



Effective Complaint Management: The Key to a Competitive Edge for Medical Device Firms

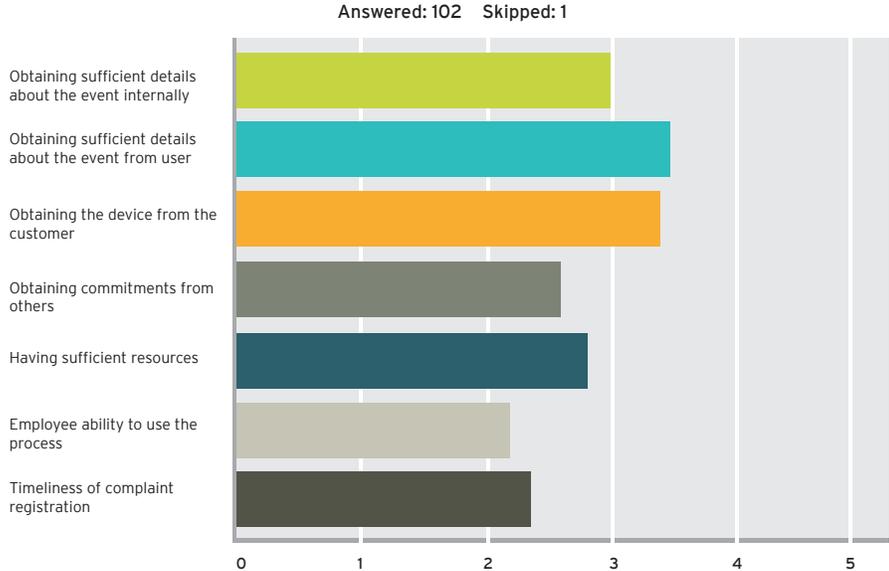
By establishing strong complaint management processes, medical device firms can make continuous improvements in patient safety, regulatory compliance and customer satisfaction.

Executive Summary

Patient safety, regulatory compliance and customer satisfaction are the top objectives for every medical

device company. And as manufacturers are well aware, meeting these requirements is not a one-time effort but one that requires continuous improvement every year. A rigorous approach to complaint management is key to accomplishing these goals; unfortunately, medical device firms face multiple challenges when it comes to complaint management, particularly when it comes to obtaining sufficient data (see Figure 1).

Complaint Management Challenges



Source: "Complaint Survey 2013," Compliance Alliance, <http://www.compliance-alliance.com/wp-content/uploads/2013/07/ComplaintSurveyResults1.pdf>.

Figure 1

Medical device firms ranked the challenges they face when it comes to meeting 21 CFR 820.198 requirements, on a scale of 1 to 5, with 1 being low difficulty and 5 being high difficulty.

This paper looks at the industry pressures faced by medical device firms, what makes the medical device complaint management process unique, common causes for complaint management failures and the type of complaint management solution needed to meet the unique requirements of the medical device industry,

Industry Pressures

The medical devices industry is highly regulated, with companies in this industry receiving marketing approvals for their products only after stringent evaluation of clinical trial data. Product quality is of supreme importance, and device companies spend enormous resources - in time, personnel and money -- to implement high-quality systems that comply with regulatory guidelines. In spite of the best efforts of device manufacturers and regulatory bodies, however, it is almost impossible for them to develop products that do not result in complaints, adverse events or a need for repairs. There are various reasons, the main being that emerging industry dynamics have put quality management under severe pressure. The race to reduce time to market, cost burden and consolidation in the industry, - all have been major contributors to this pressure.

At the far end of the product quality spectrum, the words "product recall" strike fear in the hearts of medical device manufacturers, and rightly so, as the impact of a recall can include financial loss, stock price declines, tarnishing of the brand image, lawsuits and questioning of patient safety. While a recall (either voluntary or mandated by a regulatory authority) is the ultimate manifestation of a product failure, it is usually the result of a series of failures during the manufacturing process, the documentation phase, the corrective and protective action (CAPA) system or a user-related issue. Of course, not all recalls relate to a life-threatening scenario, and it is nearly impossible to prevent them completely.¹

However, medical device manufacturers can reduce the number of observations (e.g., the U.S. FDA Form 483) they could receive during regulatory audits. According to the Food & Drug Administration, complaint management procedures were the second biggest reason for Form 483 observations being issued to device makers in 2012. In fact, medical device companies have received 259 citations related to complaint

procedures in this year alone. Additionally, some of the significant inconsistencies that the FDA has identified in companies relate to complaint-handling processes, and the majority of warning letters also point in the same direction.

Complaint and Repair in the MD Industry

To some extent, the complaint and repair process in the medical device industry is similar to the consumer goods industry; however it has its unique requirements. Medical devices are approved for marketing based on the risk they pose to patients if they fail. This risk stratification is unique to the industry and highlights the importance of applying post-marketing surveillance, both to report incidents of serious injury or death caused by device malfunctions and also to identify product issues that are likely to cause serious adverse events.

'Lindsey Alexander, "Are Recalls Preventable?" MedCity News, Aug. 26, 2013, <http://medcitynews.com/2013/08/are-recalls-preventable-5-smart-comments-from-a-linkedin-conversation-you-should-be-following/>

Other medical device-specific requirements are that all product complaints must be recorded and properly investigated before they are closed. Regulatory affairs teams need access to information related to the complaint and past trends on similar complaints before they can make a decision on whether to report, whom to report to (regulatory agencies) and how to report (type of report.) If a complaint is non-reportable, suitable justifications must be provided in the complaint file to support that assertion.

Medical Devices have a life cycle. Complaint and investigation files must be maintained for a period equal to the expected life of the device but never less than two years from the date the manufacturer releases the device for commercial distribution.

The typical process for product complaints that require an investigation is shown in Figure 2.

In response, major medical device regulatory agencies globally have clarified their mandate by requiring the following from manufacturers:

- Maintain complaint files.
- Maintain and update a CAPA process.
- Maintain a record of all customer complaint investigations.
- Report adverse events.

Regulatory agencies are very stringent about these requirements and can select any complaint or customer interaction during the audit process to check how it was managed throughout the lifecycle. Despite

their best efforts, achieving these objectives is a big challenge complicated further by human errors, complexity of global regulatory requirements and inadequate data visibility.

Typical Process for Complaints requiring an Investigation

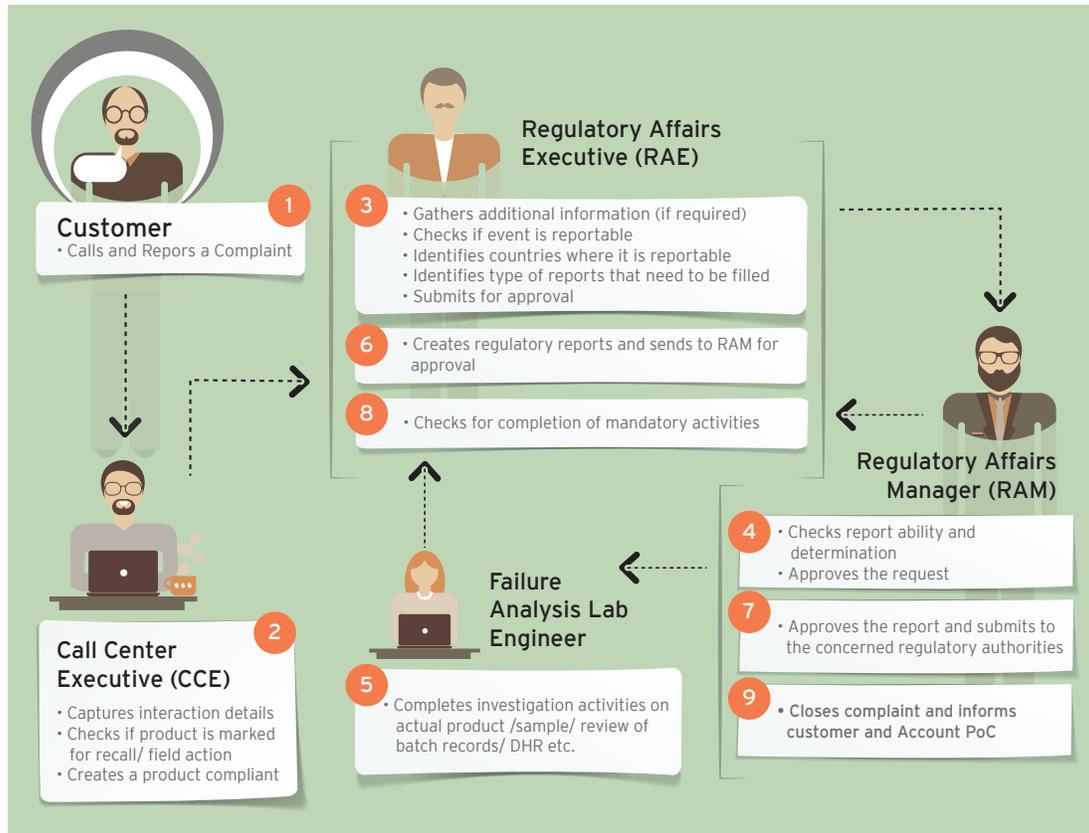


Figure 2

Causes for Complaint Management Failures

So what are the common causes for complaint management system failures? According to the *Medical Device and Diagnostic Industry (MD+DI)*, they include:

- Failure to adequately investigate root cause.
- Failure to close complaints in a timely manner.
- Failure to recognize all sources of complaints.
- Failure to report adverse events.
- Failure to establish the effectiveness of correction actions.
- Poor documentation of activities and decisions.
- Poor (or nonexistent) follow-up with complainant.

- Failure to communicate with management and across departments/divisions.

While the causes are known, it is also important to understand the contributing reasons so that appropriate remedial actions can be taken. These include:

Inefficient paper-based systems

The paper-based system for capturing and tracking complaints and repair requests makes management extremely difficult, as it is prone to human error. Thankfully, few companies rely completely on such systems; however, manual processes still exist in small pockets within the industry.

Lack of written SOPs

Standard operating procedures (SOPs) are critical for an efficient CM system. SOPs provide a common definition of various CM terminologies, identify process owners, define responsibilities, and identify standard processes, escalation mechanism and timelines that are in line with regulatory requirements and a company's quality management system. The absence of any of these attributes introduces ambiguity and subjectivity, which can result in the failure of the system to receive, review and evaluate complaints.

Insufficiently trained resources

Complaint management is a specialized field that requires thorough knowledge of regulatory requirements, timeliness, the appropriate report to be used, where to report, who to report to, etc. The skills required often vary from one product category to another within the same company. Few medical device companies have an ongoing training program to keep their regulatory affairs resources abreast with new developments.

Inefficient complaint-handling processes could arise from improper process definition or the inability to determine whether a complaint should trigger the regulatory reporting process.

Poor understanding of global regulatory requirements

Global regulatory requirements are continuously improving. Keeping track of these changes is difficult enough; understanding them is an even bigger challenge. Most medical device manufacturers market their devices globally, thereby bringing them under the scrutiny of multiple regulatory bodies (FDA, MDD, MHRA, PMDA, etc.), each with their own mandates. This amplifies the complexity of reportability determination multifold.

Poor visibility of the complaint throughout the lifecycle

Managing a complaint often involves multiple stakeholders, including service desk personnel, the regulatory affairs team, field service engineers, investigation labs (in-house, third-party, OEM), the disinfection lab, the customer, the supply chain, regulatory bodies, etc. This complex process involves multiple hand-offs, back and forth, from one stakeholder to another. Keeping track of the complaint from the "date of awareness" until it is

"closed" becomes an arduous task if the system is not supportive.

It becomes increasingly important to understand the regulatory guidelines and have visibility into the actual status of a complaint for reportable complaints as the "regulatory clock" starts ticking from the "date of awareness."

What the Industry Needs

The unique needs of the medical device industry justify a solution that meets these requirements. The medical device industry requires a holistic approach of managing complaints that provides the following:

A well-defined and harmonized complaint management process:

- Common definitions and explanation of complaint management terminologies.
- A complaint handling process that is harmonized across various divisions and Bus.
- Well-defined SOPs.
- A governance structure with workflows for managing approvals and escalations.

Properly qualified, dedicated trained resources who can make decisions on:

- Who to report to.
- When not to report a complaint and how to support that decision.
- Closing a complaint.
- Upgrade / downgrade / classify customer interactions.

Robust post marketing surveillance mechanism and the ability to meet the fundamental objectives of medical device manufacturers, including:

- Support for harmonized processes.
- The ability to capture customer feedback from all sources and classify the interaction.
- The ability to maintain complaint and investigation records.
- Support determination of reportability.
- The ability to manage complaints throughout the lifecycle.
- Quick resolution by accessing a knowledge base and CAPA records.

- Support for reporting on KPIs to key stakeholders.
- Incorporation of the FDA's proposed rule for Unique Device Identifiers.
- Incorporation of an audit trail and e-signature capability.

Medical device companies should evaluate available solutions for their flexibility, implementation time, regulatory compliance, TCO and -- most importantly - fit with the medical device industry.

Cognizant's Point of View

We believe that any solution in this area has to be specifically designed for the medical device industry and should offer an integrated view of the customer for sales, service and complaint handling activities. The medical device industry's needs are not only unique but also dynamic. We propose a solution that is flexible, scalable and configurable and that reduces the complexities typically associated with development from scratch. Cloud-based solutions, in addition to lower infrastructure and maintenance costs, will enable manufacturers to focus on key activities to achieve enhanced customer reach, improve customer satisfaction and ensure the regulatory compliance that is so critical for the medical device industry.

Cognizant offers MedVantage, an integrated sales, service and complaint handling business cloud solution that drives enhanced customer reach, improves customer satisfaction and ensures regulatory compliance specifically for the medical device industry. MedVantage is a validated system, with a complete audit trail and e-signature facility. The audit trail feature captures the reason for changes, along with the "who" and "when" content of field changes. MedVantage enables organizations to:

Capture complaints from multiple channels:

Complaints can come from any source, and since regulatory agencies have put the onus of capturing complaints on the manufacturer, the system should not restrict complaint capture from select sources. MedVantage can seamlessly integrate customer interactions from various channels, such as telephone, e-mail, the Web (partner portals) and even remote capture directly from devices to enable efficient management of service requests and product complaints.

Ensure regulatory compliance: All events in which a manufacturer's device contributes to death or serious injury must be reported within a specified timeline. The process involves multiple decision points and compliance with regulatory deadlines. MedVantage offers a simple platform to track submission dates, determine reportability using customized decision trees, support regulatory report preparation, and enable e-submission.

Comprehensive visibility of the complaint:

Manufacturers receive numerous complaints globally, and the complexity increases multifold if they have a global presence. Keeping track of the complaint, its exact status, current owners, actions necessary for the next level - all of these are important aspects that enhance the visibility of a complaint until its closure. MedVantage offers role-based access, configurable workflows and a system that alerts users on current activities and provides complete visibility of repair requests and complaints throughout the lifecycle. Graphical representation of the current status and a countdown clock provides enhanced visibility of each and individual complaint.

Harness collective intelligence:

Individuals involved in the complaint management process are likely to face challenges in selecting among available options necessary for taking the complaint to the next level. MedVantage helps address this by leveraging the collective intelligence available within the organization. It has a collaboration platform (chat, e-mail) coupled with easy access to a database of solutions to similar problems.

Looking Ahead

Going forward, the success of a complaint management system must be measured and monitored regularly on key parameters, such as:

- Trends of Complaints against Products
- Regulatory Reports due in the next 10 days - by country
- Month wise reportable complaints - by product
- Number of closed complaints in a month
- Number of reopened complaints - by product/region
- Number of complaints missing reporting deadline - by country
- Number of complaints that are not reportable

- Service Request Status by Account
- Age of Open Case by Product
- Case By Status and Priority

Considering the wide-ranging impact of an inefficient complaint management system, the time has come for medical device manufacturers to make the adequate investment in this area, which for a long time has not received the attention it deserves.

About Author:

Samir Tamhane: Samir is a seasoned techno-functional expert at Cognizant's global Life Sciences (LS) practice especially in Medical devices space. He has over 16 years of expertise and knowledge in consulting, business development and planning with the key strengths that include strategy formulation, implementation and a strong knowledge of processes, regulations and technology within the Life Sciences industry. He has managed global clients that include F500 Pharmaceutical and Medical Device companies based in US, UK and Asia Pacific. He is a functional Subject Matter Expert for Cognizant's MedVantage product - An integrated Sales, Service and Complaint Handling solution built on Salesforce service cloud specifically for the Medical Device industry. Samir can be contacted at Samir.Tamhane@cognizant.com.

About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world's leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 75 development and delivery centers worldwide and approximately 187,400 employees as of June 30, 2014, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.



Cognizant

World Headquarters

500 Frank W. Burr Blvd.
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277
Email: inquiry@cognizant.com

European Headquarters

1 Kingdom Street
Paddington Central
London W2 6BD
Phone: +44 207 297 7600
Fax: +44 207 121 0102
Email: infouk@cognizant.com

India Operations Headquarters

#5/535, Old Mahabalipuram Road
Okkiyam Pettai, Thoraipakkam
Chennai, 600 096 India
Phone: +91 (0) 44 4209 6000
Fax: +91 (0) 44 4209 6060
Email: inquiryindia@cognizant.com