GUIDE

GMP/GSDP verification guide

Operational and documentation requirements for compliance in Kenya. This guide outlines key GMP and GSDP requirements for manufacturers, importers, and distributors, supporting internal audits, supplier qualification, and PPB inspection readiness.

GSDP requirements for distributors

- Controlled storage conditions
- Temperature monitoring & excursion management
- Cleanliness & pest control
- Segregation of rejected and quarantined goods
- Documented receiving & dispatch procedures
- Transport validation
- Security & access control

GMP requirements for manufacturers

- Validated manufacturing processes
- Qualified equipment
- Controlled documentation
- Batch manufacturing records
- Change control & deviation management
- Environmental monitoring
- Quality control testing
- Stability programme compliance

SUPPLIER QUALIFICATION

Qualification is a process, not a certificate on file

A supplier certificate proves a point in time. Qualification proves you are still watching.

Supplier questionnaires
Scope, capability and compliance posture captured in writing.

Audit reports
Findings and their closure reviewed, not just received.

GMP/GSDP certificates
Checked against site, scope and expiry — not filed unread.

Risk-based evaluation

Depth of qualification proportionate to what the supplier handles.

Ongoing performance monitoring

Tracked across the relationship, with re-qualification triggers defined.

COMMON NON-CONFORMITIES

Five findings that account for most of the remediation work

None of these are exotic. All of them are avoidable with a verification checklist run on a schedule rather than in response to an inspection notice.

- Missing calibration records
- Poor documentation control
- Incomplete temperature logs
- Unqualified suppliers
- Inadequate CAPA management

Verification checklist

The full guide is available as a PDF for use in internal audits and supplier assessments. Download it below, or talk to us about applying it to your own sites.

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