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A Model of Pharmaceutical Customer Complaints and Redressal System

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ABSTRACT

Complaint handling is a Good Manufacturing Practices (GMP) requirement because all complaints is potentially about defective products that must be paid attention for complete evaluation and action to prevent recurrence. For pharmaceutical and drugs regulatory compliance, manufacturers must demonstrate strict adherence to current Good Manufacturing Practices (cGMP) with respect to their processes, controls and product manufacturing. Additionally they must also ensure that compliance is met within their supply-chain and during product distribution operation. In order to manage the complaint handling effectively, latest automated software are used having features of integrated tracking, responding and reporting.

KEYWORDS : Customer Complaint Handling, cGMP, Pharmaceutical, Good Manufacturing Practices, Good Distribution Practices

INTRODUCTION

A complaint is notification that a product in commercial distribution may be in violation of the laws and regulations administered by drugs regulatory authorities or is not as per quality standards perceived by consumers. Complaint is described product as a statement that somethings is wrong or not good enough. This may trigger stringent actions like:

- Loss of goodwill
- Loss of business orders
- Regulatory actions (eg. Warning letters, import alert etc.)
- Field alert reporting
- Forced Recalls

Numerous regulatory observations and letters are issued by USFDA against inadequate redressal actions by pharmaceutical manufacturers. The most frequent cause of these observations is that systems do not exist for receiving, logging in, reviewing, or evaluating complaints, or that the current procedures do not include provisions for adequate closures of the complaints.

Relevant references for handling customer complaint handling include following:

- USFDA - 21 CFR 211.198
- USFDA - 21 CFR 11 (For automated systems)
- ICH Q10, 3.2.2
- EU 8.2

In the year 2014, European Commission has published the final Chapter 8 of the EU Guidelines for GMP (Complaints, Quality Defects and Product Recalls), which is a comprehensive document, in addition to the other regulatory guidance papers.

GLOBAL SCENARIO OF PHARMA BUSINESS:

Over the past decade, a few whistleblower cases have spotlighted the illicit marketing practices of pharmaceutical companies in the US but relatively few similar cases have been brought in Europe. The reason for this discrepancy is unclear but probably the wider use of self-regulation in Europe deters illicit conduct.

The UK government through has decided Competition Commission against varying or removing undertakings which restrict the way in which Investment Management System (IMS) Health Incorporated sells its specialized pharmaceutical data services.

As per figure culled from IMS Health, India has slipped from the 8th rank as forecast in 2016 to the 11th position in 2017. The downgrade suggests that the market may not be growing at the pace projected earlier, and has lost value due to various reasons probability due to loss of confidence due to customer and regulatory complaints.

COMMON TYPES CUSTOMER COMPLAINTS IN PHARMA INDUSTRY

Customer's complaints are received by authorized person of quality unit of drug manufacturing organization. Such complaints may be generated due to inadequate practices adopted by Packaging, Manufacturing, Supply Chain, Transportation, Warehousing or Pharmacovigilance. Most common complaints logged by customers of pharmaceutical manufacturers are listed as under:

Causing Department	Nature of Complaints
Packaging	Seal Integrity of packs Smudged or illegible printed information thereby creating confusion about: Batch Number Price Manufacturing date and Expiry date
Manufacturing	Foreign materials, particles Appearance nonconformance Discoloration of product Assay of drug product is out of specification Impurity of product is more than specification
Pharmacovigilance	Lack of effect Adverse drug reaction Contraindications
Transportation, Logistics, & Warehousing	Temperature excursions Product Mix ups

Table-1 - Common complaints logged by customers

MANAGING CUSTOMER COMPLAINTS

The management includes overall handling and redressal of customer complaints. The Quality Assurance (QA) determines if investigation of the customer complaint is required and how the complaint will be investigated. The QA determines that which department would be made part in complaint investigation. Typically complaint handling involves following departments as per requirement:

- Quality Control (QC)
- Production (Manufacturing & Packaging)
- Supply Chain Management (SCM)
- Marketing (or Business Development)
- Research and Development (Formulation development)
- Regulatory Affairs (RA)

Figure 1: Cross Functional Team (CFT) for Complaint Handling

A well-documented standard operating procedure (SOP) enables handling of complaint and streamlines the lifecycle from event receiving, through investigation, root cause analysis, corrective & preventive action and reporting to regulatory agencies. Adherence of an effective complaint handling system is more than just a requirement, it is a good practice that can help assure a manufacturer's product to continue to meet quality attributes after it leaves premises.

As per GMP there must be a defined system for collection of complaint-related information. If an effective automated or otherwise, fully integrated quality management process and reporting system is not in place, challenges arise that put a serious strain on a company's quality management efforts. These challenges can lead to very serious consequences to entire business.

Key parts of a complaint handling program must be formulated by including following aspects in the form of Standard Operating Procedure (SOP) to:

- Describe the mode of receipt of complaint
- Define the complaint login system
- Acknowledge of complaint
- Assigning of responsibilities of team for complaint handling
- Request for complaint sample or photograph
- Review of batch documents
- Comparison with retention samples
- Review of stability samples
- Investigation approach and tools
- Establishing root cause
- Formulating corrective action and preventive action (CAPA)
- Response to complainant
- Set the time lines for implementing CAPA
- Periodic trend analysis of complaints
- Management review of complaints

Figure 2: Mechanism of Complaint Handling

Complaints should be categorized (typically in terms of critical, major or minor) so as they may be tracked and trended. Categories may also include defect type, system impacted, product, dose, etc. Trend reports should be evaluated for management review on a regular basis to identify major flaws and assure management that controls are in pace to prevent potential complaints.

Investigation and Root Cause Analysis:
Investigation should also include possible impact to other batches, the complaint history for the particular batch, and a review of the manufacturing and laboratory records for possible deviations that could have led to customer complaint.

Product complaint investigations should be completed within a standard timeline from the time the company received the complaint. The complaints those involving third-party manufacturers, may require longer timelines. If the investigation cannot be completed on time, an interim report approved by the Quality department should be issued to complainant.

Following tools are often used for investigation of customer complaints:

Review of Check-sheets:
Comprehensive standard checklists are used to investigate, what could have gone wrong that caused customer complaints. Use of batch documents, analytical data and retention (control) samples are reviewed as a part of investigation.

Brain Storming:
The probable causes are generated with people from relevant functions and personnel to reach out maximum possible reasons of complaint.

Process Mapping:
Process flow diagrams and mapping data are critically reviewed to evaluate the potential mistakes.

Ishikawa (Fish Bone) Diagram:
Reasons and complaints have relationship of cause effect. The probable causes explored from– Man, Machine, Material, Methods, Miscellaneous issues.

Why-Why analysis:
This is based on a basic philosophy that digging into the issue by asking the reasons five times 'Why' shall help to reach the root cause of the complaint.

Pareto Charting:
Amongst the data base of complaints corrective action against the most frequent problem (most recurring complaint) should be prioritized. This is also known as 80:20 rule, which indicates that- if 20 percent of major problems are solved, there shall be improvement of 80 percent in reducing the complaints.

The most critical outcome of the investigation can lead a decision of recall of concerned batch from market. If the complaint is observed to be fetal for consumers or has evidence of regulatory violations or has high risk to patient's health, there may be immediate recall under public notification. Hence, the pharmaceutical industry can assess and manage risk using recognized risk management tools and/or internal standard operating procedures (SOP). US Food Drug Administration (USFDA) has provided a non-exhaustive list of some of these tools:

- Basic risk management facilitation methods (flowcharts, check sheets, etc.)
- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects, and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP) Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Risk ranking and filtering
- Supporting statistical tools

Quality Risk Management comprises of following basis processes:

- Risk Identification
- Risk Evaluation and
- Risk Mitigation

COMPLAINT LOG-IN FACILITY:

The pharmaceutical complaint and grievance redressal mechanism largely depends upon approach of the reinforcement agency and government regulations. However, in order to enhance customer satisfaction, the manufacturing organization shall ensure that:

Each product label is accompanied with toll free number and e-mail for lodging customer grievances.

The pharmacy and medical product sales outlets are encouraged to display customer complain log-book or customer complaint boxes.

The pharmaceutical companies shall make customer relationship management (CRM) and computer terminals for logging customer complaints shall be made available at sales outlets.

AUTOMATED COMPLAINT MANAGEMENT SOFTWARE

Complaints are logged from any source like customer relationship manager (CRM) software module, phone, email, letter, website, etc. Now a days customer complaint software are used to log, respond, investigate and analyze complaints with the notion of maintaining and improving a manufacturer's quality of service process. The perquisite of automated software is the compliance with 21 CFR Part 11, by ensuring that an organization identifies, accesses, and evaluates laws, regulations, and drugs regulatory requirements.

A few prominent automated software system for complaint handling are listed below:

- Sparta System/ Trackwise
- AssurX Complaint Management software
- EtQ has developed an FDA Compliance Software
- i-Sight Quality and Corrective Action software
- NOVATEK software
- MasterControl Customer Complaints™
- QuTrack QMS - Market Complaints

The automated systems come with fully compliant audit trail and electronic signature functionality secured built-in. Using automatic task assignment as per job role, escalation and notifications to keep the process efficiently moving. . The automated analysis systems include statistical evaluation tool, identification of outliers, and identify trends that indicate a need for process change or improvement.

CONCLUSIONS:

All complaints reflect customer's anguish about quality of pharmaceutical product. Complaint can be either confirmed or invalidated through a comprehensive investigations of complaint intake with help of batch record, analytical data, and stability records and retentions sample. The successful initiation and timely closure of a complaint and mitigation for prevention is the goal of a good complaint handling management. The assessment of the risk posed by the quality defect must be critically evaluated before closure of the customer complaint case. Deployment of automated complaint tracking software are recommended ultimate interest of customers and drug manufacturers.

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