Unit 4-Complaints and Recalls

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CONTENT

- Complaints
- Evaluation of complaints
- Handling of return good
- Recalling
- Waste disposal

Complaints

WHAT ARE COMPLAINTS

‘Complaint’ is defined as a statement that something is wrong or not good enough.

Complaint is any communication, written or verbal, received directly from any customer, retailer, distributor, or representative of contract giver, regarding the quality attributes, labelling defects or any other matter. Such complaints shall be considered as market complaint.

For pharmaceutical companies, the GMP complaints are mainly confined to quality of a product, but it may also be about packaging material, such as ‘the bottle is leaking’, ‘the cap is difficult to open’, ‘the label color is fading’, ‘one tablet in the blister is missing’.

Whatever it is about, a complaint shows customer dissatisfaction about a product and, consequently, about a company.

CLASSIFICATION OF COMPLAINTS

1. A-Type Complaints Critical complaints in which product is required to be withdrawn from the market.

- Adverse Drug Reaction.
- Major health hazard causing permanent deficiency or death.
- Purity & Safety
- Potency
- Product Stability

2. B-Type Complaints Major complaints such as

- Problem with primary packaging of the product.
- Chemical / Physical attributes of the product.
- Extraneous contamination, mix-ups, etc.

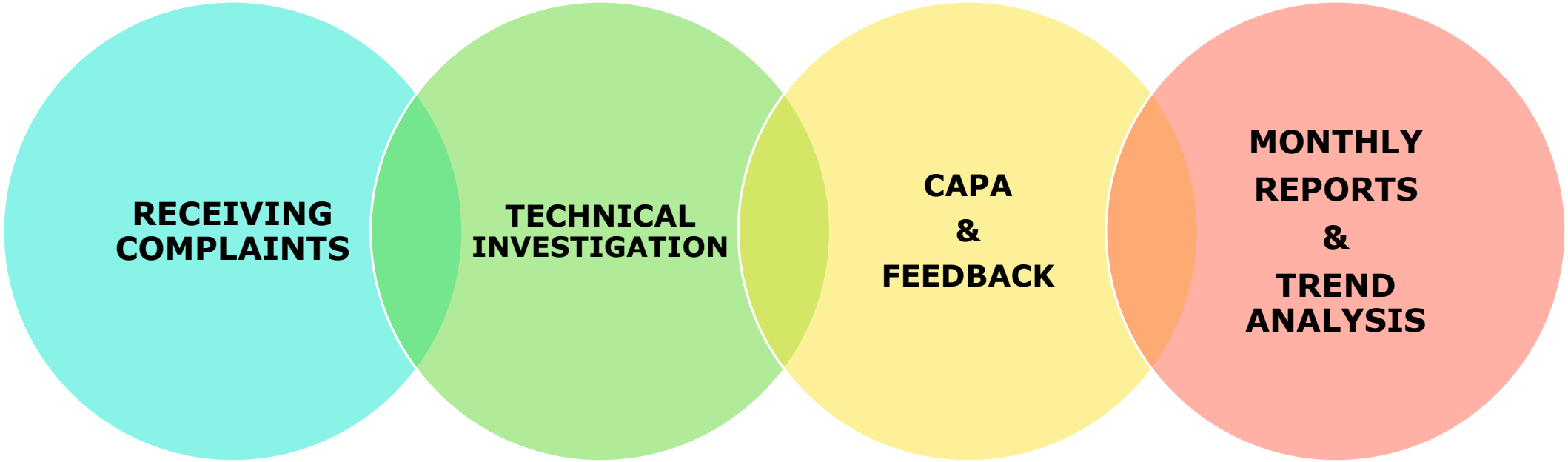
3.C-Type Complaints Minor complaints such as

- Problem related to labelling coding of batch details
- Shortages.
- Secondary packaging material problem, etc.

Responsibility

- Production Head
- Quality Assurance Head
- Unit Head.

STEPS TO DEAL WITH COMPLAINTS



STEP 1: RECEIVING COMPLAINTS

Open channels with customers in order to receive their suggestions, doubts and complaints.

These channels are toll-free numbers, e-mails, chatrooms

Most flexible channels are toll-free numbers and chat-rooms, since the customer is on-line and the company’s attendee can interview them getting a lot of details. If the complaint was sent by e-mail or to a P.O. box, the recipient must contact the customer by phone and start the interview.

Person in charge of receiving the complaints and inputting them into an appropriate investigation form that shall be addressed to the Quality Assurance unit for investigation.

The investigation form

- Basic information about the complainant, such as: name, address, phone number and e-mail
- Information about the product problem: product name, lot number, manufacturing and expiry date, detailed description of complaint, amount of product with problem and any additional information to note.

Each opened complaint should be assigned a code, e.g. a sequential and unique number, and the receipt date must be recorded

During the customer interview, it is beneficial to briefly outline the complaint handling procedure to the customer, to let him/her know what will be done about the recently received complaint and what kind of feedback will be given to the customer when the investigation is completed.

company representative should request that the possibly defective product be sent to the company for further analysis.

STEP 2: TECHNICAL INVESTIGATION

Handled by Complaint Officer

Must have a comprehensive knowledge of the manufacturing process and QC analysis.

responsible for choosing the analytical approach that best fits investigating if the complaint is confirmed or not, and conclude the investigation. This employee is the contact person that links the QA unit to all others, such as Production, Quality Control, Marketing, Finance, Legal and Regulatory Affairs units in order to determine what really happened and what the implications are for both customer and company.

Phase 1: Documentation-based

Phase 2:Laboratory analysis

The documentation based investigation consists of:

- checking if this complaint occurred previously in the same lot
- if any non-conformance was found in the lot during its production that could explain the complaint.

The primary documentation to be reviewed in this step consists of the complaint files and the batch records.

Complaint files can be consulted to check how many other complaints of the same nature had occurred to a specific lot and how they were handled.

Batch records must be verified in order to see if there was any non-conformance during the production that can explain or confirm the quality deviation, and how it was investigated and concluded.

The laboratory analysis phase consists of requesting the Quality Control (QC) laboratory to analyse both complaint samples and retained samples – the reserve samples representative of the lot manufactured.

This means that, in parallel to the customer sample, which already passed through distribution and third-party holding, the QC laboratory is performing analysis on retained samples, which were kept under appropriate conditions of temperature, humidity and light so that the identity, strength, quality and purity of the drug product was not affected.

If the customer did not send the complaint sample for analysis, the laboratory investigation will be carried out only with retained samples.

After receiving the analytical results and after performing the documentation-based investigation, the QA unit is able to finish the complaint investigation.

3 possible conclusions

Conformed complaint

Non confirmed complaint

Counterfeit/tamper suspicion

CONFIRMED COMPLAINT:

When both complaint and retained samples show out-of-specification (OOS) results

or

when only the complaint sample showed OOS results, but it is clearly a single unexplained failing product.

An example of a single unexplained failure may be when one tablet is missing in the intact blister strip in the complaint sample, but no deviation was found in the retained samples or during the in-process controls and final QC analysis recorded in the batch record. But, as a quality problem was identified in the complaint sample, the complaint is classified as confirmed.

NON-CONFIRMED COMPLAINT:

When both complaint and retained samples show results in compliance with specifications

or

when only the complaint sample show OOS results that cannot be considered a single unexplained failing product.

OOS results in a complaint sample can be attributed to misuse or mishandling, when the drug product was not kept under appropriate conditions of temperature, humidity and light so that the identity, strength, quality and purity of the drug product could be affected.

Example of a non-confirmed complaint may be when the tablets of the complaint sample show a change in their appearance that is characteristic of a light, humidity or high temperature exposure.

This complaint is classified as non-confirmed because the quality problem appeared in the complaint sample due to a product mishandling and cannot be addressed to a manufacturing deviation, since the retained sample, kept under the appropriate conditions of temperature, humidity and light, did not show the same problem.

COUNTERFEIT/TAMPER SUSPICION

When the retained sample is within the specification but the complaint sample is clearly OOS with no reason for that, such as a counterfeit or tampered drug product.

An example of counterfeit is when packaging material is different from the original; an example of tampering is when the colour of the drug product is completely different from the original or when any foreign substance was added to the product.

The Legal Affairs unit and the Competent Authorities must immediately be informed for further arrangements.

The Complaint Officer must also check if the complaint represents a serious and unexpected adverse drug experience, which is required to be reported to the health authorities, according to the specific safety reporting regulations of the respective countries.

- The complaint officer and the QA Manager must sign off the investigation form once the investigation is completed.
- The time for concluding a complaint investigation and the retention time of complaint files depend on the regulations of each country (30 days is a reasonable time).
- Complaint files should be retained for at least 1 year after the expiry date of the lot

STEP 3: CORRECTIVE ACTIONS (CAPA) AND FEEDBACK TO CUSTOMERS

For all confirmed complaints, corrective actions must be implemented:

Simple and quick training to some employees to a formal Corrective Action and Preventive Action (CAPA) handling.

The criteria for choosing appropriate action depends on the nature of the complaint and the complaint incidence.

If a CAPA is opened, a multidisciplinary team consisting of following representatives must be established:

- QA
- QC
- Regulatory Affairs
- Production Management.

If a quality problem is found in a specific lot, it is important to investigate if the same problem is also present in other lots. Therefore, the company must evaluate if there is a reasonable probability that the use of or exposure to the product with the confirmed quality problem may cause permanent injury, is life-threatening or may lead to death or to a temporary but medically reversible health problem.

In these cases, a recall must be triggered

CAPA is a tool used in process developments for elimination of causes of non conformities or other undesirable conditions. It is a part of QMS.

7 basic steps of CAPA

1. Identification
2. Evaluation
3. Investigation
4. Analysis
5. Action plan
6. Implementation
7. Follow up

Feedback to the customer

- The company must write a response letter to the complainant to explain

  -Investigation approach taken

  -Results obtained

  -Implications, in case the quality problem was confirmed.

- The customer should also be sent a free replacement

STEP 4: MONTHLY REPORTS AND TREND ANALYSIS

Monthly reports should be elaborated in order to evaluate the amount and the nature of the complaints received and to perform a trend analysis of these complaints.

The monthly reports must answer the following questions:

- How many complaints did the company receive in the period?
- How many were confirmed?
- How many were non-confirmed or were counterfeit/tamper suspicion?

It is also important to know the ‘top 10 products’ which received the majority of complaints, the nature of these complaints, batches involved, the root causes of confirmed complaints, how many free offer products were given to customers (to reimburse for the ‘complaint samples’ returned for analysis) and how much the complaint handling cost the company.

Cycle-time of complaint investigation can also be monitored in order to shorten the feedback time to customers.

A controlled copy of the monthly report must be delivered to all staff engaged with complaints, as follows: QA, QC, Production Management, Marketing, Finance, Human Resources and Regulatory and Legal Affairs.

- If the complaint is about any imported product, the original manufacturer must be notified.
- The report must be readily available for Regulatory Agency Inspectors upon request, mainly during GMP inspections.

PRODUCT COMPLAINT DATA SHEET

- Serial number assigned to the complaints.
- Exact nature of the complaints.
- Name of the complainants.
- Address of the complainants.
- Date of complaint received.
- If verbal, name of the person who received the complaint.
- Name of the product, strength and batch number of the product.
- Reference to analytical record number.

- Quantity involved in the complaint.
- Size of sample obtained from the complainant.
- Evaluation of complaint by QC department.
- Materials and records used to perform evaluation.
- Other possible affected materials, products and results of their investigation.
- Name and signature of the investigator(s) and date.
- Action taken by the company.
- Copy of reply sent to complainant.

RECALL

Recall is an action taken to withdraw/remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality, efficacy or safety.

“Recall” does not include a “market withdrawal” or “stock recovery.

“Market withdrawal” –A firm’s removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., routine equipment adjustments and repairs, etc.

“Stock recovery” –A firm’s removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use

RECALL CLASSIFICATION

Class I: there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and as well as banned under 26A of Drugs and Cosmetics Act 1940.

Class II: the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III: the use of, or exposure to, a defective product is not likely to cause any adverse health consequences

TYPES OF RECALL

1.VOLUNTARY RECALL

It can be triggered by any incident that affects the quality, safety and efficacy of the batch/product in question such as

1. If the batch or batches are found to be not complying with the regulatory specifications during the post marketing stability study

2. If the batch is found to be defective during investigation of market complaint.

3. During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc).

4. If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation.

5. If the PMS reports /**pharmacovigilance** reports indicates that there is serious safety risk associated with the product.

"the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem."

2.STATUTORY RECALL

It can be triggered in response to the direction or mandate by the Drug Regulatory Authorities (Central/State) in situations like:

1. To recall the drug product/batch, considered to be in violation of the laws, it administers such as not of standard quality etc.

2. To recall the banned drugs.

3. Labeling and / or Promotional materials, that are considered to be in violation of law.

4. Product, violation Rule 106 (Diseases under Schedule J)

LEVELS OF RECALL

The level (or depth) of recall of a product/batch shall be determined based on recall classification and level to which distribution has taken place.

i. Consumer or User Level: Consumer or user may include individual consumers, patients, physicians and hospitals.

ii. Retail Level: recall to the level immediately preceding consumer or user level. It includes retail stores, pharmacies, hospital pharmacies, dispensing physician, institutions such as clinics and nursing homes, etc.

iii. Wholesale Level: all distribution levels between the manufacturer and retailer

All Class I recalls shall be executed to the levels of Wholesale/Distributors, retail, and consumer. In such cases, public announcements shall be made using print/electronic media aids viz. Newspapers, Television, Radio etc.

All Class II recalls shall be executed up to the levels of wholesale and retail.

All Class III recalls shall be executed up to the levels of wholesale

TIME LINES FOR EFFECTIVE RECALL SYSTEM & RAPID ALERT

Class I: Within 24 hours up to a maximum of 72 hours

Class II: Maximum of 10 days

Class III: Maximum of 30 days

The recall has to be initiated immediately without any prejudice of the outcome

PROCEDURE FOR RAPID ALERT & RECALL SYSTEM

As soon as the product/batch(es) to be recalled is/are identified, licensee or representative of licensee or QA in charge shall review the information related to the defective product/batch(es) and decide about recall as per the procedure established.

Within 24 Hours of the decision taken for the recall of the product/batch(es) the communication shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, fax, SMS etc to the entire supply chain.

The licensee/representative of licensee where the product is marketed shall inform the concerned regulatory authorities where the product batch(es) in question was distributed immediately after the decision of recall has been taken. Further actions on recall will be undertaken according to class of recall.

It shall be the responsibility of the manufacturer and marketing company to inform up to retail level on the reason of recall in his freeze stock notice.

It shall be the responsibility of distributor/marketing company/ retailer to inform the stock position of product being recalled to his immediate supplier or manufacturer and also his area Drugs Inspector.

The recall notice received, the stock at that time, the procedure for freezing the stock and returned back records shall be maintained by the distributor/retailer and shall be made available for verification by area Drugs Inspector who shall verify and report on its timely freezing and return

STEPWISE RECALL PROCEDURE

The licensee/representative of licensee/Quality Head in charge shall enter the details in the ‘Recall Log’ and assign a unique recall reference number.

“Product/batch Recall Notice” shall be filled and sent by licensee/representative of licensee/ Quality Head in charge to Distributor / Marketing Company.

Distributor / Marketing Company shall immediately check the distribution record to identify the Customers and Warehouse, depots where the subject product / batches have been distributed and forward the copies of the Recall Notice to them for further necessary action.

The Head of depot(s) shall fill ‘Recall Notification’ and forward it to all distributors to return all unsold stock. Simultaneously, the Heads of respective depots /ware houses shall block the available stock. The Distribution Head shall ensure the blockage of stock for further sale by reviewing the record.

The distributor(s) shall send the “Return Feedback” along with goods (if any) to the depots. All the returned stocks shall be further forwarded to the ware houses.

The Head of ware houses shall send a periodical report to licensee/representative of licensee /QA head of the stock available with them and the returns received from depots.

Head of ware house shall reconcile the stocks of the recalled materials against the total quantity of distributed material and fill the “Summary Report of Product / Batch Recall”. The copy shall be forwarded to licensee/representative of licensee/QA in charge for review and necessary action.

FOLLOW-UP ACTION OF RECALLED GOODS

The follow-up action consists of a check on the effectiveness of the recall, an investigation of the reason for the recall and remedial action taken to prevent a recurrence of the defect.

The licensee/representative of licensee/QA Head shall monitor the recall process of product/batch to determine whether the recall is progressing satisfactorily.

The stocks of recalled goods shall be placed under “Quarantine” and stored separately under lock and key in a secure area until further decision. Wherever required, QA Head of the manufacturing site shall perform the physical inspection of recalled goods and collect sample from recalled goods for investigation to establish the root cause of the product quality defect.

The investigation of the recalled batch(es) shall be conducted as per the SOP of the licensee, on “Investigation of Non-conformities” to identify the root cause of the failure and initiate corrective and preventive actions.

Impact assessment shall be conducted on other batches of the concerned product and further extended to batch(es) of other product(s), wherever applicable.

If the cause of recall is established to be quality issue associated with any of the raw material used, then the traceability of that material shall be established in all the product/batches.

Monitoring the relevant data i.e. Material, Plant and Batch Number in respective Identify the raw material traceability in different formulations and its functions.

List all raw materials along with batch numbers and the respective quantities used in those batches.

List all the products along with batch numbers and the respective quantities used in those batches.

Calculate the total quantity by adding individual quantities used in various products / batches.

Monitoring of the material movement to get the complete overview of stock for that particular material in the plant and extract the information about total quantity received and the balance quantity.

The balance stock, if any shall be verified against the actual physical stock available.

QA shall block the remaining available stock.

All material shall be accounted for after the reconciliation.

The decision to recall, if necessary, any of the impacted batches shall be made after product quality assessment.

Based on conclusion of the investigation findings, the QA Head / representative of licensee shall direct the Distributor / Marketing Company for appropriate disposition of the batch(es) of the recalled goods as per the regulations.

MOCK RECALL

Mock recall shall be carried out for **at least one batch of any product**, dispatched for sale where maximum distributors are involved, to test the effectiveness of the arrangements of recall.

During mock recall traceability shall be performed for at least, one of the raw material used in the batches identified for mock recall.

Mock Recall shall be performed at least once for the longest distribution chain and whenever there is a change in distributor/marketing company.

Records of such mock recall should be maintained by the QA Head of the company.

Effectiveness of recall procedure can also be checked by ‘evaluation of a real recall’.

RETURNED GOODS

Reasons for returning products/goods

Quality problems

Accidental damage

ACTION TO BE TAKEN ON RETURNED PDTS

Physically examine the returned products. Check all the documents

Ask Q.C. dept. to evaluate quality of returned products.

Evaluate all aspects.

Take decision: Reprocessed and Recovered? Destroyed?

If it is possible to reprocess and recover, then such products after reprocessing and retesting may be considered for relabelling, repacking and resaling the same.

DISPOSAL OF RECALLED PRODUCTS

QA shall inform and update FDA for recalled products wherever applicable.

After FDA clearance, QA shall arrange disposal of the batches according to investigation findings, which may be repacking or destruction based on reason for product recall.

QA head shall decide the disposal of the recalled product in consultaion with plant head and QC head within 30 days after receipt of last consignment recalled product at plant warehouse.

Perform destruction as per respective SOP in presence of QA representative and security person and document the same as per procedure and record the same.

THANK YOU

http://www.jiwaji.edu/pdf/ecourse/pharmaceutical/Complaints%20and%20Recalls%20B%20Pharm%20VI%20%20%20sem%20BY%20Dr%20Abhishek%20Pandey.pdf

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/4GuidelineRecalRapidAlert.pdf