



Pharmaceutical Good Distribution Practice (GDP) Training: Wholesale and Falsified Medicines



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Introduction:

Pharmaceutical Good Distribution Practice GDP training for wholesale and falsified medicines control is a 5-day course for responsible persons, quality assurance and warehouse management at medicine wholesalers, logistics providers and hospital stores, ending with a GDP Self-Inspection Report and Remediation Plan. Distributors attract critical inspection findings when licence scope is unclear, customers are supplied without bona fides checks, returns re-enter saleable stock without evidence and suspect packs pass unnoticed. Nominees already run or oversee licensed storage and dispatch, and examine a case wholesale site through inspection walkthroughs. CoreConcept Training Center delivers this pharmaceutical GDP course.

Course Objectives:

- Apply the GDP quality system, management review and responsible person duties to the scope of a wholesale distribution licence
- Assess premises, storage zones, equipment and transport arrangements against GDP qualification and monitoring requirements
- Qualify suppliers and customers through bona fides checks so medicines are bought only from and sold only to authorised parties
- Control receipt, picking, dispatch, returns and saleable-return decisions with records that show the product history
- Detect, quarantine and report suspected falsified or substandard medicines and run recalls with traceable reconciliation
- Conduct a GDP self-inspection and produce a graded Self-Inspection Report and Remediation Plan

Target Audience:

- Managers designated as responsible person for a wholesale distribution licence
 - Quality assurance managers who approve deviations, returns and supplier and customer status
 - Warehouse managers who run receipt, storage, picking and dispatch of medicines
 - Logistics managers who oversee contracted carriers and third-party storage of medicines
 - Hospital store and central pharmacy managers who receive and redistribute medicines between sites
 - Compliance managers who prepare distribution sites for regulatory inspection
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Course Outline:

Day 1: Medicine Wholesale Landscape and GDP Current-State Review

- Medicine Supply Chain Actors From Manufacturer to Dispensing Point
- Wholesale Distribution Licence Scope and Authorised Activities
- Responsible Person Duties, Authority and Deputy Arrangements
- Substandard Versus Falsified Medical Products Definitions and Risks
- GDP Current-State Questionnaire for a Distribution Site

Day 2: PIC/S and WHO GDP Frameworks and the Quality System

- PIC/S Guide to GDP Chapter Structure and Intent
- WHO Good Storage and Distribution Practices Key Requirements
- GDP Quality Manual, Procedures and Management Review Inputs
- Quality Risk Management Applied to Distribution Activities
- Change Control and Deviation Handling in a Wholesale Operation

Day 3: Premises, Operations and Trading Partner Qualification

- Storage Zone Design With Quarantine, Rejected and Returns Areas
- Warehouse Temperature Mapping Report Review and Monitoring Points
- Transport Lane Qualification Summary and Carrier Quality Agreements
- Supplier Bona Fides Verification and Approved Supplier File
- Customer Authorisation Checks Before Every First Supply

Day 4: Returns, Recalls, Falsified Medicines and Outsourced Activities

- Saleable Return Decision Tree and Product History Evidence
- Recall Execution, Customer Notification and Stock Reconciliation
- Falsified Pack Indicators, Quarantine and Authority Reporting
- Serialisation and Track-and-Trace Verification at Receipt
- Outsourced Storage and Transport Written Agreement Audit

Day 5: Inspection Walkthrough and the GDP Self-Inspection Report

- Case Wholesale Site Walkthrough Against a GDP Checklist
 - Case Supplier and Customer File Sampling for Bona Fides Gaps
 - Case Returns and Recall Records Review With Finding Grading
 - Mock Regulatory Inspection Opening Meeting and Document Requests
 - GDP Self-Inspection Report and Remediation Plan Completion
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Skills You Will Gain:

- GDP Quality System Management
- Responsible Person Oversight
- Trading Partner Bona Fides Verification
- Storage and Transport Qualification Review
- Saleable Return Assessment
- Recall Reconciliation
- Falsified Medicine Detection
- GDP Self-Inspection Grading

Why Attend This Course:

- Deliver a GDP Self-Inspection Report and Remediation Plan to the responsible person and site management as the basis for corrective actions before the next inspection
- Decide whether a returned pack can go back to saleable stock, whether a new customer may be supplied and whether a suspect pack must be quarantined and reported
- Avoid licence suspension, critical inspection findings and recall failures caused by missing bona fides records and weak product history
- Equip warehouse, quality and customer service colleagues with the walkthrough checklist, return decision tree and falsified pack indicator list

Conclusion:

Back at the site, the participant hands the responsible person and site management a GDP Self-Inspection Report and Remediation Plan that grades findings by patient risk and assigns owners and target periods to each corrective action. Management uses it to prioritise premises work, file remediation for supplier and customer records, and the training needs of warehouse and quality staff before the next regulatory inspection. After the first follow-up self-inspection, the unit should check which findings closed, which recurred and whether returns, recalls and suspect pack reports were handled as the plan intended.

Frequently Asked Questions FAQ:

What should participants know before pharmaceutical Good Distribution Practice GDP training?

Participants should already work in licensed medicine storage, distribution or quality assurance and know their site procedures. Bringing an anonymised returns record, supplier file or recent inspection finding helps them apply the walkthrough exercises to their own operation.

How does pharmaceutical Good Distribution Practice GDP training differ from a cold chain management course?

A cold chain course concentrates on refrigeration, packaging and temperature excursions. This course covers the whole licensed wholesale quality system: responsible person duties, trading partner checks, returns, recalls, falsified medicines and self-inspection, with temperature control treated as one element among many.

Why does pharmaceutical Good Distribution Practice GDP require bona fides checks on customers?

Selling only to parties authorised to receive medicines stops product leaking into illegal channels, where diversion and falsification thrive. Documented checks before first supply, and periodic rechecks, show inspectors that every sale went to a legitimate destination.

What do participants take back from pharmaceutical Good Distribution Practice GDP training?

Participants take back a GDP Self-Inspection Report and Remediation Plan for a case wholesale site, adaptable to their own, together with a walkthrough checklist, a saleable return decision tree and a falsified pack indicator list.
