PHARMACEUTICAL QUALITY ASSURANCE

UNIT 4 NOTES

COMPLAINTS

- EVALUATION
- HANDLING OF RETURN GOOD
- RECALLING & WASTE DISPOSAL

DOCUMENT MAINTAINANCE

- BATCH FORMULA RECORD
- MASTER FORMULA RECORD
- SOP
- QUALITY REVIEW
- REPORTS & DOCUMENTS
- DISTRIBUTION RECORDS

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COMPLAINTS

- A complaints are any written, verbal statement that reports a problem related to the quality, safety or performance of the product.
- It shows costomer dissatisfaction about the company & the product.

TYPES OF COMPLAINTS

- Complaints can be following types:

① Quality Complaints

- These are complaints related to product defects such as broken tablets, discoloration, leakage.

② Adverse Reaction Complaints

- These are related with unexpected side effects or harmful reactions of product.

③ Other Complaints

- They include complaints such as lack of efficacy, labelling, container defects etc.

Source Of Complaints

In pharma sector, complaints can be raised from following sources :

- Patients or Consumers
- Doctors or Pharmacists
- Hospitals or Distributors
- Regulatory Authorities

Classification Of Complaints

Based on severity & impact on patients, complaints can be classified as follows :

① Type A (Critical)
② Type B (Major)
③ Type C (Minor)

① Type A (Critical)

- These are very serious complaints that may harm the patient.
- They involve safety risks or life threatening situations.
- They require Immediate investigation & possible product recall.

Examples :

- Wrong product or wrong label
- Contamination of product
- Presence of foreign particles (glass, metal)
- Serious adverse drug reactions

② Type B (Major)

- These complaints may affect product quality, but are not life-threatening.
- They can reduce the effectiveness or acceptability of the product.
- They require CAPA (Corrective & Preventive Action)

Examples:

- Broken Tablets
- Improper sealing or leakage
- Variation in colour or appearance

③ Type C (Minor)

- These are less serious complaints with no impact on safety or efficacy.
- They're usually related to acceptance or minor defects.
- They should be reviewed, but no urgent action needed.

Examples:

- Slight Packaging defects
- Minor printing issues

Handling & Evaluation Of Complaints

- It is the Systematic process of recieving, investigating & analyzing complaints to take CAPA.
- It involves following steps:

① Recieving complaints
② Technical Investigation
③ Corrective & Preventive Action
④ Feedback to Customer
⑤ Monthly Report & Trend Analysis

① Recieving Complaints

- Complaints can be recieved from customers, hospitals, distributors etc.
- Company must provide a support system through a toll free number or chat support.
- All complaints must be properly recorded in a product complaint Data sheet.
- Each complaint is given a unique complaint number for tracking.

Contents of a product Complaint Data Sheet

- Serial number assigned to the complaints
- Exact nature of the complaints
- Name & Address of the complainant.
- Date of the complaint recieved
- Name of the product, strength & batch number of the product
- Quantity involved in the complaint
- Size of the sample obtained by QC department
- Name & signature of the investigator & date
- Action taken by the company
- Copy of reply sent to complainant.

② Technical Investigation

- It is the most important step in complaint handling.
- In this step, we scientifically analyze the complaint to find the root cause & verify whether the complaint is valid or not.
- It involves two steps:
  - Documentation - Based Investigation
  - Laboratory Analysis

a) Documented Based Investigation

- We review all related records, such as:
  - Batch Manufacturing Record (BMR)
  - Batch Packaging Record (BPR)
  - Quality Control (QC) data
- We check any error during manufacturing or packaging.
- This helps to identify if the problem occured during production.

b) Laboratory Analyse Phase

- We test the complaint sample & retained sample in the laboratory.
- This confirms whether the defect is present in the complaint sample or whole batch.

Evaluation Of Results

- After investigation, we classify the complaint as:
  - Confirmed complaint: Defect is found, Complaint is valid.
  - Non-Confirmed complaint: No defect found, Complaint is invalid.

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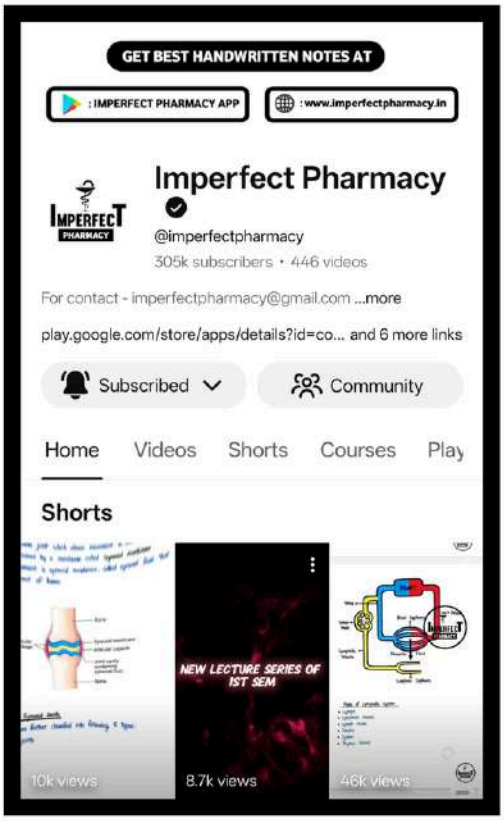

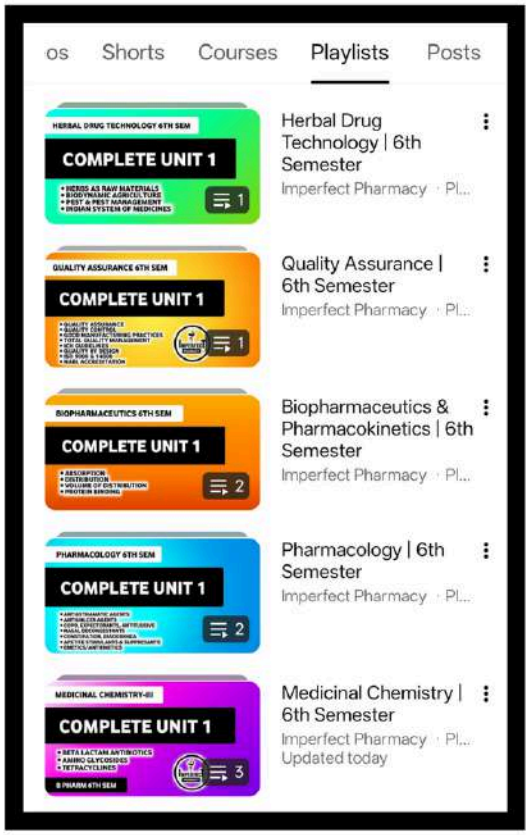

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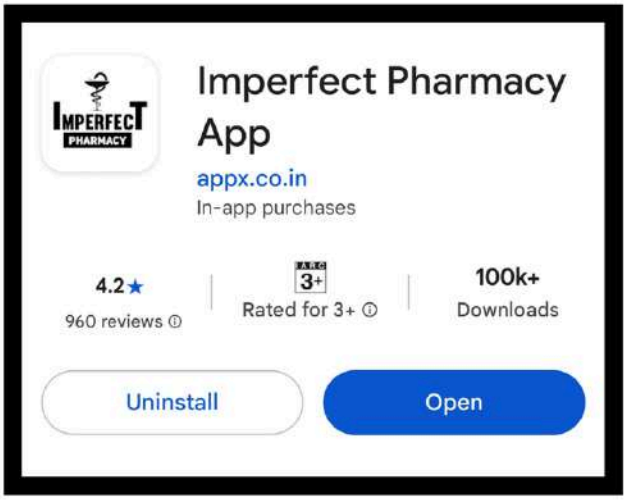

Special Case : Counterfiet / Tampering Suspicion

- IF product look suspicious, packaging, labelling & batch detail are verified & information is sent to regulatory authority to take strict action.
- This ensures protection against fake or tampered product.

③ Corrective & Preventive Control

- After completing the investigation, the company takes actions based on the root cause.
- Corrective Action means fixing the current problem.
  - Example: If tablets are breaking, adjust compression force.
- Preventive Action means stopping the problem from happening again in future.
  - Example: Improving process control or training staff.
- CAPA ensures continuous improvement & quality assurance.

④ Feedback To Customer

- After investigation & CAPA, the company provides a response to the customer.
- The feeback includes:
  - Result of investigation
  - Explanation of the issue
  - Actions taken
- Communication should be clear & professional.
- This step helps in building customer trust & satisfaction.

⑤ Monthly Report & Trend Analysis

- All complaints are recorded & reviewed regularly.
- A monthly report is prepared following:
  - Number of complaints
  - Type of complaints
  - Batch-wise details
- Trend analysis is done to:
  - Identify repeated or common problems
  - Detect increase in specific defects
- If any trend is observed immediate action is taken & process improvement is implemented
- This helps in early detection of issues & long-term quality improvement.

Time Period For Investigation Of Complaints

- Product quality Complaint : 10 Days
- Adverse Reaction Complaint : 5 Days
- Medical Complaint : 3 Days

RECORDS & MAINTINANCE

- Record & Maintenance of complaints means proper documentation, storage & review of all complaints recieved for p'ceutical products.
- All complaints should be recorded in a complaint register or data sheet.
- Each complaint must have a unique identification number.
- All investigation details & CAPA actions must be documented.
- Records should be properly maintained & easily retrievable.
- Complaint records must be reviewed periodically for trend analysis.
- All records should be retained for a specified time as per regulatory requirements.

HANDLING OF RETURN GOOD

- Returned goods are p'ceutical products that are sent back from the market (customers, distributors or retailers) to the company due to reasons like damage, expiry, defect or excess stock.

REASON FOR RETURN

- Damaging during transportation
- Expiry or near expiry
- Products defects or complaints
- Incorrect supply of product
- Excess stock in the market

STEPS IN HANDLING

① RECIEPT OF RETURNED GOODS

- Returned products are recieved & recorded properly.
- Details like product name, batch number & reason for return are noted.

② INSPECTION & VERIFICATION

- The product is checked for:
  - Physical condition (damage, leakage)
  - Seal integrity
  - Labeling & packaging
- It is verified whether the product is genuine & not tampered.

③ Evaluation

- Quality team evaluates whether the product is :
  - Safe for reuse
  - Needs reprocessing
  - Should be rejected

④ Final Decision

- Based on evaluation, the product is :
  - Re-stocked : if product is in good condition
  - Reprocessed / Repacked : If minor issues are present.
  - Destroyed : If product is damaged, expired, or unsafe.

⑤ Documentation

- All documents are properly recorded.
- Records must be maintained for future reference & audit.

DRUG RECALL

- Drug Recall is the process of removing or withdrawing a defective or potentially harmful product from the market by the manufacturer or regulatory authority to protect public health.
- It doesn't include the normal removal of products that have passed their expiry period.

TYPES OF RECALL

Product Recall can be of two types:

1. Voluntary Recall
2. Statutory Recall

1. VOLUNTARY RECALL

- The company itself initiates the recall of the product.
- It is done when the company identifies a defects or safety issue.

2. STATUTORY RECALL

- The recall is ordered by regulatory authority (CDSCO)
- It is compulsory & legally enforced.
- Done when the product violates safety or quality standards.

REASON FOR DRUG RECALL

- Quality defects (e.g., contamination, wrong composition)
- Adverse effects or safety issues
- Labeling or packaging errors
- Regulatory non-compliance

Classes Of Drug Recall

① Class I (Serious Risk)

- These are products that may cause serious health problems or death.
- They require immediate recall.

② Class II (Moderate Risk)

- Products that may cause a temporary or medically reversible health effects with low risk of serious harm.
- Recall is important but not extremely urgent.

③ Class III (Minor Defects)

- Products that are not likely to cause any health risk, usually related to minor defects like labelling or packaging errors.
- Doesn't cause significant health effect.

Steps In Drug Recall

- Identification of defective product
- Decision to recall
- Inform regulatory authority
- Notify distributors & retailers
- Withdraw product from market
- Documentation & final report

WASTE DISPOSAL

Waste disposal is the process of collecting, treating & safely disposing of waste materials generated during p'ceutical manufacturing to protect health & the environment.

TYPES OF PHARMACEUTICAL WASTE

① Solid Waste: Packeging materials, paper, plastics
② Liquid Waste: Chemical solutions, Solvents
③ Biological Waste: Cultures, Contaminated materials
④ Hazardous Waste: Toxic, flammable, or reactive substances

STEPS IN WASTE DISPOSAL

① SEPARATION OF WASTE

- Waste is separated based on type (solid, liquid, hazardous).
- Different colour-coded containers are used.
- Prevents mixing of hazardous & non-hazardous waste.

② COLLECTION & STORAGE

- Waste is collected in labelled containers.
- Stored in designated areas under controlled conditions.
- This avoids leakage & contamination.

③ Disposal

- Waste is disposed using following methods:
  - Incineration: Burning of waste at high temperature
  - Landfill: Disposal of non-hazardous waste in land
  - Chemical treatment: Neutralization of chemical waste
  - Autoclaving: Steam sterilization of biological waste

④ Documentation

- All waste disposal activities are recorded.
- Records are maintained for regulatory compliance.

DOCUMENTS

- Documents are written records that provide evidence of activities performed in pharmaceutical manufacturing & quality control.
- They ensure traceability, consistency & compliance with GMP (Good Manufacturing Practices)
- Some common documents include:

1. Batch Formula Record
2. Master Formula Record
3. Standard Operating Procedure
4. Batch Packaging Record
5. Validation Protocols

OBJECTIVES OF DOCUMENTATION

- To maintain product quality & safety
- To provide proof of compliance with regulatory requirements
- To ensure traceability of every step
- To avoid errors & mix-ups.
- To facilitate investigation & audits

MASTER FORMULA RECORD

- MFR is an authorized, approved document that contains complete instructions for manufacturing a specific p'ceutical product.
- It is prepared by R&D Department of the company.
- It serves as a standard reference document for preparing Batch Manufacturing Records (BMR).

PURPOSE OF MFR

- To ensure uniformity in production
- To maintain consistent product quality
- To minimize errors & deviations
- To provide a standard guideline for operators
- To comply with GMP requirements.

CONTENT OF MFR

- Master Formula Record (MFR) is a complete document that provides all instructions & details required for manufacturing a p'ceutical product.
- It includes following details:

① Product Details

This section includes basic identification & description of product:

- Name, logo & address of manufacturing company
- Dosage form
- Brand Name
- Generic Name
- Product Code
- Label claim (Amount of API + Excipients)
- Product description (colour, shape, appearance)
- Batch Size
- Pack size & packaging style
- Shelf life
- Storage conditions (temperature, humidity, light)

② Document Identification & Authorization

It includes:

- MFR number & date
- Superseded MFR Number (previous version)
- Effective Batch Number
- Approval by Production & QA head
- It ensures control & traceability

③ Flow Chart

- It includes flowchar of manufacturing process.
- It shows steps from dispensing → processing → final product → storage
- This helps in easy understanding of process flow.

④ Equipment Details

- This section contains list of all equipment & machines used
- Equipment identification Number
- Capacity of each equipment
- This ensures correct equipment usage

⑤ Special Instructions / Precautions

- It includes safety precautions during manufacturing.
- Special instructions for handling materials.
- This helps in maintaining safety & quality.

⑥ Calculations

- It includes calculation of active ingredients.
- Adjustment using LOD/water content for 100% potency.

⑦ Manufacturing Process

- It includes step-by-step manufacturing process like:
  - Mixing / blending steps
  - Granulation (if any)
  - Drying condition
  - Compression or filling
  - Environmental conditions (temperature, humidity)
  - This is the core part of MFR

⑧ Packing Process & Yield

- It includes list of packaging materials, quantities & label details.
- MFR also includes expected output of product which helps in checking losses & efficiency.

Preparation Of MFR

- Preparation of MFR means creating a standard document that contains all instructions required to manufacture a product.
- It is prepared by R&D team or F&D department in collaboration with Production Department.
- It is reviewed & approved by Quality Assurance Department.
- It is prepared by qualified staff like manufacturing or analytical chemists based on experience.

Steps To Prepare MFR

- MFR should be devided into Two parts
  - Manufacturing Part
  - Packaging Part
- Now following details are added step by step:

① Product Information
② Manufacturing formula
③ Manufacturing Process
④ Equipment details
⑤ Special instructions
⑥ Calculations
⑦ Quality Checks & Yields
⑧ Packaging instructions

RESPONSIBLE DEPARTMENTS

① Primary Responsibility: F & D and Production Department

② Secondary Responsibility: Quality Assurance Department

ACCOUNTABILITY

- Head - Quality Assurance shall be responsible for implementation of SOP.

BATCH MANUFACTURING RECORD

- Batch Manufacturing Record (BMR) is an official written document that contains complete step-by-step instructions & records for manufacturing a specific batch of a product.
- It ensures that product is consistency manufactured & controlled according to approved procedures (MFR).
- It can be knows as BFR

PURPOSE OF BMR

- To maintain complete traceability of each batch
- To serve as an official & legal document
- To facilicate investigation of errors & complaints
- To provide accountability & responsibility
- To ensure compliance with GMP

CONTENTS OF BMR

- BMR contains information from actual manufacturing operations performed based on MFR.
- It contains following details as followed:

① PRODUCT INFORMATION

- Name of the Product
- Dosage form (e.g. Tablet, Capsule, liquid)
- Strength of the product
- Batch Number
- Batch Size

② List Of Raw Materials

- Name of each raw materials
- Specified quantity required
- Material identification / code number
- Weighing & dispensing details

③ Manufacturing Instructions

- Detailed step-by-step manufacturing procedure
- Equipment to be used
- Processing parameters such as temperature, time & speed

④ In-Process Controls

- Tests performed during manufacturing
- Critical parameters such as:
  - Weight variation
  - pH
  - Hardness (for tablets)

⑤ Yield Details

- Theoretical Yield
- Actual Yield obtained
- Percentage yield calculation

⑥ Equipment Details

- Name & identification
- Equipment Number
- Equipment cleaning records

⑦ Signatures & Approvals

- Signature of the operator
- Signature of the Supervisor
- Approval by the Quality Assurance (QA) Department.

STANDARD OPERATING PROCEDURE

A Standard Operating Procedure (SOP) is a written & approved document that provides step-by-step instructions to perform a specific task in a consistent, safe & controlled manner.

PURPOSE OF SOP

- To ensure uniformity in work
- To maintain product quality
- To reduce errors & variability
- To ensure compliance with GMP/GLP guidelines
- To provide training guidance for employees

TYPES OF SOP

① Operational SOP: Equipment operation, Safety instructions

② Cleaning SOP: Equipment & area cleaning.

③ Quality Control SOP: Testing & Sampling.

④ Maintenance SOP: Equipment Servicing.

⑤ Safety SOP: Handling hazards & emergencies

CONTENTS OF SOP

A well-designed SOP contains the following sections:

① TITLE PAGE

- Title page includes:
  - Title of the SOP
  - SOP number (unique code)
  - Version or revision number
  - Effective Date

② PURPOSE

- This section explains why the SOP is prepared.
- It describes the objective of the procedure in a clear & concise manner.

③ RESPONSIBILITY

- This section defines roles & duties of personnel; such as:
  - Operator: Performs the tasks
  - Supervisor: Checks & Verifies
  - Quality Assurance (QA): Approves & Ensures compliance

④ MATERIALS & EQUIPMENT

- This section list all materials, tools & equipments required to perform the task.

⑤ PROCEDURES

- This is the most important part of the SOP.
- It includes:
  - Step-by-step instructions
  - Sequence of operations
  - Process conditions (time, temperature etc.)
- The procedure must be written in clear, simple & logical steps.

⑥ SAFETY & PRECAUTIONS

- This section provides safety instructions to protect personnel & equipment.
- It includes information such as:
  - Use of PPE (gloves, masks, goggles)
  - Handling of hazardous materials

⑦ DOCUMENTATION & RECORDS

- This section specifies what records must be maintained.
- Examples: Logbooks, Checklists etc.

⑧ DEVIATIONS & CORRECTIVE ACTIONS

- It explains what to do if any error or deviation occurs during the process.
- It also includes corrective & Preventive Actions (CAPA).

⑨ Approval Section

- This section ensures that the SOP is official & authorized.
- It includes information such as:
  - Prepared by
  - Reviewed by
  - Approved by

Characteristics Of A Good SOP

- Clear & easy to understand
- Step-by-step format
- Written in simple language
- Approved by QA
- Regularly reviewed & updated.

QUALITY AUDIT

- Quality Audit is a systematic, independent & documented examination of activities, processes & records to verify whether they comply with approved procedures (SOPs), GMP guidelines & regulatory requirements.
- It is a process of checking whether work is being done correctly & according to standards.

OBJECTIVES OF QUALITY AUDIT

- To ensure compliance with GMP & Regulatory guidelines.
- To verify that SOPs & Procedures are properly followed.
- To identify errors, deviations & non-compliance
- To improve quality systems & processes
- To ensure product safety, quality & consistency

TYPES OF QUALITY AUDIT

It can be classified into 3 types:

1. Internal Audit
2. External Audit
3. Regulatory Audit

① Internal Audit

- It is conducted by the company itself.
- It helps in regular monitoring & improvement.

② External Audit

- It is conducted by clients, suppliers or third parties.
- It ensures business & quality requirements are met.

③ Regulatory Audit

- It is conducted by government authorities.
- Example: Inspections by FDA, CDSCO
- It ensures compliance with legal standards.

Scope Of Quality Audit

- A quality audit may cover the following areas:
  - Production / Manufacturing
  - Quality Control (QC) laboratory
  - Quality Assurance (QA) System
  - Documentation (SOPs, BMR, Records)
  - Equipment & Maintenance
  - Personnel training & hygiene
  - Storage & Distribution

Steps Involved In Quality Audit

- Planning: Preparation of Audit Schedule & Checklist.
- Execution: Actual inspection of processes, records & facilities.
- Observation: Identification of deviation, errors, & non-compliance.
- Reporting: Preparation Audit Report.
- CAPA: Actions taken to correct & prevent future issues.

Advantages Of Quality Audit

- Improves overall quality system
- Reduces risk of errors & defects
- Ensures regulatory compliance
- Enhances process effeciency
- Supports continuous improvement

QUALITY REVIEW

- Quality Review is a periodic evaluation of processes, products & records to ensure that they meet quality standards & regulatory requirements (GMP).
- It simply means regularly checking whether everything is working properly & producing quality products.

OBJECTIVES OF QUALITY REVIEW

- To ensure consistent product quality
- To review manufacturing & control processes
- To identify trends, deviations & problems
- To improve process performance
- To ensure compliance with GMP

ELEMENTS OF QUALITY REVIEW

- Review of batch records (BMR / BFR)
- Review of deviations & CAPA
- Review of complaints & Recalls
- Review of stability data
- Review of analytical results (QC data)
- Review of yield & process consistency.

IMPORTANCE OF QUALITY REVIEW

- Helps in continuous improvement
- Detects repeated problems (trends)
- Ensures product safety & quality
- Supports regulatory inspections.

QUALITY DOCUMENTATION

- Quality Documentation refers to all written records & documents that describe & prove that activities are performed according to GMP & approved procedures.

OBJECTIVES OF QD

- To ensure compliance with GMP
- To provide evidence of performed activities
- To maintain consistency & standardization
- To ensure traceability of all operations
- To support audits & inspections.

TYPES OF QD

Quality documentation mainly includes two categories:

① Documents

② Reports

① DOCUMENTS

- Documents are written & approved instructions that describe how an activity should be performed.
- They act as guidelines or instructions:
- Example: - SOP (Standard Operating Procedure)
  - MFR (Master Formula Record)
  - Specifications
  - Protocols

② REPORTS

- Reports are written records that show the results, findings or outcomes of activities performed according to documents.
- They act as proof or evidence.
- Examples : – Batch Manufacturing Record (BMR)
  - Validation reports
  - Audit reports
  - Investigation reports
  - Test / Analysis reports

IMPORTANCE FOR QD

- Ensure regulatory compliance (GMP)
- Provides evidence during audits
- Helps in investigation of errors
- Maintains product history & traceability

DISTRIBUTION RECORDS

- Distribution records are documents that keep complete details about how & where a p'ceutical product is distributed after manufacturing.
- It is generally maintained by Warehousing Department.

DETAILS IN DISTRIBUTION RECORDS

Distributions records usually include:

- Name, strength & dosage form of product
- Batch / Lot Number
- Total quantity distributed
- Date of distribution
- Name & address of Recipient (Wholesaler, distributor or pharmacy)
- Transport details
- Storage Conditions

IMPORTANCE OF DISTRIBUTION RECORDS

- To track movement of products from manufacturer to market.
- To help in product recall if any problem occurs
- To ensure transparency & accountability
- To maintain regulatory compliance.

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