# PQ/EUL-related specialized technical assistance overview

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# Acronyms

| | |
|---|---|
| **API** | Active Pharmaceutical Ingredient |
| **CAPA** | Corrective Action and Preventive Action |
| **CRO** | Contract Research Organization |
| **EOI** | Expression of Interest |
| **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 |
| **TA** | Technical Assistance |
| **WHO** | World Health Organization |

# Outline

- Background
- Who is eligible for PQ/EUL-related specialized TA
- How to initiate the specialized TA
- How does PQ//EUL-related specialized TA work
- Some benefits for requesting specialized TA
- Additional points to note

# Background

- Specialized  Technical Assistance (TA) related to WHO PQ of products is provided by the **Local Production and Assistance (LPA) Unit,** WHO

- LPA Unit provides support to countries and regions in strengthening and promoting sustainable local production & technology transfer using a comprehensive approach to improve **timely access to quality-assured health products**

# Who is eligible for PQ/EUL-related specialized TA

## Manufacturers

- Located in LMICs
- Intend to seek **WHO PQ**
- Produce **priority health products eligible for WHO PQ**,
  - Invitations to Manufacturers and Suppliers of Medicinal Products to Submit an Expression of Interest for Product Evaluation (EOIs) for medicines
  - Vaccines Prequalification Priority List
  - List of eligible IVDS on WHO PQ IVD website

## Contract Research Organizations (CROs)

- Provide services to manufacturers located in LMICs
- Conduct clinical studies (BE studies) for priority health product listed in the current EOIs and produced by the manufacturer

# Some examples of types of specialized TA

## Manufacturers

Facility:

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

Product (API, product):

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

Organizing **training workshops** to build capacity on specific topics requested by manufacturers, e.g. Virtual cGMP Training Marathon

## 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 specialized TA

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

- email directly to Local Production and Assistance Unit localproduction@who.int
- online request form https://extranet.who.int/pqweb/content/request-technical-assistance
- proposed by WHO PQT, international procurers (Global Fund, UNICEF, etc.), government ministries, other WHO departments

# How to initiate the specialized TA

1. Request for PQ/EUL-related specialized TA
2. Completed Letter of Agreement and/or GMP pre-inspection application form to receive PQ/EUL-related specialized TA
3. Introductory meeting with the LPA Unit
    - ❖ Introduction of company, product for submission
    - ❖ Details of TA required/being requested
    - ❖ Company plan for pre-submission meeting and/or submitting to WHO PQ
4. Provision of specialized TA begins – site visits, document review, technical discussions, etc.
    - ❖ **Tailored**, **needs-based**
    - ❖ On-going communication with follow-ups and monitoring
5. WHO Prequalification / Emergency Use Listing attained

# How does PQ/EUL-related specialized TA work

- From the TA request to attainment of WHO PQ/EUL
- Open communication is essential to maximize the benefits of the specialized TA
  - Declare to the LPA Unit the intention to submit to WHO PQ and when
  - Leverage on technical expertise of LPA Unit to resolve issues toward attaining WHO PQ/EUL
  - Be transparent if similar TA is being provided by other parties
  - Reach mutually-accepted technical solutions and next steps
  - Active follow-up and monitoring of progress
- Focal point in the company is a key part of this process
  - Facilitate exchange of information, data and documents when TA is provided
  - Facilitate logistics during a QMS audit/mock GMP inspection, e.g. visa, hotel selection, local transport

# Some benefits for requesting specialized TA

## Manufacturers

- Speed up attainment of WHO PQ/EUL
- Build capacity to:
  - understand & meet WHO quality assurance standards
  - address & strengthen quality systems
- Improve quality of other products produced in the facility
- Become eligible for international, donor-sponsored tenders
- Access procurement markets

## UN agencies and other procurement agencies

- Increase the range of PQ products that can be procured
- Diversify the sources of supply of quality priority health products
- Be assured the manufacturer can produce with consistent quality

# Additional points to note

- Information gathered during the TA are not shared with WHO Prequalification Unit and are kept confidential
- Care is taken to ensure any conflict of interest is avoided with WHO Prequalification Unit
- Site inspections and evaluations of product dossiers performed for WHO PQ are independent of the outcomes of TA

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

# Thank you