Goals

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

- Perform an audit of a material handling system.
- Use a range of tools and information, including the contents of this unit to support the audit of a material handling system
- Understand and apply appropriate GMP standards/regulations to an audit of a material handling system
- Recognize compliance or non-compliance of material handling systems to applicable regulations

Definitions

Charge in of materials: A quantity of ingredient material to be used in production placed into an item of manufacturing equipment.

Components: FDA defines this as any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. The equivalent word in EU would be starting material. In this module the word component is used. The words are used interchangeably, depending on the stage of production, with a number of different terms such as: material, intermediate bulk, active pharmaceutical ingredient, excipient, starting material, raw material, goods.

Dispense: To remove a specific quantity of material from the primary material and portion into the individual secondary container for charging to a batch or prescription.

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

First In; First Out (FIFO): An inventory method that requires the oldest material to leave the warehouse before newer material.

Material: When the word material is used in this training module it means both components and packaging materials.

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

Packaging Material: Any material employed in the packaging of an API or a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Rejected material: Material not meeting acceptance criteria.

Subdivide: To remove a chemical or raw material from a large container and divide/weigh it into smaller, pre-determined amounts.

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.

the current identification label visible and legible. If a container that has been opened and/or previously subdivided, it should indicate on the container itself "OPEN" or "PARTIAL" along with the date of opening. This will prevent the container from mistakenly being used as a full container.

The subdivision process as outlined in the approved local SOP should be verified and documented by a second person. The second person should check that:

- Material was released by Quality Control
- The expiration and/or retest date is present
- The material name and/or chemical nomenclature is present
- The lot number is present
- The expiration and/or retest date is present
- Weights of subdivided containers are present
- The date the material was subdivided and the initials of the employee responsible for the subdivision are present

When a component is removed from the original container, the new container needs to have the following information:

- Component name or item code
- Receiving or control number
- Weight or measure in new container
- Batch number for which the component was dispensed
- Product name, strength, and lot number

If a material is removed from the original container, it needs to be demonstrated that content is not compromised with regard to container integrity, impact on content from container as well as the stability of content.

Charging of materials

Written production and control procedures should be present to ensure that the batch to be formulated should be at 100% of the labeled or active ingredient. When charging materials, the material identification and weight of the charge-in material should be compared to the specified material and amount indicated in the batch record. Material charges should be verified and documented in the batch record by a second person. This person may be a supervisor or second operator. During charge in the following information needs to be verified:

- The material was released by Quality (unless other systems and controls are in place to verify release)
- The material name and/or nomenclature is present
- The lot number is present
- The expiration and/or retest date is present
- The weights of the material containers are present
- The date and initials of the operator who charged the material is present

Distribution of materials

Once product is released by Quality, it may be distributed through the channels established by the site or company. Material should be properly marked with name of the product, and lot number. Finished product should be placed in appropriate shipping containers to prevent damage to the product and maintain the storage conditions indicated for the product.

Contracted storage facilities should comply with GMP for receiving, storage, handling and distribution of materials