PQT Webinar for Manufacturers, Developers, Procurement Agents, and Partners

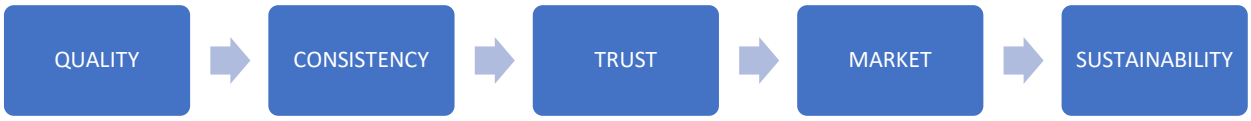
16 October 2023, 12:00 – 16:00 CET

CONCEPT NOTE

Context:

WHO prequalification (PQ) aims to promote access to key health products that meet global standards of quality, safety, and efficacy/performance, in order to optimize use of health resources and improve health outcomes. PQ is designed based on best international practice combined with assessing aspects of particular relevance for LMIC.

- WHO responded to the need of procurement agencies and WHO Member States for quality-assured health products, by creating and applying quality-assurance mechanisms.
- WHO prequalification has become a trusted and reputed symbol for promoting safety, quality and efficacy of priority health products across stakeholders. WHO prequalification promotes good quality for health products, possesses internal technical expertise and has mechanisms in place to convene external expertise.
- PQ has been instrumental in building national capacity for the manufacture, regulation and monitoring of health products – promoting harmonization, convergence, and reliance.
- National regulatory authorities (NRAs) relying on Collaborative Registration Procedure (CRP) of WHO prequalified products have achieved significant acceleration of approval timelines compared to registrations not using CRP.
- Collaboration with the WHO Prequalification (PQ) helps promote the quality of locally produced products, building the capacity of national and regional regulators and manufacturers which brings trust in locally produced products, opening them to regional and global markets, thus contributing to sustainability of local production.



Objectives:

1. Update stakeholders on the achievements of WHO Prequalification is facilitating timely and equitable access to quality assured health products, thus contributing improving global health outcomes.
2. Updating stakeholders on the challenges facing PQ and the opportunities and plans, working with stakeholders, to overcome these challenges.
3. Receiving feedback from stakeholders and how to continue to work together with PQ in the spirit of continuous improvement to meet these noble and common objectives.

Agenda:

Time (CET)	Item	Speakers
12:00 – 12:30	Welcome and introduction	Deus K. Mubangizi Unit Head WHO Prequalification Unit Rogerio Gasper Director Regulation and Prequalification Department Yukiko Nakatani Assistant Director-General Access to Medicines and Health Products Division
12:30 – 13:00	Updates on PQ of In-vitro Diagnostics (IVD)	Irena Prat Team Lead, IVD Assessment Feedback from AdvaMedDx and Mecomed
13:00 – 13:30	Updates on PQ of Vaccines, immunisation devices and cold chain equipment	Carmen Rodriguez Team Lead, Vaccines assessment Feedback from IFPMA and DCVMN
13:30 – 14:00	Updates on PQ of Medicines	Matthias Stahl Team Lead, Medicines Assessment Feedback from IFPMA and IGBA
14:00 – 14:30	Updates on PQ of Vector Control Products (VCP)	Dominic Schuller Ag. Team Lead, VCP Assessment Feedback from i2i, CropLife International and Agrocare
14:30 – 15:00	Updates on PQ inspections	Stephanie Croft, Technical Officer, PQ Inspections Feedback from IFPMA, DCVMN, IGBA, AdvaMedDX and CropLife
15:00 – 15:20	Presentation from WG on alignment of WHO policies/guidelines/recommendations with PQ processes.	Mubashar Riaz SHEIKH, Director, Quality Assurance of Norms and Standards (QNS) Rogério Gaspar Director, Regulation and Prequalification Department (RPQ)
15:20 – 16:00	Discussion, feedback, and next steps	Stakeholders