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Review Article

Systematic Approach for Complaint Handling in Pharmaceutical Industries- An Updated Review

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ABSTRACT

This article covers fundamental basics of quality complaint. Complaints show customer dissatisfaction about the quality of a pharmaceutical Product. Complaints may be about: Services, delivery, quality of product, communication, response time, documentation, billing, follow up etc. a good complaint handling system gives the company an opportunity to improve the quality of their products, being a good tool for the maintenance of Good Manufacturing Practices. A systematic procedure must be developed and implemented in order to register and investigate each complaint received and not only the Quality Assurance area must be involved. Systematic handling of complaints maintains a good relationship between customer and company. Thus the aim of this article is to discuss the main steps of a good complaint handling procedure that can be readily implemented in pharmaceutical companies.

Keywords: customer, complaint, customer satisfaction, corrective action, GMP

INTRODUCTION

'Complaint' is defined as a statement that something is wrong or not good enough. Generally in the pharmaceutical industry, complaints are regarding the quality of drug product. Complaints can be about packaging material, such as 'the bottle is leaking', 'the cap is difficult to open', 'the label colour is fading', 'one tablet in the blister is missing' or concerning the product's aspect and effect, such as 'there is no effect', 'the tablet or solution colour is different', 'the tablet is broken' and so on. Whatever it is about, a complaint shows customer dissatisfaction about a product and, consequently, about a company[1].

Who is the customer? Customers could be internal or external. An internal customer is someone within your company who uses your product or services. And an external customer is an outside organization or individual that receives a product or service from company. If customer dissatisfied with your service, they will complain. 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 [2].

Customer complaints are a fact of life in business, and dealing with them is an important part of maintaining customer satisfaction and company reputation. It finds that customer dissatisfaction through two mechanisms: Voice and Exit. If customer makes "Voice" they do complaints. "Exit" occurs when the customer stops using our products or services. To provide better customer service is a way of retaining the

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PHARMATUTOR
PHARMACY INFOPEDIA
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customer. Good customer service is important for ensuring that customers are satisfied [2].

"Recall"
–A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.
– "Recall" does not include a "market withdrawal" or "stock recovery.

"Correction"
–The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

"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., normal stock rotation practices, 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 [3].

Recall Classification Scheme [3].
• Class I Recall –
A situation in which there is a reasonable probability that use of, or exposure to, a violate product will cause serious adverse health consequences or death.

• Class II Recall –
A situation in which use of, or exposure to, a violate product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

• Class III Recall –
A situation in which use of, or exposure to, a violate product is not likely to cause adverse health consequences.

Thus, the aim of this article is to discuss the main steps of a good complaint handling procedure that can be readily implemented in pharmaceutical industries. The proposed handling system is in compliance with the GMP Guidelines of EU, USA, Brazil (ANVISA) and is presented in four steps: receiving complaints; technical investigation; corrective and preventive actions (CAPA)/feedback to customers; and monthly reports/trend analysis[1].all of which are represented below and summarized in the Flowchart 1.

CLASSIFICATION OF COMPLAINTS[2]

1. A-Type Complaints
Critical complaints in which product is required to be withdrawn from the market. Such as
• 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.
• b. Chemical / Physical attributes of the product.
• c. Extraneous contamination, mix-ups, etc.

3. C-Type Complaints
Minor complaints such as
a. Problem related to labelling / coding of batch details.
b. Shortages.

PHARMATUTOR
PHARMACY INFOPEDIA
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c. Secondary packaging material problem, etc.

Responsibility[2]

1. Production Head
2. Quality Assurance Head
3. Unit Head.

STEP 1:

RECEIVING COMPLAINTS

It is important to have open channels with customers in order to receive their suggestions, doubts and complaints. Generally, these channels are toll-free numbers, e-mails, chat-rooms. 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 (QA) unit for investigation. The 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. The investigation form must include basic information about the complainant, such as: name, address, phone number and e-mail. Information about the product problem is taken, such as: product name, lot number, manufacturing and expiry date, detailed description of complaint, amount of product with problem and any additional information to note. It is important that each opened complaint has a code, e.g. a sequential and unique number, and the receipt date must be recorded [4]. 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. Therefore, the company representative should request that the possibly defective product be sent to the company for further analysis. For the purposes of this article, this product will be called the 'complaint sample'. It should be documented on the investigation form if the complaint sample will be sent[1].

STEP 2:

TECHNICAL INVESTIGATION

Upon receipt of the investigation form, the QA unit is able to start the investigation, which can be divided in two phases: documentation-based and laboratory analysis. The 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. 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 [5]. 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. Similar to the receiving step, it is fundamental that the company elects a person in the QA unit to be in charge of

PHARMATUTOR
PHARMACY INFOPEDIA
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technical investigation of each complaint, e.g. a Complaint Officer. This person must have a comprehensive knowledge of the manufacturing process and QC analysis, since they will be 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. Therefore, these responsibilities must be included in the job description of the Complaint Officer. After receiving the analytical results and after performing the documentation-based investigation, the QA unit is able to finish the complaint investigation.

There are three possible conclusions, as follows [1]:

CONFIRMED COMPLAINT[1]:

When both complaint and retained samples showed 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[1]:

When both complaint and retained samples showed results in compliance with specifications or when only the complaint sample showed 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. An 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[1]:

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 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

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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; however, 30 days is a reasonable time to conclude an investigation. 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[1]:

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 Action (CAPA) handling. The criteria for choosing appropriate action depends on the nature of the complaint, if the deviation is a single unexplained failing product or not 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. 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. As feedback to the customer, the company must write a response letter to the complainant 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 the product (the 'complaint sample') to the company for analysis and a quality problem was found.

STEP 4:

MONTHLY REPORTS AND TREND ANALYSIS[1]:

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. Another interesting attribute to be monitored is the cycle-time of complaint investigation 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. Some companies also deliver the report to senior management staff. The report must be readily available for Regulatory Agency Inspectors upon request, mainly during GMP inspections. Therefore, these reports can be a major contributor to the Annual Product Review elaboration, since all data concerning complaints is presented month by- month in these reports.

PHARMATUTOR
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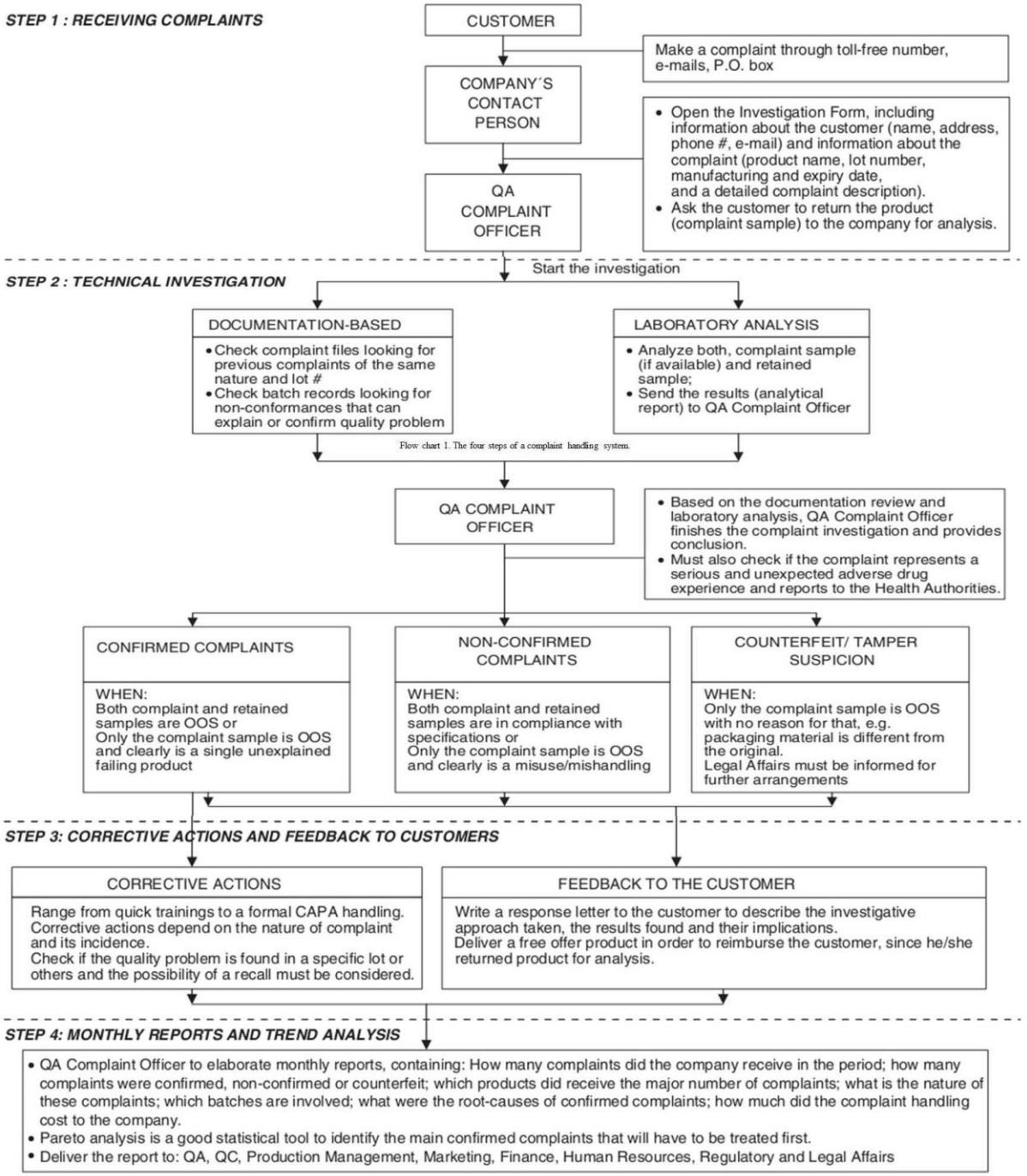

Flow chart 1. The four steps of a complaint handling system.

CONCLUSION

Complaints management is a complex problem in a unique industry and the issue promises to remain critical in the future. As a regulatory and market pressures continue to mount upon pharmaceutical companies, industry leaders will need to develop effective solutions or face the high cost inherent in

PHARMATUTOR
PHARMACY INFOPEDIA
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failed technology implementation, FDA censure and weak customer relationship. The preferred alternative is a customer-focused complaints management solution that works. And this present review reveals the various product complaints handlings in the pharmaceutical company for maintaining a good relationship between customer and company. A systematic approach to customer complaints handling increases levels of customer care, levels of customer satisfaction also monitoring of customer care**.** To get positive benefit from the complaint, it is need to have right procedure to receive, investigate and resolve complaints. Customer complaints are important for a company because they help make the company better.

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