Specialized Technical Assistance (STA) for Medicines

by WHO Local Production & Assistance (LPA) Unit

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Specialized technical assistance

WHO provides Specialized Technical Assistance (TA) 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.

- Medicines
- Vaccines
- In Vitro Diagnostics

Focus areas for medicines

General

- Regulatory pathways / procedural advice
- Regulatory writing / dossier compilation

CMC

- Active Pharmaceutical Ingredients (APIs)
- Finished Pharmaceutical Products (FPPs).

GMP

- QMS gap-assessment audit
- GMP Mock Inspection

Key advantages of STA

- ✓ **Across all stages of development and life cycle**

  For new generic products but also for locally marketed products.

- ✓ **Continuous nature**

  Queries can be raised at any moment, i.e. on a rolling basis during product development and QMS upgrading

- ✓ **Pre-data collection / pre-production**

  Feedback on planned experiments and protocols before start of testing and production.

- ✓ **Knowledge construction**

  To build understanding of the rationale behind regulatory, quality, efficacy and GMP requirements

Case 1: Enhancing QMS for WHO GMP Compliance

Situation: After an unsatisfactory WHO PQ GMP Inspection, a manufacturer requested LPA Unit support to upgrade their Quality Management System (QMS) to meet WHO GMP standards.

Intervention: LPA experts conducted a mock inspection focusing on CAPA implementation. The inspection highlighted that further improvements were needed to meet the required standards.

Outcome: The manufacturer has not yet achieved compliance with WHO GMP standards, delaying the Prequalification (PQ) status of their finished pharmaceutical product (FPP). However, the company obtained a better understanding on how to address the observations

Case 2: Enhancing dossier structuring and writing skills

Situation: A manufacturer faced challenges in compiling the pharmaceutical development section for a generic medicine that has been locally authorised and marketed for many years. Recent changes to the FPP added further complexity.

Intervention: WHO LPA experts provided guidance on the essential information required for the dossier for submission to PQ, explained the rationale for including this data, and highlighted how to build a cohesive narrative in the dossier beyond just providing data.

Outcome: The team gained a clearer understanding of how to structure the pharmaceutical development section, enabling them faster and more efficient preparation for PQ submission.

Case 3: Addressing gaps in API documentation

Situation: A manufacturer submitted the first draft of his product dossier for review by WHO LPA experts, revealing a misunderstanding about the difference between a previously accepted API and a prequalified API, and the responsibilities of the FPP manufacturer on API control.

Intervention: WHO PQ experts identified the gaps and provided clear guidance on the distinction between an accepted and a prequalified API, the difference in API data to include in the product dossier. API control and supporting data by the FPP manufacturer where also discussed.

Outcome: The manufacturer revised the dossier to align with WHO PQ standards, streamlining the review process and ensuring compliance.

Case 4: Enhancing CMC Compliance

Situation: A manufacturer developing a generic medicine for PQ was about to source the reference product to be used to support final stage of the development and the bioequivalence study.

Intervention: During an on site visit, WHO LPA experts discovered that the selected reference product was not sourced from a stringent regulatory agency.

Outcome: The reference product is now being sourced from a country with a stringent regulatory agency as defined by WHO.

Take home messages

Expert Gap Analysis:

- LPA experts identify QMS and quality gaps manufacturers might not recognize.
- Tailored support ensures these gaps are effectively addressed.

Timing

- A timely QMS gap assessment audit at an early stage reduces the risks of unsatisfactory outcomes of a WHO GMP Inspection at later stage. A mock inspection better takes place at least 6 months prior to WHO PQ GMP Inspection. If the QMS is weak, allocate 1 -2 years to upgrade, excluding any facility renovations.
- Timely support on quality issues reduces risk of unnecessary or inadequate studies and accelerates progress, reducing delays in achieving WHO prequalification.

Thank you for your attention