Unit-4

Pharmaceutical Quality Assurance

B.Pharma 6th Sem Notes

Unit: 4

- **Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
- **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling andwaste disposal.

A complaint is any communication (written or verbal) from a customer, retailer, distributor, or healthcare professional indicating dissatisfaction with a product's quality, packaging, labeling, or performance.

Types of Complaints

1. **Quality complaints** –
   - Tablet breakage
   - Discoloration
   - Particulate matter
2. **Packaging complaints** –
   - Broken containers
   - Missing labels
   - Leakage
3. **Safety complaints** –
   - Adverse drug reactions
4. **Efficacy complaints** –
   - Drug not showing expected effect

Evaluation Process:

- Record the complaint in a standardized log.
- Assign responsibility to a trained quality assurance officer.
- Investigate root cause (manufacturing defect, packaging issue, storage condition).
- Classify complaints as **critical, major, or minor** depending on risk to patient safety.
- Implement corrective and preventive actions (CAPA).

Handling of Returned Goods

Meaning

Returned goods are pharmaceutical products returned from market due to damage, expiry, recall, or customer complaint.

Reasons for Return

- Expired products
- Transport damage
- Quality complaints

- Product recall

Handling Procedure

1. **Receipt in separate area**
2. **Proper labeling** – "RETURNED GOODS"
3. **Quarantine storage**
4. **Evaluation by QA**
5. **Decision**
    - Reprocess
    - Repack
    - Destroy

Product Recall

Definition: Recall is the removal of a product from the market due to safety, quality, or regulatory concerns.

Types of Recalls:

- **Class I:** High risk to health (e.g., contamination).
- **Class II:** Temporary health issues or mislabeling.
- **Class III:** Minor defects with no health risk.

Procedure:

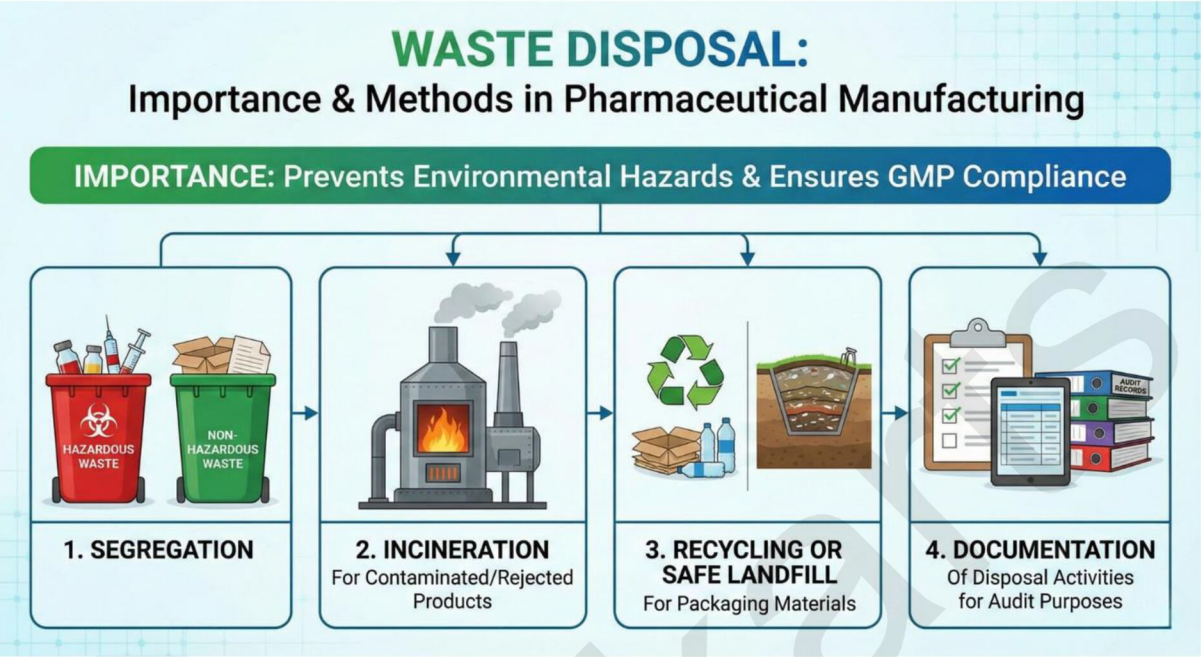
- Notify regulatory authorities and stakeholders.
- Communicate recall instructions to distributors and customers.
- Retrieve affected products and document the process.
- Conduct post-recall analysis to prevent recurrence.

Waste Disposal

- **Importance:** Prevents environmental hazards and ensures compliance with Good Manufacturing Practices (GMP).

Methods:

- Segregation of hazardous and non-hazardous waste.
- Incineration for contaminated or rejected pharmaceutical products.
- Recycling or safe landfill disposal for packaging materials.
- Documentation of disposal activities for audit purposes.



Document Maintenance in Pharmaceutical Industry

Introduction

Document maintenance is a core requirement of **Good Manufacturing Practices (GMP)**. Proper documentation ensures that pharmaceutical products are **consistently manufactured, controlled, traceable, and auditable**.
In GMP, the rule is:
"If it is not documented, it is considered not done."

Feature	Master Formula Record (MFR)	Batch Formula Record (BFR)
Definition	A standardized, approved template for manufacturing a specific product.	A batch-specific document used to record the production of a particular lot.
Contents	Ingredients, batch size, theoretical yield, and detailed processing instructions.	Batch number, actual quantities used, time-stamping of steps, and signatures.
Frequency	Prepared once and updated via Change Control.	Prepared for every single batch produced.
Purpose	To ensure consistency across all batches.	To provide an audit trail and legal evidence of production.

Standard Operating Procedure (SOP)

An SOP is a written document that provides step-by-step instructions on how to perform a routine activity.

- **Maintenance:** SOPs must be regularly reviewed (e.g., every 2–3 years) and updated to reflect current practices.
- **Control:** Only the "Current Version" should be available at the workplace. Superseded (old) versions must be withdrawn and archived to prevent accidental use.
- **Training:** Every time an SOP is revised, relevant personnel must be re-trained.

Quality Audit

A quality audit is a systematic, independent examination of the quality system to determine if activities comply with the planned arrangements (GMP/ISO).

- **Internal Audits (Self-Inspection):** Conducted by the company's own quality team to find gaps before official inspections.
- **External Audits:** Conducted by regulatory bodies (like FDA or MHRA) or by customers to verify compliance.
- **Outcome:** Generation of a **Corrective and Preventive Action (CAPA)** plan to fix any non-conformities found.

Quality Review

Specifically known as the **Annual Product Quality Review (APQR)** or **Periodic Quality Review (PQR)**, this is a regular analysis of all manufactured batches of a product.

- **Objective:** To verify the consistency of the process and identify trends (e.g., are the weights of tablets slowly drifting higher over months?).
- **Contents:** Review of starting materials, in-process controls, failed batches, deviations, and stability data.

Quality Documentation and Reports

This is a broad category encompassing all records that support the Quality Management System (QMS).

- **Validation Reports:** Documentation proving that a process, piece of equipment, or cleaning method consistently produces the desired result.
- **Deviation Reports:** Records of any time a process went "off-script," including an investigation into why it happened and the impact on product quality.
- **Change Control:** A formal system to ensure that changes to a process or facility are evaluated and approved before implementation.

Distribution Records

Definition:
Distribution records document the **movement of finished products** from manufacturing site to distributors or customers.

Contents:

- Product name and batch number
- Quantity distributed
- Date of distribution
- Name and address of consignee

Importance:

- Enables effective product recall
- Ensures traceability
- Prevents distribution of non-conforming products

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