PQ/EUL-related Specialized Technical Assistance

David Woo
Technical Officer
Local Production and Assistance Unit
Innovation and Emerging Technologies
Access to Medicines and Health Products
World Health Organization

Acronyms

API	Active Pharmaceutical Ingredient
CAPA	Corrective Action and Preventive Action
EOI	Expression of Interest
ERP	Expert Review Panel
ERPD	Expert Review Panel for Diagnostics
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practice
LMICs	Low- and Middle-Income Countries
LOA	Letter of Agreement
LPA	Local Production and Assistance
PQ	Prequalification
STA	Specialized Technical Assistance

Background

- Local Production and Assistance Unit provides support to countries & regions in strengthening local production & technology transfer using an ecosystem-wide approach to improve timely access to quality-assured health products
- PQ/EUL-related STA is unique support directly to manufacturers intending to have products:
    - prequalified by WHO
    - granted emergency use listing by WHO
    - granted a favourable risk category from Expert Review Panels (ERP, ERPD)

Who is eligible for PQ/EUL-related STA

Manufacturers

- Intend to apply or have applied for WHO PQ/EUL or ERP/ERPD
- Produce products eligible for WHO PQ/EUL and ERP/ERPD
    - Invitations to Manufacturers and Suppliers of Medicinal Products to Submit an Expression of Interest for Product Evaluation (EOIs) for APIs & FPPs
    - Vaccines Prequalification Priority List
    - List of eligible IVDS on WHO PQ IVD website

Contract Research Organizations

- Conduct clinical studies (e.g. BE studies) for a product listed in the current EOIs and produced by the manufacturer

Commercial or 3rd party Laboratories e.g. QC labs for medicines

Who is eligible for PQ/EUL-related STA

STA is prioritized for:

- Manufacturers located in an LMIC
- Manufacturers who have already submitted or plan to submit within 2 years
- Products intended to face a public health emergency
- A product that is under-represented in the PQ lists or assessment pipeline
- Manufacturers who do not have prior experience with PQ process or did not pass the screening stage after submission(s)

Some examples of STA

Manufacturers

Facility:

- **GMP/QMS gap assessment** and/or **mock GMP inspection** pre-WHO PQ
- Development of **CAPA** plan, including root cause analysis

Product (API, FPP):

- **Product-related** issues
- **Product dossier** to be submitted to WHO PQ
- Selection of appropriate products for WHO PQ

Training workshops

- Didactic and/ore hands-on training

Contract Research Organizations

- **QMS audit** of facility
- Support for **GCP** compliance
- Review of a**nalytical methods** that would be used to generate data in the clinical/BE study
- **Audit of a completed study** by the CRO that is similar to the study to be done for the FPP being submitted to WHO PQ
- Assistance with required documentation for the PQ dossier

How to initiate the STA

Different channels to request for PQ/EUL-related specialized TA:

online request form at
https://extranet.who.int/prequal/content/request-technical-assistance

email directly to Local Production and Assistance Unit
localproduction@who.int

proposed by international procurers (Global Fund, UNICEF, etc.), government ministries, other WHO departments

World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

World Health Organization

Contact us

Product Streams | Events | News | ePQS | About

Request technical assistance

We can organize specialized technical assistance only for manufacturers with a current or intended submission for prequalification of an active pharmaceutical ingredient or finished pharmaceutical product, for contract research organizations that undertake studies for finished pharmaceutical products to be submitted for prequalification and for quality control laboratories undergoing prequalification or intending to seek prequalification.

First Name *

Last Name *

Email *

Where do you live/country of residence? *

- Select -

https://extranet.who.int/prequal/content/request-technical-assistance

Some tips in completing the request form:

- Specify the actual product(s) intended for PQ submission
- Topic/Subject: “Request for specialized technical assistance”
- Message: Areas of technical assistance requested, planned submission date,

How to initiate the STA

- Submit a request for PQ/EUL-related STA
- Complete and sign the **Letter of Agreement** to receive PQ/EUL-related STA
- Arrange an introductory meeting with LPA Unit
  - Introduction of company, product
  - Details of STA required or being requested
  - Company's plan & timeline for submission for WHO PQ/EUL or ERP/ERP
- Begin provision of STA
  - Needs-based and tailored
  - On-going communication with follow-up and monitoring
- Attain WHO PQ/EUL or favourable ERP/ERPD risk category

Points to note for a successful collaboration

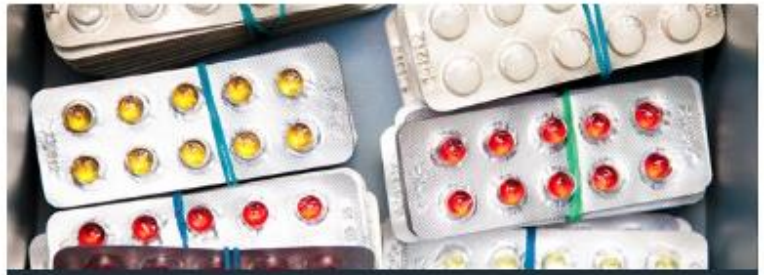
- **Focal point** in the company is key to facilitate timely exchange of information during STA
- **Open communication** is also essential
  - Leverage on technical expertise of LPA Unit to resolve issues toward PQ, EUL, ERP/ERPD
  - Be transparent if similar STA is being provided by other parties
  - Reach mutually-accepted technical solutions and next steps
  - Follow up and monitor actively
- All information exchanged between company and LPA Unit are **confidential**
- **Care** is taken to avoid conflicts of interest
- Inspections and assessments by WHO PQ Unit and STA by LPA Unit are **independent** of each other

Home / Teams / Local Production & Assistance / Technical Assistance for WHO Prequalification

WHO provides specialized technical assistance (STA) to help recipients achieve compliance with international regulatory norms and standards, so that they can attain WHO prequalification (PQ) for priority products or services, emergency use listing (EUL) and/or risk assessment for the Expert Review Panel (ERP) for medicines / Expert Review Panel for Diagnostics (ERPD) for IVDs. This applies to priority products or services and/or supply of quality-assured products required by United Nations (UN) Agencies, their partners and procurement agencies serving WHO Member States. The **Local Production & Assistance Unit (LPA)** supports the PQ or EUL of medicines, vaccines, and in vitro diagnostics, by providing complementary PQ/EUL-related technical assistance to manufacturers and quality control laboratories (QCLs) applying or planning to apply to the WHO PQ or EUL programmes.

Workshops are also organized to enhance the understanding and promote best practices amongst manufacturers on quality requirements for medical products as described in the WHO guidelines and other regulatory authorities for PQ, EUL and licensing purposes.

Specialized Technical Assistance for WHO PQ and EUL



Medicines

In Vitro Diagnostics (IVD)

Vaccines

PQ/EUL-related specialized technical assistance: https://www.who.int/teams/regulation-prequalification/lpa/technical-assistance-for-who-prequalification

Technical Training for WHO PQ and EUL

Specialized Technical Assistance - Medicines

28 February 2023 | Call for submissions

WHO provides specialized technical assistance to help recipients achieve compliance with international regulatory norms and standards, so that they can attain WHO prequalification (PQ) for priority products or services, or emergency use listing (EUL) for unlicensed products to be used in the context of a public health emergency, and/or they can supply quality-assured products required by United Nations (UN) Agencies, their partners and procurement agencies serving WHO Member States; and/or risk assessment for the Expert Review Panel (ERP) for medicines. Products eligible for WHO PQ are listed in Invitations to Manufacturers to Submit an Expression of Interest for Product Evaluation (EOIs). Products eligible for EUL are those for which eligibility of unlicensed product for assessment under this procedure has been established by WHO.

WHO CAN APPLY?

Manufacturers who are eligible for specialized technical assistance are those who:

- produce priority active ingredients (APIs) or finished pharmaceutical products (FPPs) as listed in the current EOIs for PQ
- produce products eligible for EUL
- intend to participate in tenders issued by UN-procuring organizations

Specialized technical assistance will be prioritized for:

- manufacturers from low- and middle-income countries (LMICs)
- manufacturers who have submitted or have a plan to submit to PQ within 2 years
- medicines intended to face a public health emergency
- APIs or FPPs that are under-represented in the PQ lists or pipeline
- manufacturers who do not have prior experience with the PQ process or did not proceed pass the screening stage after one or more submissions

Contract research organizations (CROs) that provide services to manufacturers of LMICs, and who conduct or plan to conduct clinical studies for FPPs found eligible for PQ or EUL.

Commercial or third-party Medicines Quality Control Laboratories (QCLs) that provide quality control testing services to LMIC manufacturers that produce or plan to produce APIs or FPPs listed on the current EOIs for prequalification.

WHAT AREAS ARE COVERED?

Technical assistance experts work with manufacturers, CROs or QCLs to develop capacity to achieve compliance with international and WHO norms and standards to attain WHO PQ or EUL. For example, for manufacturers this may relate to preparation of product dossiers and/or their achieving compliance with *WHO Good Manufacturing Practice* (GMP) while QCLs may require assistance to achieve adherence with *WHO Good*

Related Highlight

REQUEST FOR SPECIALIZED TECHNICAL ASSISTANCE

Access to information on the specialized technical assistance and online request form through this link: https://www.who.int/news-room/articles-detail/specialized-technical-assistance-medicines

Thank you

For more information and updates:

https://www.who.int/teams/regulation-prequalification/lpa

localproduction@who.int

LPA_Worldwide