

Auditing Warehouse and Distribution System

Goals

When you have completed this module, you should be able to:

- Perform an audit of warehousing and distribution
- Access and understand warehousing and distribution requirements, including licensing requirements
- Use a range of tools and information, including the contents of this module and the Internet, in support of auditing warehousing and distribution
- Understand and apply applicable GMP standards/regulations to an audit of warehousing and distribution
- Recognize compliance or non-compliance of regulations pertaining to warehousing and distribution requirements.

Definitions

FEFO: An inventory management system where the products expired first are the ones sold first. Known by the abbreviation “FEFO”, First Expire; First Out.

FIFO: An inventory management system where the products received first are the ones sold first or the oldest inventory is the first to be distributed. Known by the abbreviation “FIFO”, First In; First Out.

Finished Product: A product, which is packaged and labeled for supply to a wholesaler, hospital, pharmacy, doctor or patient. The use of this definition in this document includes medicinal products/prescription drugs.

Investigational Medicinal Product: A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including already with a marketing authorization but use or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication or when used to gain further information about the authorized form.

Manufacturer: A firm who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

In EU-regulation the definition is: A manufacturer is the holder of a Manufacturing Authorisation as described in Article 40 of Directive 2001/83/EC.

Medicinal product: (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Mis-shipment: A shipment of a drug product that is sent to the wrong location.

Prescription drug: Any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

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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.
 - Look for cracks, peeling paint in the ceiling, walls, and floor.

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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