PQ/EUL-related Specialized Technical Assistance for Diagnostics

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

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)

Why would an IVD manufacturer request for PQ/EUL-related specialized technical assistance

- “Corrective action” to **correct existing problems** in a manufacturer’s product dossier, quality management system (QMS), etc. that were uncovered during a PQ, EUL or ERPD review.
  - Problems could range from a lack of trustworthy clinical performance data to an absence of an effective ISO 13485:2016 quality management system
- “Preventive action“ to **prevent the occurrence** of future problems in analytical or clinical performance data, QMS processes, risk management measures, etc.

Who is eligible for PQ/EUL-related STA

Manufacturers

- Intend to apply or have applied for WHO PQ/EUL or ERPD
- Produce products eligible for WHO PQ/EUL and ERPD
    - List of eligible IVDS on WHO PQ IVD website
    - Expressions of interest issued by the Global Fund, e.g. HIV RDTs produced in Africa
- Made a pre-submission to WHO PQ but did not pass pre-submission screening of design dossier or QMS
- Made a submission to ERPD for risk assessment but received a risk category of 3 or 4
- Developed an innovative product that is still under R&D status (case-by-case)
- *African manufacturers of HIV RDTs submitting to ERPD*

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

Some examples of STA

Facility:

– **QMS audit** and/or **mock ISO inspection** pre-WHO PQ or ISO certification

– Development of **CAPA** plan, including root cause analysis

Product (API, FPP):

– **Product-related** issues

– **Product dossier** to be submitted to WHO PQ or ERPD

Training workshops

– Didactic and/or hands-on training

Some tips to overcome common deficiencies

✕ Quality management system	☑ Possible solutions:
• QMS is too complex for objective documentation to be easily provided	• Create a small, flexible QMS with a focus on providing the necessary objective & reproducible documentation
• CAPAs are difficult to follow through	• Create a CAPA that **monitors progress** with regular (e.g. weekly) follow-up and alerts **check if CAPAs affect final products
• Outsourced activities are not properly identified and controlled	• Identify, document, inspect and **audit** outsourced activities and sign **quality assurance agreements**

Some tips to overcome common deficiencies

✗ **Intended use claim** lacks relevant information → ☑ **T he following must be included in the intended use claim:**

- What the product is intended to detect
- The function of the product
- The clinical indication for the IVD
- The type of specimen(s) required
- The intended testing population
- The intended user

✗ Disconnect between the intended use claim and the performance claims →

☑ Intended use must be defined prior to planning and conducting performance evaluation studies.

☑ Performance claims must support the IVD intended use.

Thank you

For more information and updates:

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

localproduction@who.int

LPA_Worldwide

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

PQ/EUL-related specialized technical assistance online request:
https://extranet.who.int/pqweb/content/request-technical-assistance