CASE STUDY

Operational compliance for supplier prequalification

A pharmaceutical importer requested support ahead of an upcoming audit as part of a supplier prequalification exercise. The organization required a structured Quality Management System, formalized GSDP-aligned SOPs, strengthened documentation controls, and improved staff competency to ensure full audit readiness.

The challenge

A pre-audit assessment identified several gaps requiring correction before the supplier prequalification audit:

- Incomplete and partially implemented SOPs
- Use of generic SOPs that did not reflect GSDP requirements or operational realities
- Absence of key quality procedures
- Inconsistent documentation and calibration records
- Need for structured CAPA closure and staff retraining

The client required a fully aligned, audit-ready QMS within a defined timeline.

Approach — QMS development

A comprehensive QMS framework was designed and implemented, including:

- Revision and alignment of existing SOPs with GSDP and WHO-MQAS
- Replacement of generic SOPs with PPB-aligned, operationally accurate procedures
- Development of missing procedures
- Strengthening documentation control and calibration management
- Establishing compliance monitoring mechanisms to ensure ongoing alignment with operations

This ensured that documented procedures accurately reflected and governed daily activities — the distinction between a QMS that exists and a QMS that operates.

Audit preparation

Warehouse processes were aligned with WHO-MQAS requirements, and structured evidence packages were prepared to demonstrate compliance during the audit.

CAPA execution

Pre-audit findings were converted into structured corrective and preventive actions. SOPs were revised, documentation gaps were closed, and preventive controls were embedded to ensure sustained compliance.

Staff training

Monthly GSDP workshops were delivered to reinforce documentation discipline, operational consistency, alignment with revised procedures, and audit readiness across warehouse functions.

Results

Full SOP coverage

Across GSDP-critical warehouse operations

Strengthened controls

Documentation and calibration management

Improved competency

Staff capability and accountability across functions

All findings closed

Successful closure of every pre-audit finding

High compliance score

Achieved during the prequalification audit

Impact for clients

This engagement demonstrates capability in delivering true compliance systems, operational discipline, and risk control — not generic documentation. Organizations preparing for external audits can leverage this expertise to achieve higher audit scores, reduced regulatory risk, and sustainable quality systems.

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