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COMPLAINT MANAGEMENT SYSTEM OF FINISHED PRODUCTS IN PHARMACEUTICAL COMPANY- A GENERAL REVIEW

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ABSTRACT

Complaints are essential as they offer knowledge approaching the success of an organisation's services or products, facilitate to recognise attributes that need development, and promote to a better understanding about customer satisfaction and dissatisfaction. By reacting confidently to complaints, an organisation can upgrade its service provision. The complete complaint management outline to deliver a strong construction for accepting, evaluating, verifying, replying to, registering and working on complaints to enhance services to the public. An efficient procedure should be established and executed in sequence to record and examine each complaint accepted. Thus the aim of this article is to discuss the major phases of a valuable complaint handling procedure that can be easily executed in pharmaceutical companies.

KEYWORDS: Customer, Complaint, Complaint Handling.

INTRODUCTION

The management of all written and oral grievance concerning a pharmaceutical products will be founded and tracked. Such method will consist of requirements for evaluation of the products. Every compliant including the potential disappointment of a medication to gather any of its descriptions and, for such medicinal substance, a purpose to essential for an inspection. Such system shall consist of requirements for assessment to regulate whether the complaint signifies critical and unpredicted adverse drug reaction which is needed to be informed to Regulatory bodies.

A responsibility to appropriate complaint handling is required at all levels of an organisation. The head of the organisation, together with senior management, must have an effective complaint handling as a way of establishing the organisation's relations with the public.

The complaint handling, may desperate for employees to identify the seriousness of the consumer who has made the complaint and handle them with good manners and pay attention to their complaints about ours services. As well as offering suitable communication at correct times is possible to be as prominent to complainants as receiving the outcome.

An efficient complaint handling resolve:

- Customers can restore confidence that the administration is dedicated to appropriately focussing and answering to any complications.
- Assistance to improve relationships with the consumers.
- Improve the organisation's clarity and responsibility.

If a product complaint is detected in a batch, attention must be given to whether other batches must be verified in order to regulate whether they are also distressed.

In individual, other batches that may contain reprocessed product from the faulty batch must be examined.

Where required, suitable follow-up action, probably containing product recall, must be procured after investigation and assessment of the complaint.

A separate record should be maintain and standard procedures should be followed as a result of a complaint must be documented and referenced to the consequent batch records.

Complaints records must be frequently assessed for any suggestion of particular or reappearing complications that involves consideration and may defend the recall of marketed products.

The proficient organisations must be notified if a producer is respecting action subsequent probably defective manufacture, product deterioration, a doubtful product or any other severe quality problems with a product.

Classification of Complaints

The classification of complaints are divided according to customer dissatisfaction about product or services. Classified as:

1. Class-A Complaints

This are Life-threatening complaint in which product is compulsory to be take away from the market. Such as

- Unfavourable Drug response.
- Main health threat producing long-lasting weakness or mortality.
- Cleanness & safety.
- Strength.
- Product firmness.

The procedure for recall of Class-A Complaints be approaching to execute to the levels of wholesale/Distributors, retail and consumer. In such cases, communal declarations shall be reached using print/electronic media, Newspapers, Television, and Radio etc.

Established on the set of hazards comprised, a time line of within 1 day up to a maximum of 3 days for Class- A complaints.

Corrective Action and Preventive Action

The examination of the recalled batches be going to be performed as per the SOP of the manufacturer, on "Review of Non-conformities" to find the origin of the breakdown and instruct corrective and preventive actions.

An effective evaluation will be performed on other batches of the related product and additionally prolonged to batches of other products, anywhere relevant.

2. Class-B Complaints

Class- B complaints are major complaints such as,

- Difficulty with primary packing of the product.
- Chemical/physical characteristics of the product.
- Irrelevant contamination, mix-ups, etc.

The procedure for recall of Type-B Complaints be going to be accomplished to the levels of wholesale and retail.

Based on the category of risks involved, for class-B Complaints recollect up to a maximum of 10 days.

Corrective Action and Preventive Action

It will be the liability of distributor/marketing Company/ retailer to update the stock status of product have being withdrawn to his immediate supplier or manufacturer.

By following Good Manufacturing practices or other regulatory guidelines during manufacturing of the product to prevent contamination and mix-ups.

Also by conducting relevant pre-formulation studies to prevent the Chemical/physical attributes of the product.

Materials must examined to prevent these types complaints by using good quality material for primary packing.

3. Class-C Complaints

Class-C complaints are minor complaints such as,

- Issues associated to labelling/ coding of batch details.
- Shortages.
- Secondary packaging material issues etc.

The procedure for recall of Class-C Complaints will be accomplished to the levels of wholesale.

Based on the category of risks involved, for Type-C Complaints recall up to a maximum of 30 days is permitted.

Corrective Action and Preventive Action

These types' complaints must be corrected during the labelling/ coding of batch or if already the coding is completed must be recode as per SOP and guidelines.

For the shortages complaints product must be produced immediately to meet consumer satisfaction of the product.

Care should be taken for packaging material problem by replacing with good quality materials for Secondary packaging material problem.

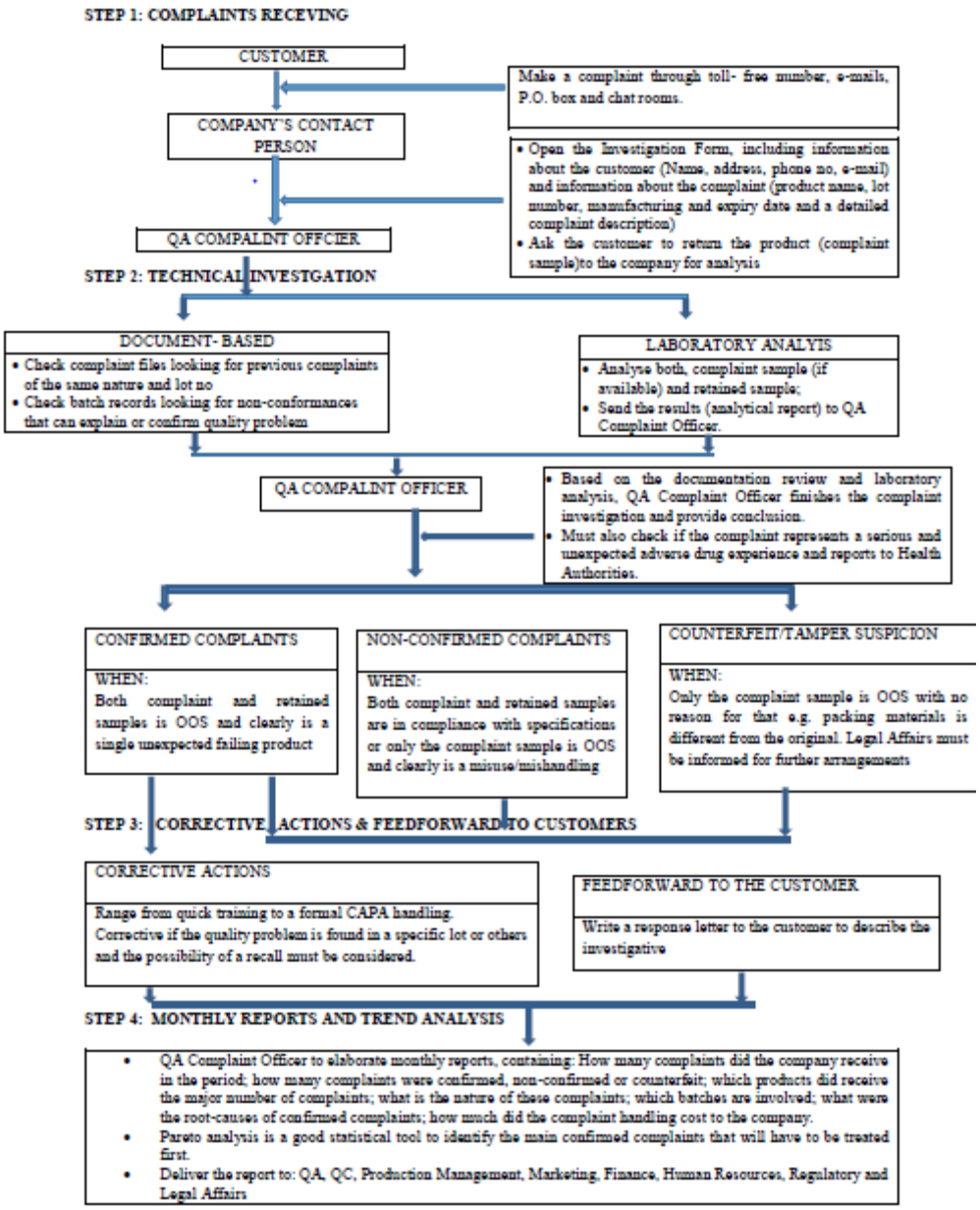

Fig. 1: Flow Chart of complaint handling system.

Steps involved in Handling of Complaints

STEP 1: Compliant accepting.

Essential to maintain exposed networks with consumers in order to obtain their statements, queries and grievances. Normally, these networks are toll-free numbers, e-mails, chat-rooms and P.O. boxes.

- The maximum adaptable networks are toll-free numbers and chat-rooms.
- An individual must be allotted responsible of accepting complaints and entering them into suitable examination procedure that will be recorded.

- The assessment procedure should contains:
- Evidence about the complainant; (Sample for complain registration)

Name

Address

Phone No

E-mail

- Information about the drug product;

Product Name

Lot No

MFG & Exp date

Detailed description of the compliant

STEP 2: Technical Investigation.

Upon receiving of the investigation form, the QA unit is able to start the investigation. It is divided into phases:

- Documentation based investigation.
- Laboratory analysis.

Documentation based investigation

The major documentation to be assessed comprises of

Compliant files: This is represented to verify how many other grievances of the same class had appeared to particular lot and how they were controlled.

Batch records should be confirmed in turn to see if there was any non-conformance during the production.

Laboratory analysis

It contains of requesting the Quality Control (QC) laboratory to examine.

Complaint samples- are the purchaser sample.

Reserved samples- the reserve samples representative of the lot produced (which were reserved under suitable requirements of temperature, humidity and light so that the medicinal product was not altered).

The organisation selects an individual in the QA unit to be responsible of methodological inspection of every complaint, e.g. a complaint officer.

There are three possible conclusions, as follows:

- Confirmed complaints.
- Non-confirmed complaints.
- Counterfeit / tamper suspicion.

Confirmed complaints

- When both complaint samples pointed out-of-specification outcomes or when only the complaint showed OOS results.

Example: A single unsolved malfunction could be when one tablet is skipping in the intact blister strip in the compliant sample, but no deviation was found in the reserved samples or during the in-process controls and final QC analysis in the batch record.

Non-Confirmed complaints

- When both complaints and reserved samples disclosed results in accordance with specifications or when only the complaints sample revealed OOS results.
- OOS results in a compliant sample can be attributed to mistreat or mismanagement, when the medicinal product was not kept under suitable conditions of temperature, humidity and light so that the identity, strength, quality and purity of the medicinal product can be affected.

Example: Tablets of the compliant sample show a change in the appearance that is characteristic of light, humidity or high temperature exposure.

Counterfeit/ Tamper suspicion

- When the reserved sample within the specification but the compliant sample is evidently OOS with no reason for that, such as a counterfeit or tampered drug product.

Example: When packaging material is distinct 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 complaint officer must also check if the compliant represents a serious and unexpected adverse drug experience.

- The complaint officer and QA Manager must sign off the investigation form once the investigation is completed.
- 30 days is a reasonable time to conclude an investigation.
- Compliant files should be retained for at least 1 year after the expiry date of the lot.

STEP 3: Corrective actions and Feedback to Customers.

- For all verified complaints, corrective actions should be implemented. These activities can range from a simple and quick training to some employees to formal corrective action and preventive action (CAPA) handling.
- If a CAPA is opened, a multi displinary team containing of representatives of QA, QC, Regulatory Affairs and Production Management must be established.
- Regarding non-confirmed complaints commencing from misuse or inadequate handling of the drug product. The consumer must obtain a written reply mutually with scientific data on the accurate use and handling.
- As response to the consumer, the organisation should write a reply letter to the pursuer to clarify the inspection method taken, the outcomes obtained and any inferences, in case the quality problem was verified.
- The consumer must be sent a free replacement product together with the response letter, since the consumer returned the product (the 'compliant sample') to the company for analysis and a quality problem was found.

STEP 4: Monthly Reports and Trend Analysis.

- Periodically reports must be detailed adequate to estimate the quantity and type of complaints obtained and to operate a trend assessment of these complaints.

The monthly reports should resolve 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?

- Graphic systems of revealing information are valuable adjuncts to data examination and demonstration.
- The report should be instantly accessible generally throughout cGMP reviews.

ANNEXURE: 01.

A. Sample for complainant registration.

Complainant Registration Form
Date: Name: Address: Phone No: E-Mail: Complaint Details:

B. Sample for complaint registration.

Drug Product Details: **To be filled by QA: Complaint No:** Name of Product: Batch No: Mfg. Date: Exp. Date: Dosage form: Marketing Authorization Number/Mfg. Lic Number: Nature of complaint: Critical/Major/Minor Physical Description of the compliant sample:
Review & Investigation by QA: Sign/Date: (QA In-charge)
Review & Investigation by QC: Report of Analysis (if any) Sign/Date: (QC In-charge)
Review & Investigation by Production: Sign/Date: (Production In-charge)
Corrective/Preventive Action taken: QA department (Sign/Date)

CONCLUSION

Complaint management is a complicated problem in unique industry and the issue assures to remain critical in future. As a governing and market pressures maintain to mount upon medical industries, leaders shall require improving useful solutions or tackling the high price essential in failed technology accomplishment, FDA censure and exhausted consumer relationship. The desired another is a consumer - aimed complaints management solution that controls. And this present review reveals the various product complaints handling in the pharmaceutical company and by feedforward to customer about the action taken against the product complaint for maintaining a valuable connection between consumer and organisations. Utilization of systematized complaint tracing software is suggested extreme concern of consumer and medicine producers. An efficient handling of customer complaints increase customer satisfaction also monitoring of customer care. To get positive benefit from the compliant, 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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Note

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REFERENCES

1. Glaucia Karime Braga Complaint Handling in Pharmaceutical Companies Quality Assurance J. Wiley Inter Science, 2007; 11: 16–21.
2. Professor John McMillan AO Acting NSW Ombudsman, Effective complaint handling guidelines, 3rd Edition February 2017.
3. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Good Manufacturing Practices Guide for Active Pharmaceuticals Ingredients-Q7-Chapter 15: Complaints and Recall, 2000.
4. WHO good manufacturing practices for pharmaceutical products: main principles.
5. www.pharmaguideline.com
6. CDSCO Guidelines On Recall and Rapid Alert System for Drugs (Including Biologicals & Vaccines)
7. US 48 Food & Drug administration, 21 code federal regulation-part, 211. 198.
8. Current Good Manufacturing Practices of pharmaceuticals- Manohar.A.Potdar.
9. [SCHEDULE M] Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.
10. Challuri, A., COMPLAINT HANDLING. Handling of Returned Goods recovered materials and reprocessing & Complaints & Recalls Dept. of Pharmaceutics., 2012; 7-34.
11. United States Pharmacopeia (USP), 1083.1 Quality Management Systems.

12. Q9: Quality Risk Management, U.S. Department of Health and Human Services Food and Drug Administration Centre for Drug Evaluation and Research (CDER) Centre for Biologics Evaluation and Research (CBER), 2006.
13. Neil F. O'Flaherty, Esq. Recall of drug and medical devices: Whats required Whats expected and practical pointers The Legal Background for FDA Medical Device and Drug Recalls 08-15.
14. Shirwadkar BB, Desai SR, Disouza JI, Systematic Approach for Handling of Customer Complaints Int. J. for Pharm Res. Sch. (IJPRS): 2014; V-3, I-1: 594-98.
15. Regulamento Tecnico das Boas Praticaspara a Fabricac¸ao de Medicamentos. Agencia Nacional de Vigilancia Sanitaria, Agosto, 2003.
16. https://www.researchgate.net/publication/308595149_A_Model_of_Pharmaceutical_Customer_Complaints_and_Redressal_System.