



## FREQUENTLY ASKED QUESTIONS

### Local Supplier Qualification & Monitoring Program (LSQMP)

#### 1. What is the Local Supplier Qualification & Monitoring Program (LSQMP)?

LSQMP is a comprehensive compliance and quality assurance initiative developed by Qual-Med Yemen to systematically assess, qualify, and continuously monitor local pharmaceutical suppliers (distributors and wholesalers) within Yemen's complex supply chain environment. Designed in alignment with internationally recognized standards, including WHO Good Storage and Distribution Practices (GSDP) and EU Good Distribution Practices (GDP).

#### 2. What Are the Main Objectives of the LSQMP?

- **Qualify Suppliers to Global Standards:** Rigorously qualify all engaged local suppliers to meet the stringent requirements of WHO GSDP and EU GDP.
- **Ensure Continuous Compliance and Operational Excellence:** Implement proactive monitoring to guarantee the consistent maintenance of robust quality management systems and the achievement of operational excellence among local suppliers.
- **Minimize the Risk of Substandard Medicines:** Drastically reduce the potential for substandard or falsified medicines entering the supply chain, ensuring the highest possible level of product integrity.
- **Guarantee Medicine Quality for Public Health:** Uphold the quality and integrity of all distributed medicines, directly safeguarding patient health and public safety.
- **Provide Transparent Data for Informed Decisions:** Deliver timely, reliable, and comprehensive audit data to empower global partners in making confident and informed decisions regarding local pharmaceutical suppliers.
- **Facilitate International Recognition and Growth:** Actively support local suppliers in obtaining internationally recognized certifications, thereby enhancing their market access and fostering sustainable growth.

#### 3. What standards does LSQMP follow?

- LSQMP strictly follows WHO GSDP and EU GDP guidelines, ensuring supplier compliance with best international practices for pharmaceutical storage, distribution, and quality assurance.

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## 5. Who Benefits From LSQMP?



### For Local Suppliers

- **Boost Operational Excellence:** Improve operational quality and management for product integrity, safety, efficacy, and traceability.
- **Enhance Global Credibility & Access:** Strengthen international partnerships, unlocking tenders from quality-focused organizations.
- **Enable International GSDP Certification:** Facilitate achieving globally recognized certification to enhance international standing.



### For Donors/NGOs

- reducing the risk of purchasing sub-standard and/ or falsified medicines when procuring from local suppliers involved in this program.
- The opportunity to easily identify suppliers compliant with EU and WHO quality standards
- Access to reliable audit information



### FOR Global Pharmaceutical Companies

- Ensures your local distributor meets global quality (WHO GSDP/ EC GDP) standards and your contractual expectations, safeguarding product integrity and reputation, streamlining distributors' supply chains, and fostering reliable partnerships in a challenging market.
- Access to reliable audit information

## 6. Who funds the LSQMP audits and supplier development activities?

- The funding for LSQMP activities is flexible and depends on the context of each partnership. In many cases, global pharmaceutical companies, donors, or procurement agencies sponsor audits and capacity-building efforts to ensure supplier compliance and supply chain integrity. also, local suppliers may self-fund their participation to enhance their market competitiveness and readiness for international tenders. Custom funding arrangements, including cost-sharing models, can be negotiated based on the project scope and stakeholder needs.

## 7. What are the costs associated with participating in LSQMP?

- The costs of participating in LSQMP vary depending on the scope of assessment, supplier size, and required support services. Typically, fees cover initial audits, ongoing monitoring visits, training sessions, and advisory support.
- Qual-Med Yemen offers transparent cost structures and works with stakeholders to tailor financial arrangements suitable for their specific context and objectives.

## **8. What is the first step for a local supplier to join the LSQMP?**

- The process for a local supplier to join the LSQMP begins when Qual-Med Yemen receives a request to conduct an audit. This request can originate from one of two sources:
  - An invitation from a global pharmaceutical company, donor organization, or procurement agency that is interested in assessing the supplier's capabilities.
  - A direct application from the local pharmaceutical supplier seeking to be qualified under the LSQMP.
- Upon receiving such a request, Qual-Med Yemen initiates the program's first phase, which involves developing the Terms of Reference (TOR) and a budget.
- QUAL-MED YEMEN shares the draft TOR and budget with the designated lead organization (if multiple parties are involved) for their review and input.
- If required, an introductory meeting is organized between QUALMED YEMEN, the lead organization, and other participating entities to ensure mutual understanding and address any initial questions.
- Once the TOR and budget are mutually agreed upon, QUAL-MED YEMEN issues formal service agreements to the participating organizations for their signature.

## **9. How often are suppliers audited or reassessed?**

- Audit frequency depends on the supplier's risk classification: high-risk suppliers may be audited semi-annually, while low-risk suppliers are typically reassessed annually. Continuous monitoring includes regular KPI tracking and CAPA implementation reviews.

## **10. What support does LSQMP provide to local suppliers?**

- Beyond audits, LSQMP offers:
  - Training workshops on GSDP/GDP and quality management.
  - Technical advisory services for implementing improvements.

- Development of corrective and preventive action plans (CAPA).
- Continuous guidance to meet evolving international standards.

**11. Can international pharmaceutical companies/donors request supplier audits ?**

- Yes. Global pharma companies, donors, or purchasers can commission Qual-Med Yemen to audit local suppliers to verify compliance and support supply chain integrity.