

CASE STUDY

Integrated Complaints Management – Key to Rapid Resolution for Internal & Supplier Nonconformances and Customer Issues

In Brief

Customer Profile: This global medical diagnostic company develops, produces, and markets medical diagnostic products for near-patient, or point-of-care testing. Its product line is sold in more than 120 countries.

Situation: Since increasing distribution, the growing need to quickly process any incoming complaints, resolve issues to satisfy customers, and maintain a continuous state of regulatory compliance, had clearly emerged.

Solution: This company implemented SmartSolve to raise the bar with its response processes for complaints. The solution effectively removed risk, improved efficiencies, replaced outdated systems, and thus, enabled improved process automation, visibility, and reporting.

Business Type: Medical Device Products Manufacturer

Users: More than 500 users within this company's European and North American facilities.

Pilgrim Quality's SmartSolve® Solutions: Complaint Management, Nonconformance Management, Supplier Quality Management, CAPA Management, and Audit Management.

Life Sciences organizations today are seeing a growing occurrence of adverse events, safety problems, and product recalls, driving them to take an integrated approach to product quality, safety, and risk management. However, this diversified manufacturer upholds its positive public perception by continually striving to be ahead of the curve on all fronts.

Recently, this manufacturer had a vision to implement an integrated compliance system to support this commitment to quality and safety. The goal was to unite operations at its multiple manufacturing and distribution sites and drive global product quality and customer satisfaction.

Challenge

A very detailed and process-oriented company, this global enterprise has a keen eye on continuous improvement. With manufacturing operations on one side of the globe, and a primary distribution center on the other, this company wanted to establish an enterprise-wide automated, yet flexible, process for fielding external product complaints and tracing the causal internal nonconformances.

Previously, complaints were recorded in multiple, disparate forms, both paper-based and electronic. Later, when one electronic form was adopted across the organization, the company found that though it was universal in format, it lacked the functionality and flexibility necessary for capturing and recording the

distinct data needed among the various locations.

The Quality group wanted to modify the form to enhance its functionality and flexibility for broader use, such as allowing administrators to modify the form's questions and select which questions would be generated depending on the particular complaint raised. If the detail and presentation of the complaint report forwarded by QA could be better, the corresponding CAPA investigation process would be executed more efficiently. However, management quickly recognized the costs required to modify the existing form would require a significant amount of both IT and budgetary resources.

To overcome those challenges, this company needed to implement a corporate-wide complaint reporting process that would allow administrators themselves to modify complaint recording forms. This would, in turn, support individuals further downstream in the complaints handling process by providing them very specific customer and product complaint information for first-level analysis.

With a global presence and long-standing favorable reputation for quality and customer satisfaction, this manufacturer selected Pilgrim Quality Solutions' Web-based SmartSolve® platform to support customer complaints and key related quality, compliance, and risk management processes.

Solution

Since its implementation, SmartSolve has bolstered complaints receiving and handling, internal and supplier nonconformance management, CAPA processing, and internal and external auditing.

With its configurable form for complaint recording, built on industry best practices, SmartSolve allows this manufacturer to capture relevant complaint information across the entire organization, including its primary distributor site. The electronically generated in-take form is built based on five criteria

that are posed to the complaint reporter. The reporter selects those applicable, and this, in turn, generates between five and 20 questions which are posed to the reporter. The compliant form is then submitted for evaluation and analysis.

The administrators are now able to create and/or modify the questions as needed per specific circumstances, such as product version changes or new insight based on previous inquiries/complaints. In the case of the distributor, this allows them to more easily enter the required information and ensures that the quality of the information reported to the manufacturer is appropriate. With accurate information being fed to the manufacturer, investigation and resolution are efficiently expedited.

Complaint Management not only streamlines the entire complaint collection resolution lifecycle — from complaint capture to investigation, through regulatory reporting, resolution, and customer communications — it also enables enterprise-wide standardized complaint handling processes. This manufacturer can now manage deviations and incidents in real time to quickly identify resolution strategies and take fast action to resolve problems.

In addition, email notifications, commitment tracking, and escalation capabilities help eliminate bottlenecks and ensure rapid resolution. Activity logs and customer letters are stored in a single, centralized solution. And, powerful reporting and trending capabilities provide fast, accurate information, helping management make meaningful and effective decisions with the ability to drill-down into issues and offer valuable insight into the top recurring complaints and time required to resolve issues.

Business Benefits

With the addition of Complaint Management and its integrated systems, this company has effectively realized a significant return on its investment. In addition to expediting the initial intake and

acknowledgment of customer complaints, this company has seen a significant reduction in the cycle time for closing out complaints, aided by improved visibility of a given complaint from the customer's perspective (the custom-generated questionnaires), and a more adequate and efficient flow of information downstream to resolution.

With SmartSolve Nonconformance Management capabilities, this manufacturer now has clear visibility into its internal processes enabling it to identify problem sources. The capabilities of SmartSolve Supplier Quality Management permit visibility into what products or components are being returned by customers, shining a light on quality concerns to address to prevent recurrence.

SmartSolve Audit Management acts as a continuous feedback mechanism for this medical device producer to obtain critical insight. This enables the company to assess its processes against both internal and external standards.

In essence, SmartSolve enabled this globally recognized medical device manufacturer to experience:

- Truly increased efficiency and productivity
- Improved complaint receiving and recording
- Shortened complaint time-to-resolution
- Increased management oversight
- Improved global enterprise communication
- Harmonized/standardized business processes
- Reduced volume of paperwork
- Reduction in escalations
- Regulatory compliance

About Pilgrim Quality Solutions

Established in 1993, Pilgrim Software is the most experienced enterprise quality management provider in the life sciences industry with more than 750,000 end-users.

Pilgrim is dedicated to research and development and incorporates industry best practices into its products resulting in solutions that are specifically targeted to streamline critical quality processes and provide the bottom-line results that life sciences organizations demand. Built on leading web-based open architecture standards, Pilgrim's cost-effective solutions incorporate industry best practices and limit the need for extensive training, saving customers implementation time and labor costs.

Visit www.pilgrimquality.com for more information.

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