

COMPLAINTS

A 'Complaint' simply designates, that something is wrong or not good enough. Generally, in the pharmaceutical industry, complaints are regarding the quality of drug product. A complaint shows customer dissatisfaction about a product and consequently, about a company.

Principle

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All complaints and other information concerning potentially defective products should be carefully reviewed according to written procedures and the corrective action should be taken.

NEED FOR COMPLAINT HANDLING SYSYTEM

- It gives the company an opportunity to improve the quality of the product.
- It is helpful to maintain cGMP.
- It maintains committed relationship between the customer and company.
- It is the regulatory obligations.

Objective

To immediately recall, investigate or to take remedial measures against the defective product.

Responsibility

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The quality manager along with manager of the complaint related department.

TYPES OF COMPLAINTS

Basically it's of three types

- 1. Quality Complaints:** originate at consumer level and concern with physical, chemical and biological properties or condition of labeling and/or packaging of the product.
- 2. Adverse reaction Complaints:** Due to allergic reactions of any other untoward reaction or fatal reaction or near fatal reaction.
- 3. Other medically related Complaints:** Include Complaints such as lack of efficacy or clinical response.
 - Time period for investigation after receipt of complaints:
 1. Product quality complaints- within 10 days
 2. Adverse reaction complaints- within 5 days
 3. Medical complaint- within 3 days
 - Complaint records shall be maintained at least one year after expiration date of medicines. Complaint records shall be reviewed and a monthly summary shall be prepared for the management.
 - Also the complaints are categorized as following
 - ✓ CRITICAL DEFECTS
 - ✓ MAJOR DEFECTS
 - ✓ MINOR DEFECTS

Critical Defects

- Those defects which can be life threatening and require the company to take immediate action by all reasonable means, whether in or out of business hours.

- Examples
 - ✓ Product labelled with incorrect name or incorrect strength.
 - ✓ Counterfeit or deliberately tampered with product.
 - ✓ Microbiological contamination of a sterile product.

Major Defects

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- Those defects which may put the patient at some risk but are not life-threatening and will require that batch recall or product withdrawal within a few days.
- Examples
 - ✓ Any labeling/leaflet misinformation (or lack of information) which represents a significant hazard to the patient
 - ✓ Microbial contamination of non-sterile products with some risk for patients.
 - ✓ Non-compliance to specifications (e.g. active ingredients assay).

Minor Defects

- Those defects which present only a minor risk to the patient-batch recall or product withdrawal would normally be initiated within a few days.
- Examples
 - ✓ Readily visible isolated packaging/closure faults.
 - ✓ Contamination which may cause spoilage or dirt and where there is minimal risk to the patient.

Key points for handling Complaints

- Don't take it personally.
- Never act on a complaint without hearing (at least) two sides to the story.
- Say what you will do and do what you say; set the time frame
- Keep notes

Contents of a product complaint data sheet

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

Steps involved in handling of complaints

1. Receiving Complaints

It is important to have a open channels with customers in order to receive their suggestions, doubts and complaints. Generally, these channels are toll free number, e-mails, chat rooms and P.O. boxes. Whatever the channel, it is necessary to have a 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.

2. Technical Investigation

upon receipt of the investigation form, the QA unit is able to start the investigation, which can be divided into two phases: DOCUMENTATION-BASED and LABORATORY ANALYSIS.

Documentation-based investigation-Consists of checking if this complaint occurred previously in the same lot or 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.

Laboratory analysis phase- Consists of requesting the Quality Control (QC) laboratory to analyze both complaint samples and retained samples- the reserve samples representative of the lot manufactured.

If the customer did not send the complaint sample for analysis, the laboratory investigation will be carried out only with retained samples. Similar to the receiving step, it is fundamental that the company elects a person in the QA unit to be in charge of technical investigation of each complaint, **e.g.** Complaint Officer.

After receiving the analytical results, there are three possible conclusions, as follows:

- I. Confirmed Complaint
- II. Non-Confirmed complaints
- III. Counterfeit/Tamper suspicion

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3. Corrective Actions and Preventive Actions

Corrective Actions: eliminate detected non-conformity

- It aims to correct an existing non-conformity and to avoid reoccurrence of the same non-conformity.
- Examples: arises from manufacturing deviations, OOS investigations, complaints audit findings, recalls.

Preventive Actions: Prevent Non-Conformity occurrence

- It aims to avoid the initial occurrence of a non-conformity by pro-actively implementing improvements.
- Examples: results from trending in process data, of analytical data, of audit findings, trending of root causes for non-conformities or complaints, from product quality reviews (annual product reviews), quality risk analysis.

For all confirmed complaints, corrective actions must be implemented. these actions can range from a simple and quick training to some employees to a formal Corrective action and Preventive active (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 representatives of QA, QC, Regulatory affairs and Production Management must be established.

Concerning non-conformed complaints originating from the misuse or inadequate handling of the drug product, even if there is no need for internal corrective actions, corrective measures should be implemented to provide orientation to the customer.

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Regarding counterfeit or tampered suspicious complaints, a response letter should also be sent to the customer, but the legal affairs unit must be copied for further arrangements.

4. Feedback to Customers

As feedback to the customer, the company must write a response letter to the complaint to explain the investigation approach taken, the results obtained and any implications, in case the quality problem was confirmed. The customer should be sent a free replacement product together with the response letter, since the customer returned to the product (the Complaint Sample) to the company for analysis and a quality problem was found.

5. 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.

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Recordings of Complaints

It is the responsibility of the in-charge, Quality control to see that each complaint is recorded, evaluated and reported to the management. Records of complaints should include the following information:

1. Content Complaints - these should Include:

- Name, dosage form, package form, batch no.
- Date and the place of occurrence of complaints
- Cause of complaints
- Name and address of complaint in detail

2. Results of investigation – These should include:

- Regarding market place, circulation condition and condition in which the defect was observed.
- Results of investigation of analysis and testing records, production and storage records

3. Evaluation

4. Follow up measures – It includes:

- Reply to the complainant.
- Remedial action so that complaint of this type should not reoccur.

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