

CASE STUDY

Adopting an Automated CAPA System Establishes a Harmonized Global Quality Process

In Brief

Customer Profile: This company is a worldwide developer, manufacturer and marketer of medical devices for interventional medical specialties. Approximately 24,000 employees at 12 geographically dispersed manufacturing facilities support the availability of products in nearly 100 countries worldwide.

Situation: After merging with another leading Life Science enterprise and acquiring other medical device companies, it needed a standardized global, enterprise-wide Nonconforming Event or Prevention (NCE/P) and CAPA management system to streamline and optimize these processes across all sites.

Solution: By implementing Pilgrim Quality Solutions' CAPA Management, the company established a common workflow across all global sites, permitting ongoing oversight into quality and compliance issues, and solidifying its reputation as the global leader in the non-invasive medical industry.

Business Type: Medical Device Developer, Manufacturer, Marketer

Users: Quality Systems at its headquarters and across the Americas, Europe and EMEA

Pilgrim Quality's SmartSolve® Solution: CAPA Management

This leading global medical device company's net sales have increased substantially since its formation over 30 years ago. Its growth has been fueled in part by strategic acquisitions designed to improve its ability to take advantage of growth opportunities in the medical device industry. Its strategic acquisitions have added promising new technologies to its pipeline and enabled the firm to offer one of the broadest product portfolios in the world for use in less-invasive procedures.

Recently, new leadership, a global strategy, and a continued commitment to meaningful innovation set the stage for a new era of growth for this enterprise. The company continued to expand internationally, particularly in the emerging markets of Brazil, Russia, India and China.

With its global manufacturing and marketing on the rise, the company continues to implement new systems designed to provide improved quality, reliability and service, greater efficiency, and lowered supply chain costs. It has substantially increased its focus on process controls and validation, supplier controls, distribution controls, and providing its operations teams with the training and tools necessary to drive continuous improvement in product quality. The company continuously examines its operations and general business activities to identify cost-improvement opportunities to enhance its operational effectiveness.

This company is committed to providing high quality products to its customers, so to meet this commitment, it has implemented updated quality systems and concepts across the enterprise. Its quality system starts with the initial product specification and continues through the design of the product, component specification process, and the manufacturing, sale and servicing of the product. The quality system is intended to build in quality and process control and to utilize continuous improvement concepts throughout the product life. These systems are designed to enable the company to satisfy the various international quality system regulations.

Challenge

Over the years since undertaking numerous acquisitions, including its largest nearly a decade ago, the company inherited numerous disparate quality processes, many manual or hybrid. With each, it has had to contend with adapting the standard business operations of those companies to integrate with its own. These adaptations, along with the company's expanding global operations, highlighted one particular quality process that needed to be both revamped and harmonized.

The company needed to establish a global standardized Nonconforming Event or Prevention (NCEP) and CAPA management system that would support its initiative to streamline these processes and eliminate cumbersome and potential error-prone paper processes. Improved cycle time, greater consistency in the application of problem-solving tools, and improved control of nonconforming material were major objectives of a single NCEP/CAPA system.

Additionally, with the global regulatory environment becoming increasingly stringent and unpredictable, and certain regulators requiring local data as well as global data, it was increasingly critical that this company would be able to confidently address quality

issues and provide the supporting documentation to validate its quality procedures, anywhere and at any time.

Solution

After assessing multiple providers, including several incumbent software firms and other leading quality and compliance management vendors, this global medical device company chose to implement Pilgrim Quality Solutions' CAPA Management. Based on review criteria, Pilgrim offered the best fit with the company's IT strategic plans and roadmap for further harmonization and cost reductions: a scalable architecture joined to a flexible workflow solution and backed by a world-class organization.

The global business processes to be automated in the NCEP and CAPA system would bring together the common needs of various functional groups across 20 operational locations. It defined an approach to a solution which will facilitate collaboration, provide resource and knowledge sharing, and ultimately increase efficiency and productivity across the entire organization.

Specific features and benefits in Pilgrim's solution that appealed to this company included:

- Standard workflows to drive a consistent process across the enterprise
- Form-level validations to enforce business rules on high-risk issues
- Powerful ad-hoc reporting capabilities with the embedded SmartInsight® toolset
- Standard audit-facing reports with fully integrated Crystal® reporting
- Customizable dashboards to provide clear visibility of pending due dates by site and user
- Easily configured contextual help icons to reinforce learning
- Hands-on, pragmatic and highly effective consulting and integration support

Business Benefits:

The implementation of its eCAPA program built on Pilgrim's solution marks the first time this company has deployed a validated quality and compliance solution platform globally. Since implementation, the company has achieved a more efficient, effective and simplified CAPA process, enabling it to identify and correct issues more quickly for its customers and patients and be more competitive in the world market.

The program has contributed to the achievement of zero CAPA-related FDA 483 observations in over two dozen inspections across 20 locations.

Benefits realized by the company include:

- Optimized the efficiency and effectiveness of its CAPA process
- Eliminated hard-copy processes for transactions, documentation, reporting and trending CAPA and nonconformance events
- Standardized processes to produce consistent results and document them
- Allowed universal access to CAPA records to support audit management
- Facilitated trending of emerging issues to enable meaningful preventive actions
- Improved visibility to CAPA workflow for transformational change to total time-to-CAPA-completion
- Uses electronic signature to streamline oversight and reviews
- Significantly reduced complexity and eliminated more than 150 SOPs

When organizations such as this worldwide enterprise implement Pilgrim's solution, they can leverage its flexibilities and global capabilities to improve operational efficiencies while reducing risk and enhancing compliance.

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 for more information.

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