

Preparing for regulatory and partner audits in Kenya

A structured approach to inspection readiness for pharmaceutical manufacturers, distributors, and MAHs operating in Kenya — documentation requirements, facility expectations, team preparation, and the gaps identified most often during PPB and WHO inspections.

— 01 — CORE PRINCIPLES

Four things every inspector assumes you already know

01

Evidence, not assurance

Compliance must be demonstrated through evidence, not verbal assurance.

02

Systems, not individuals

Inspectors evaluate systems, not individuals.

03

Complete and controlled

Documentation must be complete, current, and controlled.

Discipline, not preparation

Facilities must reflect consistent operational discipline, not temporary preparation.

02 — DOCUMENTATION READINESS**Complete, approved, and accessible**

Ensure every one of the following is in place before an inspection date is confirmed — not after.

A Quality system

- ✓ Quality Manual
- ✓ SOPs — GSDP, GMP, Deviation, Change Control, CAPA, Recall, Complaints, QRM
- ✓ Training records

B Operations

- ✓ Batch records / distribution logs
- ✓ Supplier qualification files
- ✓ Cleaning and sanitization logs
- ✓ Temperature mapping reports
- ✓ Calibration & maintenance records

C Regulatory

- ✓ Product registration certificates
- ✓ Variations & renewal history
- ✓ Recall & mock recall reports



— 03 — FACILITY READINESS

What inspectors expect to see on the floor

The facility either reflects the documentation or contradicts it. There is no third outcome.



Storage areas

Clean, organized, and clearly labeled.



Restricted zones

Controlled access, with entry logged and reviewable.



Calibrated equipment

With visible status labels showing current calibration state.



Temperature monitoring

Continuous systems with alarms, and excursions investigated.



Pest control records

Current contracts, service reports, and trend review.



Fire safety

Equipment in place with evacuation plans displayed.



Segregation

Quarantined, rejected, expired and returned goods physically separated.

04 - TEAM PREPARATION

Train staff to

- ✓ Answer questions clearly and factually
- ✓ Demonstrate processes using SOPs
- ✓ Retrieve documents quickly
- ✓ Escalate issues appropriately
- ✓ Avoid speculation or assumptions

05 - COMMON FINDINGS

What goes wrong in Kenya

- ✓ Missing or obsolete SOPs
- ✓ Poor documentation practices
- ✓ Incomplete supplier qualification
- ✓ Temperature excursions not investigated
- ✓ Uncontrolled access to storage areas
- ✓ Inadequate recall readiness

— 06 — FINAL READINESS REVIEW

Run the mock audit two to four weeks out

Conduct a mock audit two to four weeks before inspection. Document all findings and close gaps with CAPAs. Any closer and there is no time to correct what you find; any earlier and the evidence will have drifted by the time inspectors arrive.

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