



Complaints Management: Integrating and Automating the Process

To strengthen their brand and fortify customer relationships, device manufacturers require a standards-based, next-generation platform that keeps the business and its customers connected throughout the complaints-management life cycle.

Executive Summary

The medical devices industry is somewhat unique, due to the many operational attributes that set it apart from other sectors. For example, it is a regulated sector with a strong manufacturing base, and serves a wide array of customers – from consumers, physicians and nurses, to hospitals and care facilities.

Meeting the needs and expectations of these various customer types presents many challenges for device makers, who must also comply with regulatory and complaint-filing standards.

This white paper examines how an integrated approach to handling complaints can help medical device companies enhance the customer experience and meet if not exceed regulatory norms.

The Complaints Management Process and Value Chain

For companies in the medical-devices industry, complaints management starts with capturing complaints filed by device users, or by sales or service representatives working for channel partners. Once a complaint is received, it is categorized and documented. A clinical analysis is then performed to ascertain whether the user's device must be returned for further investigation. Reportability is determined by running a pre-configured decision tree.¹ If needs be, reports are then filed to the appropriate regulatory bodies. Depending on the type of complaint, corrective and protective actions (CAPA) are performed and recorded.

The steps involved in a typical complaint management process are illustrated in Figure 1 (next page).



The Complaint Management Process



Figure 1

Many departments are involved in the complaint-management process, and each plays a crucial role (See Figure 2, next page).

The Missing Link

Our studies of the marketplace reveal that most device manufacturers manage complaints using decentralized systems, which can vary across

departments. These companies often use single or multiple call-center applications to record customer interactions, feed those exchanges to a complaint-management application for medical affairs to perform clinical analysis and reporting, then forward them to a quality application for CAPA. A separate field-service application

is typically used to perform failure analysis and manage sample returns.

Each of these processes perform well within their own domain, but the complainant (i.e., the customer) is kept out of the loop. Although complaint management is typically a customer-facing activity (the complainant interacts with the sales rep or customer service rep), in the case of the medical-device industry, the process is typically decentralized.

Below are some major, customer-specific challenges resulting from decentralized systems.

- The customer experience suffers due to a disconnect in the communications loop regarding complaint status and actions taken based on the filed complaint.
- The absence of a customer-complaint feedback mechanism.
- Error-prone and delayed refunds/returns.
- Delays in responses and updates to customers due to isolated applications.

Manufacturers should treat system silos and decentralization as an opportunity to transform an unhappy customer into an advocate of the manufacturer's brand and its devices.

Functional Responsibilities for Complaints Management

Department	Responsibility
Customer Service/Field Sales/ Field Service	<ul style="list-style-type: none"> Record interactions. Document complaint details. Send acknowledgment.
Regulatory Affairs/Medical Affairs	<ul style="list-style-type: none"> Analyze complaints. Conduct clinical analysis. Determine reportability. Identify the reporting authority/regulatory body. Create a report. Submit initial and supplemental reports.
Quality Assurance & CAPA Council	<ul style="list-style-type: none"> Initiate the CAPA (corrective and preventive actions) process. Identify and define corrective and preventive actions. Assign actions to respective departments. Track and manage actions through closure.
Investigation Lab	<ul style="list-style-type: none"> Investigate samples. Perform a failure analysis. Identify the root cause of complaints.
Product Engineering/Logistics/Sales	<ul style="list-style-type: none"> Implement corrective actions.

Figure 2

Manufacturers should treat system silos and decentralization as an opportunity to transform an unhappy customer into an advocate of the manufacturer's brand and its devices.

Resolving the Disconnect

Hosted on Salesforce.com's cloud platform, Cognizant's MedVantage™ addresses the divide that exists between customer service and quality processes. It also integrates with MedDRA, other drug dictionaries and patient registries. Among its features:

- A contact center for capturing interactions
 - Complaint categorization
 - Clinical analysis
 - Reportability determination
 - Regulatory reporting
 - Return management
 - Repair and product investigation
 - Root cause analysis and CAPA
 - Reports and analytics
- More specifically, MedVantage offers:
- A configurable, workflow-driven complaints process for process automation
 - Configurable scripts for the contact center to manage and categorize interactions
 - A comprehensive customer feedback system
 - Configurable decision trees for regulatory reporting
 - The ability to generate MedWatch forms for reporting
 - Support for EU and Canada reporting
 - A time clock for generating reporting alerts
 - A workflow-driven CAPA process
 - Configurable alerts and notifications
 - Audit trails and e-signatures – enhancing security and reliability
 - 21 CFR Part 11 and Annexe 11 compliant
 - M2M capability for proactive maintenance and remote service
 - Real-time updates on refund/replacement availability
 - Real-time feeds with location-based service

A Fully Integrated, Automated Solution

Benefits	Solution Components
A Consistent Customer Experience	<ul style="list-style-type: none"> • Offers a uniform, centralized contact-center platform.
Improved Customer Satisfaction	<ul style="list-style-type: none"> • Provides regular, automated updates to customers on the status of their complaint and actions taken to resolve the issue. • Employs real-time feeds on the location of field service personnel. • Captures customer feedback from every source. • Supports outbound calls explaining disposition steps to follow. • Improves response and resolution time with automated process and scripts.
Increased Customer Loyalty	<ul style="list-style-type: none"> • Offers an automated return/refund process for customers. • Outbound calls to customers provide regular updates on the status of their complaint and refund. • Provides proactive maintenance of devices.

Figure 3

The Business Benefits of MedVantage

An integrated complaint-management product such as MedVantage can enhance the customer experience and increase brand loyalty while remaining compliant with stringent regulatory norms. For example, a medical-devices client involved in the discovery and marketing of specialty diagnostics has already achieved a 25% increase in customer satisfaction within three months of installation. In addition, the company claims a 30% surge in timely complaint-filing.

Figure 3 above illustrates how MedVantage can help medical device companies develop a customer-centric complaint management value chain.

Looking Forward: Next Steps

Medical device manufacturers looking to significantly improve the customer experience by transforming how they manage and resolve complaints can employ our KPI-driven approaches and methodologies to develop a next-generation complaint-management solution.

To get started, we recommend the following:

- Perform due diligence on existing processes and identify gaps.
- Prepare a roadmap for building an integrated complaints and customer-experience solution.
- Make a decision on buy versus build.
- Perform an analysis regarding leading, cloud-based complaint and quality-management products, such as MedVantage.

In today's digital world, medical device manufacturers must find ways to enrich their customers' experiences and secure their loyalty. Complaint management is, and will remain a major industry challenge. However, creating a customer-focused, integrated strategy can help device makers turn unhappy customers into advocates.

Footnote

¹ A decision tree is a graph that employs tree-like branches to illustrate every possible outcome of a decision.

About the Author

Sougata Chakraborty is a Cognizant CRM Product Manager within the company's Enterprise Applications Systems business unit. With fifteen-plus years of experience in CRM consultancy, Sougata focuses on pre-sales and solution development, and is the acting product manager for MedVantage™, Cognizant's proprietary BusinessCloud solution. He holds a Bachelor of Engineering in metallurgical engineering from the Indian Institute of Engineering, Science and Technology (formerly Bengal Engineering College, Shibpur). He can be reached at Sougata.Chakraborty@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 211,500 employees as of December 31, 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 (0) 20 7297 7600
Fax: +44 (0) 20 7121 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