In Brief

Customer Profile: This medical and consumer products company manufactures and markets the most complete line of home personal health care products sold in America and distributed by retailers in more than 60 countries.

Situation: The company recently became a Medical Device manufacturer when it began producing and distributing several diagnostic products that are considered medical devices by FDA regulations. Therefore, it desired a complaint handling solution that ensures both product quality and FDA compliance.

Solution: This manufacturing company selected Complaint Management to enable the execution of effective, timely resolutions for customer issues.

Business Type: Medical Device

Users: Approximately 100 employees among both the Quality and Complaints departments are using SmartSolve as part of their daily job function.

Pilgrim Quality’s SmartSolve® Solution:
  •  Complaint Management

A leader in home personal health care products sold in America manufactures and distributes more than 250 types of these popular consumer goods, as well as products classified as medical devices. It employs more than 1,000 at its U.S.-based headquarters and sales production sites worldwide. At its headquarters, its Quality and Consumer Relations divisions manage issues that impact the company’s industry and regulatory compliance, product quality, and customer satisfaction.

Challenge

Prior to implementation, this company’s Customer Call Center operation had been managing customer complaints through primarily manual processes, requiring representatives to retrofit pertinent data into generic, standardized paper-based forms and spreadsheets that provided only for manual trending and reporting via those spreadsheets. Incoming complaints were logged on paper; the paper documents were scanned into electronic format, then passed over to the Quality group for handling.

Likewise, the resolution process was also manual. Complaint reports were forwarded to the manufacturing sites to which the products in question were traced, then returned to headquarters for follow-through.
The existing manual system hindered the company's ability to capture and share complaint information across the entire organization, and led to unnecessary processing time and resolution cost.

The company recognized that the ongoing liabilities of continuing to operate manually outweighed their trepidation to commit to implementing an automated, enterprise-wide complaint management system. This enterprise needed a quality and complaint management system that would unite related functions worldwide, improve its efficiency and productivity, and maintain ongoing compliance and customer satisfaction.

After evaluating nearly a dozen such systems, they prioritized their pressing concerns into a shortlist of solution requirements: an out-of-the-box solution that would minimize complications with installation and integration; logical interface between disparate system responsibilities; minimal IT dependence; rapid implementation time; manageable long-term maintenance; and lower purchase and overall costs.

### Solution

Pilgrim Quality Solutions was ultimately selected as the chosen provider for its ability to satisfy all of these criteria. Pilgrim built best practices into SmartSolve Complaint Management, its closed-loop, web-based complaint management solution. The best practices approach takes root, in part, in Pilgrim’s thorough understanding of the FDA requirements to which this company is required to adhere.

Complaint Management also offered the company a simple solution to meet contact management requirements because it easily integrated with the already-in-use Contact Management System (CMS) for Call Center users. While the existing CMS recorded key data (who is the customer complainant, what product was purchased, what was the defect), SmartSolve integrated with the CMS system to provide customized forms that automatically trigger an appropriate, product-specific set of questions required to investigate and resolve the typical complaints received.

Complaint Management, with its configurable workflow models, allows companies to capture complete information about a complaint among the company’s four specific category codes. Forms contain customer information, product identification criteria, sample returns, and complaint type (such as inquiries). Complaint Management affords the ability to make rapid, informed decisions about complaint validity and resolution strategies.

“The Pilgrim solution impressed us because it is a configurable solution, but not overly configurable so as to extend or complicate deployment, and it provided enough structure and enough visibility to balance out what configuration we did require,” according to the company’s manager of Application Support and Services.

The entire implementation process, including the integration and system validation, was completed in four months. “Had we not used the OQ type of product validation, the project might have taken longer, but Pilgrim was there to offer support throughout, and actually provided a good validation example to follow,” the manager said.

### Business Benefits

Since the solution was implemented, this leading provider of health products has realized many benefits, particularly in the area of processing efficiencies. They have been able to implement consistently effective, timely resolutions to customer issues which has helped ensure industry and regulatory compliance, improve product quality, and reduce costs associated with customer complaints.
Major soft cost savings have included:

- Streamlined complaint resolution lifecycle from complaint capture, to investigation, through resolution and customer communications
- Rapid end-to-end processing of complaints among entire enterprise worldwide
- Standardized complaint handling processes across the organization
- Management of deviations and incidents in real-time for quick identification of resolution strategies, enabling quicker action to resolve problems
- Email notifications, commitment tracking, and escalation capabilities to help eliminate bottlenecks and ensure rapid resolution
- Ability to manage complete customer communication with activity logs and customer letters stored in a single, centralized solution
- Streamlined regulatory submissions through the use of standard, but configurable automated decision trees to assist in medical device reportability reviews (MedWatch forms) for the FDA
- More efficient tracking of MDRs
- Increased management oversight through powerful reporting and trending capabilities
- Ability to drill-down into issues and offer valuable insight into the top recurring complaints and time required to resolve issues

As this company continues to lead the way in the health and wellness products category, it is next looking to implement Document Management, Audit Management, CAPA Management, and Training Management to further support the streamlining of its operations. Their goals for this expansion are achieving even greater efficiencies, productivity, cost savings, risk avoidance, and overall customer satisfaction.

**About Pilgrim Quality Solutions**

Established in 1993, Pilgrim Quality Solutions 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](http://www.pilgrimquality.com) for more information.

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