Improve Complaint Management for Medical Devices:

How to Handle Medical Device Complaints and Mitigate Common Challenges

Complaint handling and regulatory reporting are fundamental requirements in the life sciences industry, as well as a critical part of any quality management program, with direct implications for operations, device design, risk management, and more. Complaint management focuses on resolving customer grievances, identifying opportunities to make systemic and product improvements, and developing better and safer medical devices.

The importance of an effective complaint management system is being realized with increasing competition and the global regulations becoming more stringent surrounding post-market surveillance for medical devices. The global medical device complaint management market was worth around $6.9 Billion in 2022 and is predicted to grow to around $12.4 Billion by 2030 with a CAGR of ~7.5% between 2023 and 2030.[1]

An effective complaint management system decreases regulatory risk and increases company's growth and profitability, customer satisfaction and brand loyalty. Non-routine quality events — such as major observations, recalls, warning letters, and consent decrees, along with associated warranties and lawsuits — costs the industry between $2.5 billion and $5 billion per year on average.[2]

Complaint Management Workflow

Companies that get their complaint management process right can use it to improve their products and reduce risk to their patients as well as the company. Those that do not get it right run the risk of future product failures, recalls, regulatory actions, remediation activities, and more.

Each company will have its own complaint handling workflow. However, there are several common elements that organizations build their workflow around. It is critical to identify vulnerabilities in these areas in the early stages of process development to ensure smooth running and reduce risks.

Complaint Intake: Consolidate various sources and channels of complaint receipt such as phone calls, emails, fax, web forms, social media, as well as internal communications. Hire skilled professionals who can identify complaints and adverse events and escalate them in a timely manner.

Complaint Investigation: Establish collaborative framework to manage complaint processing across cross-functional departments to support various stages of complaint investigation as well as perform root cause analysis. It is also important to identify reportable and adverse events related to device malfunctions to ensure patient safety.

Complaint Data Analysis: Perform trend analysis on complaint data to evaluate and investigate most common issues and able to take proactive, corrective, and preventive measures to prevent recurrence of the complaint as well as field safety actions.

Regulatory Authority Notification: Promptly review and escalate reportable and adverse events to appropriate regulatory authorities and perform medical device reporting as required in a timely manner.

Customer Feedback: Respond and compensate the customer in response to their complaint to ensure customer satisfaction and loyalty. Customer should be provided feedback on the progress of complaint investigation and steps the company is taking to ensure such events do not recur.

Continuous Monitoring and Periodic Review: Accelerate continuous quality improvement by incorporating periodic review of complaint handling processes across cross-functional departments as well as the whole organization. It is essential to perform process compliance and effectiveness monitoring to sustain quality of the processes as well as the product.

Common Challenges in Complaint Management

There are several complaint handling problems that organizations are facing today which can be easily remediated to avoid facing severe consequences.

- Inexperienced or lack of skilled professionals who mis-categorize genuine complaints.
- Improper handling of malfunctioned or damaged devices.
- Incomplete or inadequate complaint records missing critical information.
- User error due to poor complaint handling procedures.
- Multi-lingual users leading to inefficient processing and missed information.
- Improper complaint classification and severity.
- Long complaint closure times due to poor alignment between cross-functional teams, and more.

Consequences of Being Out of Compliance

It is critical to have a complaint management system that is compliant with various global regulations such as 21 CFR 820 and 21 CFR 803, ISO 13485, EU MDR, and so on. There is a lot of emphasis on the post-market surveillance activities for medical devices by regulatory authorities to ensure that no complaints are missed.

Regulatory authorities perform inspections to review a medical device manufacturer's complaint handling system. They verify that the data is complete, accurate and is being recorded in a timely manner, and that investigations are conducted to determine root cause where possible. It is required that corrective and preventive actions are taken for significant quality issues. In addition, they review complaint files to verify that all reportable and adverse events have been reported in an appropriate manner and that rationales have been documented for events that are non-reportable.

In the event that a company's complaint management system is not complaint with the regulations, the regulatory authorities take various actions depending on the severity of the violations.

- Citations
- Warning letters
- Removal of the product from market
- Prohibition of marketing and future sales
- Destruction of the product
- Market recalls and field safety notices (FSN)
- Injunctions and seizures
- Civil money penalties and criminal prosecution

Our Approach

Optimizing end-to-end process flows and aligning improvement initiatives are essential to achieving a favorable impact on business top and bottom lines. Within FTI's Life Sciences, our professionals have advanced client's compliance and alignment with regulatory and risk management. We will work with you to create a proactive approach that fits your company's needs, goals, and ideal future state. Here's our approach:

- **Discovery:** By gaining the voice of the customer within each functional area and interviewing key stakeholders, we will review the current state and perform gap analysis and root cause analysis to make recommendations for an optimal future state.
- **Design:** Upon acceptance, FTI collaborates with functional teams to develop procedures and toolkits to support end-to-end processes.
- **Company adoption:** FTI can support execution in the event of a recall or conduct training across the organization to educate staff at all levels.

Remediating the Complaint Management process – Medical Device Company | A Case Study

A global medical device manufacturing company engaged the FTI Life Sciences practice to provide direct support to their complaint handling team as an Interim Complaints Manager, which included oversight of the day-to-day complaint handling activities as well as remediation of their complaint handling process.

The client struggled with a significant and growing number of open and aging complaints and the complaint handling team struggled to keep up with this growing complaint backlog. In addition, an Internal Audit was conducted across five client sites in United States, which identified several observations related to the client's Quality Management System (QMS) and the complaint management process. The client also received a Form 483 from FDA in May 2022 following an FDA inspection, which had several observations related to their complaint handling and MDR-related processes.

FTI assumed immediate oversight of the complaint handling team and began an investigation into the root cause of open and aging complaints. FTI also developed a remediation plan by identifying gaps in their process and developing and implementing a new complaint handling process. FTI conducted a workshop with stakeholders and developed a new standard operating procedure (SOP) to align complaint handling processes across all US sites.

[1] Zipp, Ricky. "Medical Device Recalls Hit Two-Year High in Q2, Report Finds." MedTech Dive, August 18, 2022. https://www.medtechdive.com/news/device-recalls-two-year-high-q2-sedgwick/629979/.

[2] The business case for Medical Device Quality - McKinsey & Company. Accessed October 24, 2023. https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/public%20sector/regulatory%20excellence/the_business_case_for_medical_device_quality.ashx.

ANTHONY GOTZIS
Senior Managing Director
215.622.7588
Anthony.Gotzis@fticonsulting.com

PAT SHAFER
Managing Director
646.379.8307
Pat.Shafer@fticonsulting.com

ANCY JOHNSON
Senior Director
267.407.2587
Ancy.Johnson@fticonsulting.com