UNIT-4

LECTURE-2

PHARMACEUTICAL PRODUCT RECALL

- RECALL STRATEGY: A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for recall.

- DEPTH OF RECALL: Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer.

RECALL NUMBER: Number assigned for each recalled product by a responsible centre. This number consists first of a letter designating the responsible centre (letter codes), a 3-digit sequential number indicating the number of recalls. Initiated by that centre during the fiscal year, and a 1-digit number indicating the fiscal year the recall was initiated.

For e.g., F-100-2 identifies the 100th recall initiated by the Centre for Food Safety and Applied Nutrition in FY-2002.

Letter	Centre/Office
F	Foods-CFSAN
D	Drugs-Centre for Drug Evaluation and Research (CDER)
Z	Medical Devices & Radiological Health-CDRH
V	Veterinary Medicine- Centre for Veterinary Medicine (CVM)
B	Biologics-Centre for Biologics Evaluation and Research (CBER)
N	Medical Devices (Voluntary Safety Alerts and Notifications)
A	Audit Numbers issued by the District performing the recall, the Centres, Office of Enforcement Division of Compliance Management and Operations [DCMO], or the Division of Field Investigation [DFI] to monitor recalls requiring audit checks.

RECALL TEAM

The Team is responsible for co-ordinating all aspects of the product recall. A recall coordinator, is to be appointed and members of a recall team identified from the various functional areas. Together the team will assist the Recall Coordinator in the event of the recall.

The Recall Management Team list shall be updated at least four times a year to ensure all names, contact phone numbers and responsibilities of team members

Name	Alternate person	Business phone	After hours phone	Responsibilities during recall
Chief Executive Officer	Production Manager			➢ Decision making ➢ Media communication ➢ Contacting accounts ➢ CFIA/Health departments contact ➢ Obtaining legal counsel
Q.A Manager	Production Manager			➢ Q.A/Technical advisory ➢ Complaint investigation ➢ DFIA/Health departments contact

LIST OF FORMS REQUIRED FOR RECALL

- Notification of Withdrawal
- Notification of Recall
- Recall Log
- Problem Report
- QA Incident Hold Form
- Receiving Log
- Shipping Log
- Recipe(s)

Process Flow of Statutory recall

Initiated by DDA

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Received by Manufacturer/Authorized Importer

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Communication to Distributors/Wholesalers / Retailers (as applicable)

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Distributor / Wholesalers calls back the distributed quantity of product / batch

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Receipt, labeling & storage of recalled stock

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Investigation of Product / Batch by QA

↓

Root Cause Identification, CAPA & Documentation

↓

Communication of Investigation findings

↓

Reconciliation & Disposition of recalled batch (if any)

↓

Closure of recall

VOLUNTERY RECALL BY MANUFACTURERS :

Identification of a potential non-compliance Issue

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Communication to QA

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QA to take decision on recall as per the SOP of the manufacturing firm

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Inform DDA where product is marketed

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Recall log-in by QA

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Communication to Distributor / Wholesalers

↓

Distributor / Wholesalers calls back the distributed quantity of product / batch (es)

↓

Receipt, labeling & storage of recalled stock

↓

Investigation of Product / Batch by QA

↓

Root Cause Identification, CAPA & Documentation

↓

Communication of Investigation findings

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Reconciliation & Disposition of recalled batch (if any) ⟶ Closure of recall

RECALL NOTIFICATION/ INSPECTION

- Potentially violative product which may lead/ has lead to a class I or class II recall, an inspection should be made to determine the root cause(s) of the problem(s). If the firm has failed to take appropriate preventive action, violations should be documented for possible regulatory action.

INSPECTION PROCEDURES

- To identify the root cause for the recall and assure the firm has implemented procedures to prevent it from reoccurring.
- Verify the steps taken were sufficient in depth and scope and reflect the correct conclusions about both the problem and correction.
- Determine if the firm conducted a failure analysis using techniques such as fault tree analysis or failure mode analyses, considering things such as the length of time the product has been manufactured and sold, complaints or returns for the same or similar problems, any reworking of product prior to release or distribution which may have been due to the same or similar problems and, process or personnel changes which occurred about the time the problem appeared.

For all recall inspections in addition to verifying the identification of the root cause:

1. Issue a notice of inspection (FDA 482)
2. Discuss the suspected problem with management and review the firm's complaint file.
3. Investigate all areas, control points and/or circumstances which may have a bearing on the product's deficiency.
4. Fully develop individual responsibility for the problem.
5. Review batch records, processing logs and/or other types of records for violative lots and associated lots.
6. Review and obtain copies of the firm's quality control/analytical data.
7. Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. If corrective action is not underway, determine the firm's timetable for achieving correction.
8. Determine what action the firm has taken or plans to take, and the time frames involved, regarding questionable product(s) remaining in commerce.

RECALL DECISION FOLLOW –UP

- If the firm has decided to recall, steps to be followed:

1. Management should obtain their FDA District's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers and the FDA.
2. Obtain an official sample of the recalled product.
3. Obtain a complete distribution list of all shipments of the suspect lot(s), including foreign distribution.
4. Obtain specimens or copies of all labels and labeling associated with the recalled product.
5. Obtain complete copies of all recall communications issued or planned including the text of phone conversations, and submit them to District's recall coordinator.
6. Advise the firm on handling the returned products. Coordinator must witness or otherwise verify the reconditioning or destruction of the products returned under the recall.

CORRECTIVE ACTION

1. Describe the corrective action taken to correct the immediate problem, e.g., redesign, modify SOP, process validation, etc.
2. Qualify / validate the corrective action.
3. Establish the responsibility to assure that the corrective action would be implemented and satisfactorily completed?
4. Action taken to prevent recurrence of the non-conformance, e.g., training, increased process monitoring, etc.
5. Information provided to those responsible for the areas in which the non-conformance occurred.
6. To determine changes needed in procedures and to validate and implement the changes.

RECALL PROCEDURE

1. **Recall alert**: A recall situation exists or is planned; a twenty four hour alert will be given to the firm by the authority.
2. **Recommendation for recall number**: A memorandum should be prepared as soon as the recall number is available & transmitted to the District co-ordinator through the supervisor.
3. **Recall product**: For each recalled product, provide: its name; type (eg: tablet, sugar coated); strength, size, form; route of administration; shipping or unit package; & a brief description of the product. Indicate whether it is a prescription (RX) or over the counter (OTC) product. If the health hazard is dependent on use, consult the firm's catalogue, the red book or similar sources for that information.

   Also provide: the brand name, name, address, of the responsible firm the on label; complete copy of all labelling (including product inserts or information sheets) should be documented.
4. **Code:** List all lot &/or serial number, product number, manufacturer numbers, etc which appears on the product or its labelling.
5. **Recalling firm/manufacturer**: Provide complete name & address of the recalling firm & identify the type of firm i.e., manufacturer, importer, own label distributor. Provide complete name & address of the manufacturer if different from the recalling firm.

6. **Reasons for re-call recommendation**: Provide detailed information as to how the product is defective & violates the related statutes.

a. Include any analytical findings in qualitative &/or quantitative terms, from the firm.

b. Provide inspectional (e.g. GMP) or other evidence, where appropriate.

c. List in chronological order any complaints, injuries, or associated problems with the product.

Explain all state involvement in the recall, including sample collection or the analysis, recall agreement or initiation, recall monitoring and product disposition.

7. **Volume of product in commerce**: Provide total product distributed, also estimated amount & availability of stocks remaining on the market, at all levels. Include product expiration dates or shelf-life expectancy.

8. **Distribution pattern**: Report the areas of distribution, the number of direct accounts, and the approximate percentage of each type of consignee. List foreign countries & government military &/or civil units/agencies to which products were distributed.

9. **Firm's recall strategy**: Describe the firm's planned recall strategy. The firm's strategy should include the intended course of action when an account which distributed the recalled product is found out of business. Include the date the recall was initiated.

10. **Firm official**: Report the name, title, location, & telephone number of the firm official to be contacted concerning the re-call.

11. **Audit program**: Report appropriate action taken & also provide details of any publicity issued or planned by the firm, the state or local government.

    Provide proposed program for monitoring the recall, include time table for reviewing the recall status.

12. **Monitoring recalls**:

I. *Inspections to monitor recall progress*: Re-inspect the firm between the initiation & close out of recall to monitor its progress & verify the recalled product's disposition.

II. *Recall audit checks*: A recall audit check is a personnel visit, telephone call, letter, or a combination there of to a consignee of a recalling firm or a user or a consumer in the chain of distribution. It is made to verify all consignees at the recall depth specified by the strategy have received notification about the recall & have taken appropriate action.