

Auditing a Material Handling System

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Prepared by:		Date:		Supersedes:	
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Audit Training Manual: 016

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Explanation of Topic

Introduction

Material handling starts when components and packaging materials are received onto a pharmaceutical or Active Pharmaceutical Ingredient (API) plant site and ends when the product/material is distributed. Material includes components or starting materials, (e.g., raw materials), API intermediates and excipients and packaging materials used for APIs or finished products.

Some examples of materials are:

- Solvents in tank wagons
- Chemicals received by API manufacturers
- Active Pharmaceutical Ingredients for finished products
- Printed packaging materials or labels used in packaging
- Primary packaging materials such as glass vials, plastic bottles and aluminum foil
- In-process materials such as bulk tablets, granulations, etc.

Material handling refers to one of nine stages within the pharmaceutical process.

Material Handling Stages

- Receiving materials
- Storing materials
- Sampling/testing materials
- Release of materials
- Transferring materials
- Subdividing/dispensing materials
- Charging in of materials
- Distributing materials
- Rejected/Returned/Recalled materials

Each of these stages should have a written approved procedure or series of procedures describing activities to be taken during each step.

The goal of this training module is to describe how to audit a material handling system using the appropriate GMP standards. The GMP requirements detailed in this module are directly applicable to finished dosage and API manufacturing sites and should be applied to other suppliers on a sliding scale, the scale being dependent on the product or service being audited. In addition, the auditor should consider the risks associated with the material handling system that would potentially result in product not meeting customer specifications or regulatory requirements.

Focus of Audit

As an auditor, not only should you focus on what the material handling activities are but also how they take place throughout the plant. A suggested way to audit is to take a finished product and trace it back to its components and packaging material to see if the paper trail is intact. Observing product at its various in-process stages, (how it is labeled, transported, and managed) will also provide you with valuable information. Focus on steps taken to ensure that there are no mix-ups, or potentials for contamination and/or cross contamination. Observe how the quality of materials is preserved throughout

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reconciles the amount of goods ordered, the amount received and the amount used. There should also be a detailed site procedure in place for destruction of material waste.

Incoming materials should be processed immediately upon receipt to ensure that the materials are secured and stored under appropriate environmental conditions. Materials requiring cold storage and/or low humidity should be stored accordingly upon receipt.

Any doubt about material identity, any damage likely to affect the integrity or quality of the material, and any suspected contamination must be reported to the Quality Unit/Quality Assurance.

Storing materials

Suitable conditions for storing and sampling of starting materials and packaging materials must be provided. Any special storage conditions required by specifications should be met.

Once materials have been received, they must be stored under quarantine until tested or examined and released. Quarantine status may be controlled either through an electronic/automatic system, providing the system is validated or a manual system controlled by status labeling. When material is released for use by Quality, it may be held in a storage area or warehouse until disposition.

Material should be held under the environmental conditions (specific temperature or humidity, in the dark, etc.) indicated by the vendor or as supported by stability. Conditions should be monitored and recorded, as applicable. Temperature mapping studies should be performed to demonstrate the suitability of the storage facilities and support choice of points to monitor temperature and to determine any special material storage location. The storage areas should be well maintained and clean. Access should be controlled and limited to appropriate personnel.

Rules for Storage

- Same materials with different batch numbers should be adequately segregated to avoid potential mix-ups.
- Released material should not be stored in the same area as rejected, returned or recalled materials.
- Cleaning solutions should not be stored next to in-process or finished pharmaceuticals/products.
- Materials should be stored off the floor.
- Process solvents should be stored in dedicated and/or cleaned tanks (according to a validated cleaning procedure).

Storage areas should be in good order. Procedures should be in place to ensure that material is within retest/expiration dates. Procedures for reconciliation should be in place as needed. This is of particular importance for labels and material that may be returned from production for storage.

Materials being held locally should follow the first in, first out (FIFO) rule. The oldest material should be used first. An inventory management system where the products expired first are the ones sold first may also be used. It is known by the abbreviation "FEFO", First Expire; First Out. Retest and/or expiration dates should always be checked before use.

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Sampling should be performed by personnel and by methods approved by the Quality Unit/Quality Assurance under conditions and with a technique that will give a representative sample and preserve the initial quality of sample and sampled material with regard to microbiological, physical and chemical aspects. The sampling method should specify the number of containers to be sampled, which part of the container to sample and the sample size. If samples are pooled (composited), it should be clear who will pool (composite) and homogenize them.

Sampling utensils and sampling containers should be clean. If reusable utensils are used for sampling potent or toxic materials, cleaning validation should be conducted and completed before the sampling procedure is accepted. It is not recommended that reusable utensils be used to sample these materials.

All samples should be adequately documented and labeled according to site procedure. Once a material is accepted by the site its status should be changed in the material control system using accepted site practices as outlined in an approved SOP.

Materials beyond their retest date may be sampled and re-evaluated according to site procedures and supplier recommendations. The criteria should be clearly defined with regards to frequency, tests to be performed and by whom and the number of times an expiration time can be extended.

Evaluation and Release

Deliveries of materials should be tested, evaluated and released by the Quality Unit/QA as appropriate, according to site procedures.

Transferring materials

As materials are moved throughout the facility, they should be clearly labeled and identified as to what stage they are in. Containers should be closed and sealed to prevent contamination, both from the environment and other products, and to prevent tampering.

Appropriate paperwork should accompany the transfer and be completed concurrently with the transfer. Precautions should be taken to keep materials secure during transfer. This may include special seals both on the interior (primary seals), and on containers (secondary). Finished product labels should be securely transferred to prevent unauthorized access. The secure transfer of labels may be accomplished in a number of ways, including transfer in tamper proof "cages", locked with numbered and labeled unique seals.

When material is transferred between areas, precautions should be taken to prevent:

- Product mix-ups
- Contamination of product or components
- Use of wrong material in manufacturing
- Tampering of product

Subdividing/Dispensing materials

At times it is necessary to subdivide material for use in pharmaceutical operations. The area in which the subdivision takes place should be a controlled area with only the material to be subdivided present in the area.

Containers, those currently holding the material and those the material will be placed into, should be free from dust and dirt. If a container is recycled, i.e., used for a different lot, the sticker or identification from the previous lot should be removed or defaced, with

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Rejected, returned, and recalled materials

Rejected material should be clearly marked and quarantined from other material in a restricted area. If the material was rejected during receipt, it should either be returned to the supplier or destroyed. All actions should be approved and documented by authorized personnel.

The process for receiving returned goods must be described in an approved procedure. Returned goods must be clearly identified and segregated. Before placing returned goods into good stock, there must be an investigation. The investigation should include details of the storage (e.g., environmental conditions) and handling of the material prior to returning to the site. Returned goods must undergo physical examination and may require analysis. The criteria for returning material/products to usable stock must be well defined, approved by QA and the final decision made by appropriately trained and qualified persons.

In the event of a recall, returned materials should be segregated from all other material and clearly labeled as recalled material. All recalled material should be documented. There should be an approved SOP that describes in detail what actions take place during a recall.

Excess of printed packaging materials bearing batch numbers or other batch specific printing must be destroyed in connection with the line clearance procedure.

Training of Personnel

All personnel who are involved in receiving, weighing, transporting, storing, sampling, and distributing either work-in-process materials or finished product must be trained in their job functions, including applicable GMPs.

Summary

At all times, materials used in manufacturing and packaging should be under strict control. Care should be taken in transporting materials to prevent contamination, product mix-ups, and problems in manufacturing with wrong materials.

Key Parameters in Auditing a Material Handling System

Prior to the audit

- Review the type of products made at the site.
- Determine what type of materials the site receives.

During the audit of the material handling system

- Inspect the warehouse.
 - Verify that components, drug product containers, and closures are received, identified, stored, handled, sampled, tested, and approved or rejected according to the site's SOP.
 - Verify that materials are stored off the floor.
 - Verify that environmental conditions monitored and recorded, as appropriate.
 - Verify that there is controlled access to receiving and storage areas.
 - Verify that pest control procedures are in place.
 - Verify that the sampling area is a controlled environment designed to prevent contamination