WHO Prequalification of Medicines and Vaccines Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The WHO Prequalification Programme (PQP) is the only global initiative assuring the quality, safety, and efficacy of priority medicines and vaccines for United Nations (UN) procurement agencies like UNICEF and Gavi. WHO Prequalification of Medicines and Vaccines Training Course provides pharmaceutical and public health professionals with the critical, trending regulatory knowledge required to successfully navigate the complex submission and inspection landscape for the 2024-2025 cycle and beyond. We delve into the latest ICH guidelines (M13A Bioequivalence), emerging regulatory reliance pathways, and the programmatic suitability requirements for products targeting high-burden diseases such as HIV/AIDS, Tuberculosis, Malaria, and new pandemic countermeasures like the Mpox vaccine.

This intensive training is a strategic investment focused on accelerating product access in low- and middle-income countries (LMICs) while ensuring robust Good Manufacturing Practice (GMP) and Quality Management System (QMS) compliance. Participants will master the intricacies of the eCTD dossier preparation, delve into Quality Risk Management (QRM) methodologies, and analyze real-world case studies on regulatory approvals and post-prequalification surveillance. By gaining proficiency in global regulatory harmonization and the application of Real-World Evidence (RWE), graduates will be equipped to drive their organization's global health impact and competitive advantage in the multisource generics market.

Programme Curriculum

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Course Duration

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Course Objectives

1. Master the latest WHO Prequalification (PQ) Procedure and its four product streams.
2. Analyze the impact of Regulatory Harmonization and reliance models on dossier submission strategy.
3. Prepare a compliant, high-quality eCTD dossier aligned with WHO's Common Technical Document (CTD) requirements.
4. Implement robust Quality Risk Management (QRM) principles throughout the product lifecycle, from R&D to post-market.
5. Interpret the current ICH Guidelines for generic product development and submission.
6. Ensure Good Manufacturing Practice (GMP) compliance for successful WHO Site and Quality Control (QC) Laboratory inspections.
7. Evaluate the Programmatic Suitability of a product for use in resource-limited settings
8. Apply the principles of Good Clinical Practice (GCP) and Bioequivalence/Biosimilarity study design for generics.
9. Develop effective strategies for managing Post-Prequalification Variations and maintenance activities.
10. Analyze the latest Pharmacovigilance and Post-Market Surveillance requirements for WHO-listed products.
11. Understand the role of Real-World Evidence (RWE) in supporting dossier updates and safety profiles.
12. Mitigate supply chain and Global Access challenges for essential medicines and vaccines.
13. Address the unique regulatory and quality requirements for Pediatric Formulations and fixed-dose combinations (FDCs).

Target Audience

1. Regulatory Affairs Professionals
2. Quality Assurance (QA) and Quality Control (QC) Personnel
3. Pharmaceutical Manufacturers (CEO, CMO, Directors)
4. Clinical Research Organizations (CROs)
5. Public Health Officials and National Regulatory Authorities (NRAs)

6. R&D Scientists and Product Development Managers
7. Supply Chain and Global Access Strategists
8. Medical and Scientific Writers

Course Modules

Module 1: The Foundation of WHO Prequalification

- History, scope, and strategic importance of the WHO PQP.
- Medicines, Vaccines, Diagnostics, and Vector Control.
- The role of the PQP in global health and the Essential Medicines List (EML).
- Overview of the WHO-PQ five-step process.
- Case Study: The impact of WHO PQ on access to first-line HIV/AIDS combination therapies.

Module 2: The EOI and Regulatory Pathway Selection

- Understanding the Expression of Interest (EOI) criteria for priority products.
- Requirements for selecting a Stringent Regulatory Authority (SRA) approved product.
- The abridged (SRA) route versus the full dossier route.
- Pre-submission meetings and effective engagement with the WHO PQT team.
- Case Study: Criteria for prioritizing a new multi-drug resistant TB medicine for PQ.

Module 3: Quality Management Systems (QMS) for PQ

- Core principles of ICH Q10 and the Pharmaceutical Quality System (PQS).
- Integrating Quality Risk Management into daily operations (ICH Q9).
- Management responsibilities and resource management for quality.
- Handling Out-of-Specification (OOS) results and Corrective and Preventive Actions
- Case Study: Analyzing a systemic failure in a QMS that led to a product delisting.

Module 4: Good Manufacturing Practice (GMP) Readiness

- Detailed review of WHO GMP guidelines and international convergence (PIC/S).
- Key requirements for facility design, utilities, and HVAC systems.
- Validation master plans.
- Training and qualification requirements for manufacturing and QC personnel.
- Case Study: Preparing a facility for the WHO GMP Inspection of a sterile vaccine fill-and-finish plant.

Module 5: The eCTD Dossier Structure (Module 1-5)

- Introduction to the Electronic Common Technical Document (eCTD) format.
- Detailed breakdown of Module 1 (Administrative and Product Information).
- Summaries and Overviews (Quality Overall Summary).
- Quality (CMC - Chemical, Manufacturing, and Controls) requirements.
- Structuring an eCTD for a generic medicine to meet WHO-PQ specifications.

Module 6: Quality: Drug Substance (Module 3.2.S)

- Active Pharmaceutical Ingredient (API) compliance and sourcing.
- Detailed characterization, manufacturing process, and control of materials.
- Managing impurities and degradation products (ICH Q3A/Q3B).
- The importance of the API Master File (APIMF) and its submission to WHO.

- Case Study: Assessing the quality data for a novel, difficult-to-synthesize antimalarial API.

Module 7: Quality: Drug Product (Module 3.2.P)

- Formulation development, excipients, and stability studies (ICH Q1A-Q1F).
- Manufacturing process description, batch formula, and process controls.
- Finished product specifications and analytical method validation.
- Dissolution testing and its significance for immediate and modified-release products.
- Case Study: Quality assessment of a Fixed-Dose Combination (FDC) for pediatric use.

Module 8: Biopharmaceutics and Bioequivalence (BE) Studies

- The regulatory basis for Bioequivalence (BE) and interchangeability for generics.
- Applying the WHO Biowaiver Guideline for BCS-based waivers
- Designing, executing, and reporting BE clinical trials
- Statistical analysis and interpretation of pharmacokinetic data.
- Case Study: Evaluating a BE study report for a first-line antiretroviral (ARV) tablet.

Module 9: Non-Clinical and Clinical Overview (Modules 4 & 5)

- Summarizing non-clinical data for generic submissions.
- The role of existing literature in establishing safety and efficacy.
- Clinical Efficacy and Safety Summary for multisource products.
- Good Clinical Practice (GCP) audits and regulatory expectations.
- Case Study: Justifying the clinical safety profile of a multisource Hepatitis C medicine using reliance on SRA data.

Module 10: WHO Site and QC Lab Inspection

- Preparing for the WHO GMP Inspection: self-audits and gap analysis.
- Understanding the inspection team, scope, and focus areas.
- Common deficiencies and how to draft effective CAPA plans.
- Post-inspection follow-up and the resolution of observations.
- Case Study: Review of a WHO inspection of a vaccine manufacturing facility and subsequent actions.

Module 11: Programmatic Suitability & Packaging

- Assessing the product's fitness-for-use in low-resource settings.
- Requirements for packaging, container-closure systems, and patient information leaflets (PIL).
- Cold-Chain Management requirements for heat-sensitive vaccines.
- Labeling requirements for procurement by UN agencies.
- Case Study: Evaluating the programmatic suitability of a new oral polio vaccine's packaging and stability data.

Module 12: Prequalification of Vaccines

- Specific regulatory requirements for vaccines: Consistency of production.
- The Programmematic Suitability for Prequalification (PSPQ) for vaccines.
- Clinical development and post-licensure safety surveillance.
- The role of National Regulatory Authorities (NRAs) in vaccine PQ.
- Case Study: The WHO Prequalification of the Mpox vaccine and its recommendation for 'off-label' use.

Module 13: Post-Prequalification Activities

- Managing product changes and Variations to the approved dossier.
- Annual reporting requirements and product quality reviews.
- Handling changes in API or finished product manufacturers.
- Maintaining a state of compliance and preparing for re-inspection.
- Case Study: Processing a major post-PQ variation for a change in a pediatric HIV drug formulation.

Module 14: Pharmacovigilance and Safety Monitoring

- Implementing a robust Pharmacovigilance (PV) system for WHO-listed products.
- Adverse Event (AE) reporting, signal detection, and risk-benefit analysis.
- Developing and executing a Risk Management Plan (RMP).
- Product recalls, rapid alerts, and other post-market actions.
- Case Study: Handling a safety signal for a prequalified vaccine

Module 15: Future Trends and Global Health Initiatives

- The rise of Digital Health and its impact on regulatory processes.
- New guidance on Real-World Evidence (RWE) for regulatory decision-making.
- The role of WHO's PQP in preparing for future pandemics and disease outbreaks.
- The concept of Regulatory Reliance and work-sharing between NRAs.
- Case Study: Integrating Biologics and Biosimilars into the future WHO PQ landscape.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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