Abstract

Product Complaints Management is an essential and critical component in the Pharmaceutical industry from the regulatory and compliance perspective. Immediate and real-time response to urgent customer requests and returns is critical in the industry, because product failure can truly be a fatal situation for customers – something that can translate to a legal exposure for manufacturers. Hence, there is a need of a single, uniform, and secured platform to manage product complaints right from initiation through closure.
Complaint Management is important but hard to manage

Product complaint is a topic of interest for all the Pharmaceutical companies, medical device manufacturers, consumer healthcare companies and various other industries governed by regulatory authorities. The approach taken by many Pharmaceutical Companies is that of addressing complaint management as a process that is not related to the overall management of customer relationships. When presented with the concept of complaints management, many executives reply that their company has a complaint handling tool and, therefore, the area is not an issue at all. However, in all likelihood, those executives – and their companies – may not have an effective complaints management capability.

Complaints management forms the consumer management. A properly executed complaints management program, can decrease customer maintenance costs, increase revenues, and improve a company’s ability to track historical customer and product trends – useful to forecast future market, product, and customer needs.

In the Pharmaceutical industry, complaints management is critical but hard to manage. This is because the industry is diverse and includes nearly any physical product used in the health care industry. This also makes ensuring compliance with government regulations a difficult task. In this industry documentation is critical, and attempting to ensure a tightly-managed process in the business environment can be very complex and expensive.

Hence, there is a clear need of having an effective Complaint Management Solution, in view of the points mentioned below:

- Insufficient product complaint handling was and still is one of the top FDA findings in published 483 warning letters.
  - Failure to have written procedures that describe drug product complaint handling
  - Failure to have adequate complaint procedures for adverse drug experiences
  - Failure to establish and follow adequate procedures for handling and investigating complaints regarding product quality
  - Failure to determine a need for an investigation and failure to conduct investigations
  - Failure for presenting a complaint file and appropriate investigations of complaints conducted
  - Not adequate clarity around what can be reported as a adverse event and what not
  - Inadequate integration with CAPA systems and the regulatory procedures

- Regulatory and competitive pressures are forcing organizations to change their product complaint management strategy.

- Dynamic and stringent regulatory landscape is making it mandatory for organizations, to track, record, and report all complaints with respect to product quality and safety; and to take appropriate follow-up actions to prevent reoccurrence of such incidents.
The step-by-step solution to the problem

Analyzing the above situation, we can conclude that there is a need for a single, uniform, and secured solution to manage product complaints right from initiation through closure. The solution should include real-time visibility to track each product compliant through its life cycle. The solution should be easily configurable to support the variety of users involved in the complaint management lifecycle. In view of the diverse interactions of the complaint management system, the solution should be easily integrated with the other quality management processes that are critical for regulatory compliance such as change control, audit management, and CAPA.

In this solution, the complaints management process is divided into the following stages:

**Basic workflow for product complaint handling in pharma**

![Basic workflow for product complaint handling in pharma](image)

Some of the salient features of good complaint management solution are:

1. Functionality breadth and depth:
   - Web-based application integrated with workflow
   - Escalation management
   - Single complaint with multiple processing (Parent-Child Notifications)
   - Reminders
   - Reports
   - Complaint Closure Form
   - Multiple language capability
   - Document Management system integrated to record all attachments & reports with individual complaint
   - Electronic signatures
   - Integration with sales and distribution processes
   - Integration with adverse event handling processes
2. Standardized and automated system: The system needs to be centralized, integrated, and standardized to report the event or problem to the regulatory authorities in the required time (typically 15-30 days). The system should not have integration overheads and heavy manual operations.

3. Safety and security of system: The solution will interface with multiple systems in sales, customer relationship, production, material management, design, and drug development and regulatory requirements. It would have huge data flows which are mission critical and can create loop holes into information security. The architecture of the solution should ensure complete data security.

4. Performance of solution: The technical solution need to perform with required efficiency as it would contain multiple integration points, workflows, and data elements. The solution should encompass clear business rules, SOPs, and workflows in a simple architectural form. The solution should have efficient and easy to use notification engine as well as a high-performance reporting engine.

Exploring the solution further

In this solution, the following functionalities should be covered, at various stages of Complaint Management process:

- **Receipt**: Functionality to consolidate different channels of complaint receipt such as web form, email, fax, telephone, sales team escalation, and so on into one uniform platform. Customer should have either a web portal to log complaints online or a toll free number to submit complaints.

- **Data and Complaint Management**: The solution should be able to automatically capture critical information related to product complaint. The solution should also include online tracking of product complaints from receipt through final sign-off. It should include storage, archival, and retrieval of all the product compliant-related documents. Data Upload is an important requirement of the receipt functionality, where investigational data pertaining to the complaint can be uploaded during the complaint lifecycle.

- **Routing and escalation**: Automatic routing of complaints depending upon the severity and type of complaint for further investigations. For example, Quality problems to QC & production or safety problems to drug safety. This ensures automatic escalation of the non-completed actions in the workflow. The solution should include automated Trigger for internal corrective and preventive action.

- **Task management**: Automatic task management features for compliant processing.

- **Processing and Reporting**: Collaborative framework to manage compliant processing across various cross functional departments such as production, R&D, Quality control, Drug safety, and so on. The solution should also include an option to view compliant summaries, in-process complaints, investigation outcome, and perform trend analysis as per type, product, and department.
- **User Management**: The functionality to track users and their actions involved in the complaint processing.

Briefly, the solution should provide an integrated approach to the complaint management, where it can interact with various stakeholders of the process such as manufacturers, patients, doctors, and regulatory authorities. The core functionality should be integrated with call center processes, product life cycle processes, and peripheral applications that provide functionalities not covered by ERP. The below diagram illustrates the solution.
How the Solution solves the Problem

The robust Complaint Management solution provides both processes and technology for gathering, classifying, and preserving product information in order to anticipate, diagnose, and resolve product-related problems. It offers direct access to specific product details that allow quick problem resolution, and a web-based entry and status reporting system for customer service. Triggers can alert Quality personnel to critical or recurring customer reports for specified products. Such alerts are invaluable for enabling quick defect-correction and customer notification before a problem becomes widespread.

This solution should be driven by specific ROI levers including reduced warranty costs, mitigation of regulatory fines, reduced refund/return error owing to accurate information, and reduced cost of compliance. The solution also results in reduced costs of compliance through minimum time and costs of processing complaints, uniform compliance, and a high quality of content among all partners.

With this solution, companies can look forward to getting the following benefits:

- Standardized, consistent and complete global complaint handling process and data collection.
- Increased data consistency and enhanced reporting capability.
- Increased customer loyalty through improved response time.
- Increased security with Part 11 compliance.
- All complaints captured in one single database.
- Complaint data consistency.
- Standardized process can be rolled out globally, within short time frame.

Conclusion

Complaints management is a complex problem in a unique industry, and the issue promises to remain critical in the future. As regulatory and market pressures continue to mount upon pharmaceutical companies, industry leaders will need to develop effective solutions or face the high costs inherent in failed technology implementations, FDA censure, and weak customer relationships. The preferred alternative is a customer-focused complaints management solution that works.
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