# WHO training toolkit on SFMP: frequently asked questions

## General information

### Why was the SFMP training toolkit developed?

WHO developed this toolkit on substandard and falsified medical products (SFMPs) to fill a need for comprehensive and multidisciplinary training and continued education for learners and health-care professionals, regulatory authorities, and other stakeholders on SFMPs. Aligned with the WHO prevent–detect–respond strategy on SFMPs, the toolkit aims to harmonize training initiatives and build capacity by equipping the health workforce with the knowledge, skills and resources necessary to prevent, detect and respond to SFMPs effectively.

### Who is the target audience for the toolkit?

The toolkit is targeted at university/college educators (undergraduate and postgraduate levels), instructors for continuing professional education and trainers for in-service training, which can include international organizations, regulatory professionals and civil society, among others. It aims to equip these professionals with the tools, knowledge and skills to deliver effective training on SFMPs.

The trainer's toolkit is designed to support the implementation of training programmes based on a competency-based approach (knowledge, skills and attitudes) for a wide range of learners within 3 levels of health-care professionals, namely: health service providers, health management personnel, and regulators and policy-makers.

### How were the target audience levels and roles defined?

The target audience levels and roles for the SFMP training toolkit were defined through a comprehensive process that considered the different needs and responsibilities of various stakeholders involved in combating SFMPs. A wide range of experts globally contributed to the process to ensure the toolkit addressed the real-world needs and contexts of its users.

Health authorities and regulatory bodies play a critical role in ensuring equitable access to safe, effective and high-quality medicines. While pharmaceutical development and regulation are mainly carried out by regulatory authorities, these functions are not exclusively limited to these entities. Multilateral stakeholder collaboration is essential to combat SFMPs because the problem is transnational, complex and multifaceted. Students in life sciences and all operators in the medical

product supply chain should be made aware of the problem of SFMPs because they play a vital part in safeguarding public health. Early awareness and training provide these professionals with the knowledge and skills to identify risks, uphold quality standards, and contribute to a culture of vigilance and accountability across the supply chain. This proactive approach strengthens prevention and detection efforts, ultimately protecting patients and health systems.

## How was the toolkit developed?

The toolkit was developed through extensive collaboration, research and input from experts across the globe. It builds on several years of experience in designing and implementing face-to-face and online training for health regulators delivered by WHO technical teams.

The toolkit builds on a pilot training programme in 2020–2021, which WHO initiated to strengthen pharmacist training on SFMPs. The pilot programme was implemented in partnership with the International Pharmaceutical Federation, with funding from the European Commission. The programme aimed to integrate standardized bilingual training into pharmacy curricula across selected anglophone and francophone universities in sub-Saharan Africa. The International Pharmaceutical Federation led the project through 4 phases — consultation, development, deployment and evaluation — working closely with an informal technical advisory group composed of academic and regulatory experts. The curriculum was built around WHO's prevent–detect–respond strategy and developed using the "adopt and adapt" principle to ensure contextual flexibility. Six modular teaching units were created, supported by a competency framework, curriculum guide and teacher training resources. Despite challenges posed by the coronavirus disease 2019 (COVID-19) pandemic, the programme was successfully piloted in Cameroon, Nigeria, Senegal, Uganda and United Republic of Tanzania, with strong engagement from university leadership and positive feedback from students and faculty.

WHO, together with a consortium of 5 academic institutions (EHESP-International, France; Institute of Tropical Medicine, Belgium; Geneva University Hospitals, Switzerland; University of Douala, Cameroon; and Cheikh Anta Diop University Dakar, Senegal) and with the support of a consultant, developed the technical and operational aspects of the toolkit. An initial round of expert consultations mapped the elements of the pilot programme to be updated, while WHO technical teams collated existing tools and resources.

A wide range of experts from around the world provided feedback on the toolkit through a public consultation, on the PleaseReview platform, that lasted 10 weeks (June to August 2023). WHO established an informal technical advisory group composed of WHO team leads and select experts to consider all feedback from the public consultation and accurately adopt relevant suggestions.

### How does the toolkit ensure cultural appropriateness?

The developers of the toolkit strove to ensure that the content of the toolkit took into account the wide variety of contexts of trainers, learners and health-care professionals so as to create an inclusive and effective learning environment. The developers included diverse experts from various academic and cultural backgrounds who evaluated the toolkit content for cultural representation, accuracy and appropriateness. The toolkit was also designed to be flexible and adaptable. Trainers are encouraged to modify the content to fit the local cultural context, including language, examples, case studies and scenarios that resonate with the learners' backgrounds. The toolkit will continue to incorporate feedback from learners and trainers to improve content and ensure it remains locally relevant.

## Toolkit components

### What are the main components of the toolkit?

The toolkit includes the following components, which each corresponds to a "tool": (i) competency framework, outlining specific and cross-cutting competencies to tackle SFMPs; (ii) curriculum guide, with comprehensive content and learning objectives organized into 4 modules (background, prevent, detect, respond); (iii) trainer's guide, providing step-by-step instructions for implementing and delivering training programmes; and (iv) technical resources, including WHO reports, guidelines, scientific publications and other relevant materials. These components provide a comprehensive set of materials to help trainers effectively plan, develop and deliver tailored SFMP training programmes. The toolkit includes practical guidance materials such as visual inspection checklists, guidelines for taking good photographs of suspected SFMP samples and an aide-mémoire for SFMP incident management. It also has further supplementary training resources, exercises, case studies and an e-course on SFMPs.

### What topics are covered in the curriculum guide?

The curriculum guide has 4 main modules, each addressing an important aspect of combating SFMPs. The following are the topics covered.

- Module A (background) introduces definitions, causes, risks and the global impact of SFMPs and describes WHO's strategic response.
- Module B (prevent) focuses on strategies to prevent SFMPs across the product life cycle, emphasizing regulatory oversight, supply-chain integrity and public awareness.
- Module C (detect) covers methods for identifying SFMPs through inspections, laboratory testing, field technologies and reporting systems.

- Module D (respond) details how to manage SFMP incidents through risk assessment, patient care, product recalls and effective communication.

## What are the learning objectives for each module?

Each module in the toolkit has specific learning objectives that define the knowledge, skills and attitudes required for 3 levels of health personnel: health service providers, health management personnel and regulators and policy-makers. These objectives are aligned with the WHO prevent–detect–respond strategy and tailored to the roles and responsibilities of each audience level.

Module A: background on SFMPs

- Knowledge: understand definitions, global impact, determinants and WHO's prevent–detect–respond strategy.
- Skills: identify causes and consequences of SFMPs; interpret alerts and data.
- Attitudes: recognize SFMPs as a public health threat; reflect on roles to tackle them.

Module B: prevent

- Knowledge: understand supply-chain vulnerabilities, regulatory roles and the principles of good manufacturing practice.
- Skills: apply preventive actions in procurement, storage and communication.
- Attitudes: promote awareness, advocate for prevention strategies and support public education.

Module C: detect

- Knowledge: understand detection methods, regulatory tools and roles of stakeholders.
- Skills: conduct visual inspections, use reporting systems and apply surveillance tools.
- Attitudes: value detection as part of professional responsibility; promote vigilance.

Module D: respond

- Knowledge: understand risk assessment, incident response and communication protocols.
- Skills: report and manage cases; communicate effectively with stakeholders and the public.
- Attitudes: embrace patient-centred responses; advocate for systemic improvements.

# Implementation and adaptation

### What is a competency framework, or competency-based training?

A competency framework is an inventory of the competencies required to carry out a professional activity. This trainer's toolkit includes such a framework that outlines the essential competencies required to effectively combat SFMPs at various levels of the health system. The framework is aligned with 2 WHO competency frameworks – Global competency framework for regulators of medicines and Global competency framework for universal health coverage – and enhances the overall capacity to tackle SFMPs effectively. This framework is an initial step in developing a competency-based education approach to SFMPs.

In the competency-based approach – or outcome-based education – the competencies targeted by the training programme dictate its design, implementation approach and assessment method. This approach ensures that the educational process is aligned with the desired outcomes. It focuses on the development of specific skills and knowledge that learners must demonstrate by the end of training and/or can carry out in their professional activities.

### How is the competency framework organized?

The competency framework in the toolkit is structured around 3 thematic domains – prevention, detection and response – aligned with WHO's prevent–detect–respond strategy. These are complemented by 4 cross-cutting domains: communication and health advocacy; collaboration; leadership; and education, training and research. Each domain includes key competencies that are further broken down into observable enabling competencies (e.g. demand forecasting or risk assessment).

The framework is tailored to 3 levels of health personnel: health service providers, health management personnel, and regulators and policy-makers. It is designed to be adaptable to local roles and regulatory contexts.

### How can trainers adapt the toolkit to their context?

The toolkit is not intended as a stand-alone resource but rather a flexible set of online materials that can be customized to various target audiences and contexts. Trainers are encouraged to adopt and adapt the materials based on the local environment, available resources, needs, requirements, characteristics and experience of learners. The following steps outline the process of adapting the toolkit.

1. Start by exploring the toolkit website
    - On the toolkit's homepage, review the main components: competency framework, curriculum guide, trainer's guide and technical resources.

- Use the step-by-step guide (section 4.4) to orient yourself. This outlines how to define your audience, select relevant competencies and build a course using the toolkit.

2. Assess your learners' needs and context

- Identify the level of your audience: health service providers, health management personnel, or regulators and policy-makers.
- Use the competency framework (section 2) to match the appropriate knowledge, skills and attitudes for each level.
- Consider local regulations, available infrastructure and learners' prior experience.

3. Adopt relevant materials

- Select modules (A–D) and learning objectives that align with learners' roles and training goals.
- Use the curriculum guide (section 3) to find structured content, learning outcomes and recommended activities for each module.

4. Adapt to your setting

- Modify examples, case studies and exercises to reflect local realities (e.g. national SFMP incidents and supply-chain structures).
- Choose delivery methods that suit your context, whether in-person, online or hybrid, and adjust the depth and duration of content accordingly.

5. Prioritize tools in the following order

- Competency framework: to define what learners need to achieve.
- Curriculum guide: to select modules and learning objectives.
- Trainer's guide: to plan delivery, teaching methods and assessments.
- Technical resources: to enrich training with case studies, checklists and WHO alerts.

6. Use the toolkit website to download resources

- Download editable templates, lesson plans and exercises.
- Customize PowerPoint decks, handout and assessment tools to suit your learners.
- Use the WHO e-course and module platform for blended or self-paced learning.

Trainers should familiarize themselves with the content and structure of the toolkit and assess the needs and competency levels of their target audience. Next, trainers can use the toolkit to develop personalized lesson plans that align with the objectives and competencies of their learners. A combination of teaching methods (e.g. lectures, case studies, simulations and practical exercises) that are relevant and accessible to the learners can be used to enhance learning.

## How can the toolkit be integrated into existing training and curricula?

The toolkit is designed to be flexibly integrated into existing training programmes and curricula by aligning its content with current educational objectives and avoiding redundancy. The toolkit supports a competency-based approach, encouraging trainers to match learning activities and assessments with clearly defined learning outcomes. Central to its integration is the adopt and adapt principle: trainers can adopt relevant materials and resources directly from the toolkit and adapt them to suit local contexts, learner profiles, available resources and institutional priorities. This ensures that the training remains relevant, context-sensitive and complementary to existing efforts. The toolkit also provides structured guidance, modular content and practical tools that can be embedded into undergraduate, postgraduate and continuing education courses. Trainers should focus on aligning learning activities and assessments with intended learning outcomes. Incorporating the issue of SFMPs into life sciences curricula offers the opportunity to connect theory with real-world public health challenges. Given the cross-cutting nature of SFMPs, university and college educators can embed the topic across disciplines – from regulatory affairs and ethics to pharmacology and analytical chemistry. For example, detection techniques can be taught as practical applications of chemical analysis, while public health modules can explore the societal impact of and policy responses to SFMPs. This approach not only enhances students' understanding but also prepares them to become vigilant and responsible professionals in the medical product supply chain.

## What are some effective teaching methods for SFMP training?

The toolkit describes and offers a range of effective teaching methods: lectures and presentations to provide theoretical knowledge; case studies and problem-solving exercises to apply knowledge to real-world scenarios; simulations and role-playing to practice skills in a controlled environment; group discussions and workshops to encourage interaction and collaborative learning; and practical exercises to develop hands-on skills, such as visual inspection of medical products.

## What are key considerations for preparing and delivering SFMP training?

Effective preparation and delivery of SFMP training require a structured and learner-centred approach. Trainers should begin by developing clear lesson plans aligned with the intended learning outcomes and competencies. This includes selecting appropriate modules, adapting content to the learners' context, and preparing relevant learning materials, exercises and assessments. The adopt and adapt principle from the toolkit encourages trainers to tailor content to local needs, resources and learner profiles.

Trainers should also ensure the training environment is conducive to learning, considering factors such as group size, available teaching technologies and opportunities for interaction. A mix of teaching methods, such as case studies,

simulations, group work and visual inspections, should be used to engage learners across different levels (health service providers, management personnel and regulators/policy-makers). Additionally, trainers can:

- prepare and test all materials and equipment in advance;
- use a variety of assessment tools (e.g. quizzes, role plays and practical exercises) to evaluate learning;
- foster interprofessional collaboration and discussion;
- encourage reflection and feedback to continuously improve the training.

By following these principles and using the toolkit's modular structure, trainers can deliver effective, context-sensitive education that strengthens capacity to prevent, detect and respond to SFMPs.

Trainers should prepare lesson plans, obtain necessary learning materials, organize assessment materials and ensure that the training environment is conducive to learning. They should also consider the size of the group and the availability of teaching technology.

### How can trainers evaluate the effectiveness of their training programmes?

Trainers can use various assessment methods. These include pre- and post-training assessments to measure knowledge and skills gained, as well as formative and summative assessments to evaluate learners' progress. Feedback from learners should be collected through evaluation forms to assess the structure, content, delivery and overall experience of the training. Further evaluations include observation and practical assessments to evaluate participants' performance during practical exercises, and simulation and follow-up surveys to assess the long-term effect of the training on participants' professional practice.

## Additional support

### How can trainers stay updated on the latest developments in SFMPs?

Trainers are encouraged to regularly review WHO publications, guidelines and scientific literature. They can also participate in continuous professional development and training programmes and engage with professional networks and communities of practice to share knowledge and experiences.

### Where can trainers find additional resources and support?

Trainers can access additional resources and support through the WHO website, the online portal for the trainer's toolkit, and by contacting WHO directly for specific

queries or assistance. Trainers should also regularly review updates and new publications from WHO and other relevant organizations.