

Auditing Warehouse and Distribution System

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Audit Training Manual: 012

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Quarantine: The status of starting or packaging materials, intermediate, bulk or finished products isolated physically or by other effective means whilst awaiting a decision on their release or refusal.

Sample: A unit of a prescription drug/medicinal product that is not intended for sale but is intended for physicians.

Stop shipment: A drug shipment that is placed on hold pending investigation.

Wholesale Distributor: Any person or firm engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

In EU-regulation wholesale distribution includes: all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

Explanation of Topic

Warehousing and Distribution covers all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

Since the drug product may not be under company control during warehousing and distribution the distributor is responsible for making sure that no drug gets to an illegal market or is compromised/adulterated and sold on the market.

This training module will outline the steps to follow in performing a quality assurance (QA) audit of Warehousing and distribution. The auditor should cover several GMP Systems and need to be familiar with Good Distribution Practice, GDP as described in the reference section. GDP includes requirements on:

- Quality System
- Personnel
- Documentation
- Premises
- Storage and delivery on Medicinal Products

Personnel

Wholesalers may not have a "Quality Unit/Quality Assurance function" in place as in most GMP operations. However a representative should be appointed in each warehouse and distribution point and this representative should have defined authority and responsibility for ensuring that a quality system is implemented and maintained. This may not be a full time job and he or she may have other tasks.

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be set based upon the requirements of the product being stored. Placement of measuring probes should be based on appropriate mapping studies.

There should be a system to manage stock rotation thus ensuring that material with the earliest expiry date is used first. Regular and frequent checks to verify that the system is operating correctly should be performed.

Transportation and Distribution

Products should only be distributed to authorized wholesalers or to other units authorized to receive/supply product. Products should be distributed in such a way that:

- Product identification is maintained.
- Products do not contaminate, and are not contaminated by, other products or materials.
- Adequate precautions are taken against spillage, breakage, theft or tampering.
- Products are secure and not exposed to unacceptable degrees of heat, cold, light, moisture or other adverse influences.
- Cold chain is maintained if required
- Temperature is monitored if required

Returns

Returns should be handled in a way that the following is ensured:

- Non-defective finished product, which has been returned, should be separated from saleable stock to prevent redistribution until a decision has been reached regarding their disposal, or recovery.
- Finished product, which has left the care of the wholesaler, should only be returned to saleable stock if examination, testing or other investigations prove the drug meets appropriate standards and the site is in agreement
- Records of returns should be kept.

Controlled Drugs

If the wholesaler/distributor handles controlled drugs, special precautions need to be in place to ensure safe storage and transportation of these products. The auditor needs to consult and be familiar with the applicable legislation.

Key Parameters in Auditing Warehousing and Distribution

Prior to the audit

- Find out what prescription drug products/medicinal products are at the site.
- Determine if any products have special storage or handling requirements including controlled drugs.
- If available, review observations/actions from previous regulatory inspections
- Review observations/actions from previous audits.
- Review listed reference materials to assure that you are familiar with the regulatory requirements.
- Obtain a list of reported product quality complaints.

During the audit

- Inspect the facility and equipments:
 - Tour the facility.

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- Verify that an appropriate system for self inspections have been implemented
- Ensure that personnel have received adequate training.
 - Verify that there is a documented training program.
 - Review actual training documentation for specific employees.
 - Verify that drug screens and criminal background checks were performed prior to hiring (US requirement).
 - Verify that job-specific training is conducted and documented for employees.
 - Verify that training is conducted with sufficient frequency to assure that employees remain familiar with applicable regulations.
 - Verify that there are clearly written job descriptions for employees.
 - Verify that the training program incorporates requirements for temporary employees and consultants.
 - Review list or organization chart of officers, directors, managers and other persons in charge, including a description of their duties and a summary of their qualification.
 - Verify annual GMP/GDP training is performed.
 - Verify that a record with an employee's name, signature, and initials written by the employee, exists.
- Review the materials system and ensure that there is adequate documentation.
 - Verify that the firm has written approved SOPs/procedures that include:
 - Generation, change control, approval and issuance of SOPs.
 - Receipt of prescription drugs/medicinal products.
 - Distribution of prescription drugs/medicinal products, including stop shipments, mis-shipments, and FIFO.
 - Conducting an inventory of prescription drugs/medicinal products, including correcting all errors and inaccuracies.
 - Returned, outdated, damaged, deteriorated, misbranded or adulterated prescription drugs/medicinal products.
 - Storage of prescription drugs/Medicinal Products.
 - Recall and/or withdrawal of prescription drugs/medicinal products from the marketplace.
 - Identifying, recording and reporting losses or thefts of prescription drugs/medicinal products.
 - Documenting deviations and notifying the site.
 - Managing temperature sensitive products.
 - Managing penicillins or other sensitizing agent spills.
 - Review actual inventories performed.
 - Review actual receiving records.
 - Verify that there are procedures in place to ensure retention of the records for every receipt, distribution or disposition of prescription drug product/medicinal product for the required retention time
 - Review loss/thefts investigations and reports.
 - Review the returned/damaged drug log and verify that inventory received matches inventory sent to a site approved reverse distributor.
 - Ensure that computer systems used to maintain drug inventory and distribution records are validated and subject to change control.
 - Ensure that computer systems are controlled to prevent diversion and theft of drug inventory.
 - Review the management and control of road , air and sea transportation