WELCOME

TO

This is an Education Platform

We Provide PDF Notes for Pharmacy Students

Web Site http://www.fdspharmacy.in/

You tube https://www.youtube.com/c/FDSpharmacy

Telegram https://t.me/Fdspharmacy

App https://play.google.com/store/apps/details?id=com.FDSPharmacyMedia.FDSPharmacy

E-mail fdspharmacyinfo@gmail.com

PHARMACEUTICAL QUALITY ASSURANCE

UNIT 4

TOPIC :

- **Complaints :** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Complaints, Returned Goods, Drug Recall and Waste Disposal

Complaints

→ A complaint is any written, verbal, or electronic communication that reports a problem related to the quality, safety, efficacy, packaging, labeling, or performance of a pharmaceutical product.

→ Complaints indicate customer dissatisfaction and help manufacturers identify defects and improve product quality.

Objectives of Complaint Handling

- Ensure patient safety.
- Investigate product defects.
- Identify root causes.
- Implement Corrective and Preventive Actions (CAPA).
- Maintain product quality.
- Comply with regulatory requirements.
- Improve customer satisfaction.

Types of Complaints

1. Quality Complaints

➢ These complaints are related to defects in the pharmaceutical product.

Examples

- Broken tablets
- Cracked capsules
- Discoloration
- Leakage
- Contamination
- Incorrect weight

2. Adverse Reaction Complaints

- These complaints involve unexpected side effects or harmful reactions caused by a product.

Examples

- Allergic reactions
- Skin rashes
- Severe adverse effects
- Unexpected toxicity

3. Other Complaints

- Complaints not directly related to product quality.

Examples

- Lack of efficacy
- Labeling errors
- Packaging defects
- Delivery issues

Sources of Complaints

Complaints may originate from:

Patients or Consumers

- Users reporting product-related problems.

Doctors

- Medical professionals observing defects or adverse effects.

Pharmacists

- Reporting quality or packaging issues.

Hospitals

- Reporting product failures or adverse events.

Distributors and Retailers

- Identifying defects during distribution.

Regulatory Authorities

- Reporting compliance-related issues.

Classification of Complaints

➢ Based on severity and patient risk, complaints are classified into three categories.

Type A (Critical Complaints)

→ Critical complaints are serious complaints that may pose a significant risk to patient health or life.

Characteristics

- Life-threatening.
- Serious safety concerns.
- Immediate investigation required.
- May lead to product recall.

Examples

- Wrong product supplied.
- Incorrect labeling.
- Microbial contamination.
- Glass particles in product.
- Metal contamination.
- Serious adverse drug reactions.

Type B (Major Complaints)

→ Major complaints affect product quality but are not immediately life-threatening.

Characteristics

- May reduce effectiveness.
- Affect product acceptability.
- Require CAPA implementation.

Examples

- Broken tablets.

- Leakage.
- Improper sealing.
- Color variation.
- Weight variation.

Type C (Minor Complaints)

→ Minor complaints have little or no impact on product safety or efficacy.

Characteristics

- Cosmetic defects.
- No significant health risk.
- Routine review required.

Examples

- Printing defects.
- Minor packaging damage.
- Label misalignment.

Handling and Evaluation of Complaints

➢ Complaint handling is a systematic process used to investigate and resolve complaints.

Steps In Complaint Handling

1. Receiving Complaint

Sources

- Customers
- Pharmacists
- Hospitals
- Distributors
- Regulatory agencies

Procedure

- Record complaint immediately.
- Assign complaint number.
- Enter details into complaint register.

Product Complaint Data Sheet

The following information should be recorded:

- Complaint number
- Date received
- Product name
- Strength
- Batch number

- Quantity involved
- Nature of complaint
- Customer name and address
- Sample quantity received
- Investigator details
- Investigation findings
- CAPA details
- Customer response

Technical Investigation

→ Scientific evaluation of a complaint to determine its root cause and validity.

A. DOCUMENT-BASED INVESTIGATION

Relevant records are reviewed.

Documents Reviewed

Batch Manufacturing Record (BMR)

- Provides manufacturing details.

Batch Packaging Record (BPR)

- Provides packaging details.

Quality Control Records

- Includes test results and release records.

Purpose

- Identify manufacturing errors.
- Detect packaging issues.
- Trace process deviations.

B. Laboratory Analysis

Procedure

- Test complaint sample.
- Compare with retained sample.
- Conduct physical and chemical tests.
- Evaluate product quality.

Purpose

Determine whether the defect actually exists.

Evaluation of Results

After investigation, complaints are classified as:

Confirmed Complaint

→ Complaint is valid and defect is verified.

Example

- Testing confirms tablet hardness failure.

Non-Confirmed Complaint

→ No defect found during investigation.

Example

- Complaint sample meets specifications.

Counterfeit or Tampering Complaints

→ Complaints involving suspected fake or tampered products.

Investigation

- Verify packaging.
- Check labeling.
- Confirm batch details.
- Compare with original records.

Action

- Notify regulatory authorities.
- Conduct market investigation.
- Initiate recall if necessary.

Corrective and Preventive Action (CAPA)

Corrective Action

→ Action taken to eliminate the existing problem.

Examples

- Adjust tablet compression force.
- Repair equipment.
- Replace defective materials.

Preventive Action

→ Action taken to prevent recurrence.

Examples

- Employee retraining.
- Process improvement.
- Additional quality checks.

Benefits of CAPA

- Continuous improvement.
- Better product quality.
- Reduced complaints.
- Regulatory compliance.

Customer Feedback

After investigation:

- Inform customer of findings.
- Explain root cause.
- Describe corrective actions.
- Provide professional response.

Importance

- Builds trust.
- Improves customer satisfaction.
- Enhances company reputation.

Monthly Report and Trend Analysis

All complaints should be reviewed periodically.

Monthly Report Includes

- Total complaints received.
- Product-wise complaints.
- Batch-wise complaints.
- Complaint categories.
- Investigation status.

Trend Analysis

Purpose

- Identify recurring defects.
- Detect quality trends.
- Prevent future problems.

Benefits

- Early detection of issues.
- Continuous quality improvement.
- Better risk management.

Time Limit for Complaint Investigation

Complaint Type	Investigation Time
Product Quality Complaint	10 Days
Adverse Reaction Complaint	5 Days
Medical Complaint	3 Days

Records and Maintenance of Complaints

Requirements

- Maintain complaint register.
- Assign unique complaint number.
- Document investigation findings.
- Record CAPA implementation.
- Maintain customer communication records.

Importance

- Supports audits.
- Facilitates trend analysis.

Handling of Returned Goods

→ Returned goods are pharmaceutical products sent back from the market due to defects, damage, expiry, excess stock, or customer complaints.

Reasons for Return of Goods

1. Damage During Transportation

- Broken or damaged packages.

2. Expired Products

- Products reaching expiry date.

3. Product Defects

- Quality-related complaints.

4. Incorrect Supply

- Wrong product supplied.

5. Excess Market Stock

- Unsold inventory returned.

Steps In Handling Returned Goods

1. Receipt of Returned Goods

Procedure

- Receive returned products.
- Record details.
- Assign return reference number.

Information Recorded

- Product name
- Batch number
- Quantity
- Reason for return

2. Inspection and Verification

Products are checked for:

- Physical damage
- Leakage
- Seal integrity
- Packaging condition
- Labeling accuracy
- Signs of tampering

3. Evaluation

Quality Assurance evaluates whether the product is:

- Suitable for reuse.
- Suitable for reprocessing.
- Unsuitable and requires destruction.

4. Final Decision

Re-stocking

- Product returned to inventory if acceptable.

Reprocessing/Repacking

- Minor defects corrected.

Destruction

- Damaged, expired, or unsafe products destroyed.

5. Documentation

Maintain records of:

- Receipt
- Inspection
- Evaluation

- Final disposition

Drug Recall

→ Drug recall is the process of removing or withdrawing defective, unsafe, or potentially harmful pharmaceutical products from the market.

→ The purpose of recall is to protect public health.

Objectives of Drug Recall

- Protect patients.
- Remove defective products.
- Prevent adverse effects.
- Maintain regulatory compliance.
- Preserve company reputation.

Types of Drug Recall

1. Voluntary Recall

→ Recall initiated by the manufacturer.

Reasons

- Quality defects.
- Safety concerns.
- Manufacturing errors.

2. Statutory Recall

→ Recall ordered by regulatory authorities.

Characteristics

- Legally enforced.
- Mandatory compliance required.

Reasons for Drug Recall

Quality Defects

- Contamination
- Incorrect potency
- Manufacturing defects

Safety Issues

- Serious adverse effects
- Toxicity concerns

Labeling Errors

- Wrong label
- Missing information

Regulatory Violations

- Non-compliance with standards

Classes of Drug Recall

Class I Recall

→ Products that may cause serious health consequences or death.

Examples

- Contaminated injectables.
- Incorrect active ingredient.

Action

- Immediate recall.

Class II Recall

→ Products that may cause temporary or medically reversible health effects.

Examples

- Minor potency variations.
- Packaging defects affecting quality.

Action

- Prompt recall required.

Class III Recall

→ Products unlikely to cause health hazards.

Examples

- Minor labeling errors.
- Cosmetic packaging defects.

Action

- Routine recall procedures.

Steps In Drug Recall

Step 1

- Identification of defective product.

Step 2

- Recall decision.

Step 3

- Inform regulatory authority.

Step 4

- Notify distributors and retailers.

Step 5

- Withdraw product from market.

Step 6

- Maintain recall records.

Step 7

- Prepare final recall report.

Waste Disposal

→ Waste disposal is the collection, treatment, and safe disposal of waste generated during pharmaceutical manufacturing and laboratory operations.

→ Proper waste disposal protects human health and the environment.

Objectives of Waste Disposal

- Prevent contamination.
- Protect workers.
- Protect environment.
- Comply with regulations.
- Promote safe manufacturing practices.

Types of Pharmaceutical Waste

1. Solid Waste

Examples:

- Paper
- Plastic
- Packaging materials
- Glass

2. Liquid Waste

Examples:

- Solvents
- Chemical solutions
- Washing liquids

3. Biological Waste

Examples:

- Culture media
- Microbial cultures
- Contaminated materials

4. Hazardous Waste

Examples:

- Toxic chemicals

- Flammable substances

Steps In Waste Disposal

1. Segregation Of Waste

Procedure

- Separate waste according to category.
- Use color-coded containers.
- Prevent mixing of hazardous and non-hazardous waste.

Benefits

- Easier treatment.
- Improved safety.
- Regulatory compliance.

2. Collection And Storage

Procedure

- Collect waste in labeled containers.
- Store in designated areas.
- Maintain controlled conditions.

Benefits

- Prevents leakage.
- Prevents contamination.
- Improves safety.

3. DISPOSAL METHODS

A. Incineration

- High-temperature burning of waste.

Suitable For

- Biological waste
- Hazardous waste

B. Landfill

- Disposal of non-hazardous waste in designated landfill sites.

C. Chemical Treatment

- Neutralization or detoxification of chemical waste.

D. Autoclaving

- Steam sterilization of biological waste.

Benefits

- Destroys microorganisms.
- Makes waste safe for disposal.

4. Documentation

→ All waste disposal activities should be recorded.

Records Include

- Waste type
- Quantity
- Disposal method
- Disposal date
- Responsible personnel

Importance

- Regulatory compliance.
- Audit support.
- Environmental monitoring.