure

### 10) Removal of Annexes that are better placed in the SOPs or outside the QMS

### 11) Rename Appendix into Annex

### 12) Revised and updated references to documented information sections

### 13) Appointment and granting of authority for QMS responsibilities of QA staff moved to Director RPQ

### 14) Revision of quality policy statement adjusted to 3 years from annually

### 15) Management of risks linked to WHO CRE\(^1\) policy and implemented at RPQ level

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\(^1\) Compliance, Risk Management and Ethics, [http://intranet.who.int/homes/cre/about/](http://intranet.who.int/homes/cre/about/)

For easy reference, the below table cross-references the sections in this Quality Manual with the relevant clauses in the ISO 9001:2015 standard and the WHO TRS 1025 - Annex 13: Guideline on the implementation of QMSs for NRAs.

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