

CASE STUDY

Establishing Operational Harmony through Integrated Quality and Compliance

In Brief

Customer Profile: This North American company is a global leader in the field of filtration, separation and purification processing equipment for the pharmaceutical, biotech, and industrial markets.

Situation: The company had more than a dozen separate Life Sciences units worldwide operating independent quality and compliance management systems, ranging from point solutions woven together with manual interactions, to home-grown systems.

Solution: SmartSolve® now standardizes quality and compliance management systems across the enterprise, with all sites sharing data to rapidly resolve any quality or regulatory issues that arise.

Business Type: Medical Devices & Processing Equipment

Users: More than 5,000 employees in more than 40 locations around the world.

Pilgrim Quality's SmartSolve® Solutions: Audit Management, CAPA Management, Change Management, Complaint Management, Document Management, Nonconformance Management, and Training Management

Challenge

This company is comprised of more than a dozen separate Life Sciences sites, with nearly as many disparate systems for managing customer complaints and adverse events, corrective and preventive actions, and internal and external audits. Without a standardized platform for these critical management systems, the company faced multiple challenges for ongoing quality and compliance objectives.

Internally, having multiple disparate systems forced the company to contend with lengthy cycle times for activity completion; multiple, non-synchronized views of metrics; and delayed identification, analysis, and reporting of adverse events, nonconformances, customer complaints, and regulatory concerns. At the executive level, it was facing potential operational inefficiencies, cost inefficiencies, regulatory risk, and possible loss of customer confidence.

As such, this company realized it needed a single quality and compliance software system to consistently meet customer expectations by leveraging industry best practices. To meet its global requirements, the system would need to unite its employees, improve their efficiency and productivity, and account for differences in language and time across its multiple sites around the world.

Solution

Recognizing the vulnerabilities of a non-harmonized quality and compliance management operation, management evaluated the various systems in use among their multiple Life Sciences divisions. They also researched alternative platforms including Pilgrim Quality Solutions' SmartSolve®.

The company selected Pilgrim because "it had it all in one — a single set of solutions to help with global harmonization," said one IT manager. "Otherwise, we could have been looking at implementing five or six different systems, then integrating them, a monumental task on its own, and training our internal users. From a regulatory standpoint, the standardization is key. All our sites are doing things the same way across the board, and auditors are impressed.

"From a performance standpoint, Pilgrim's solution appealed to us in large part because it enables us to trend and report on metrics in real time, and technically, the system is pretty simple to configure and maintain," he continued."

The company initially implemented SmartSolve Complaint Management globally, enabling it to track and trend all complaints by customer, product, and line of business, as well as assess the overall cycle time to resolution. As a direct result of the solution's capabilities, over a six-month period the company saw a 90 percent decrease in complaints open more than 30 days. The progress has remained steady since.

"Since the solution has been in place, we've seen a tremendous increase in productivity resulting in, on average within our Medical division, a 60 percent cycle time reduction in completing most tasks," management reported. "We can drill down from a global level, and have the visibility now to identify the source of the problem and bottlenecks, and then measure the cycle time to assess whether we're meeting our own standards for turn-around time."

The rollout of Pilgrim's Corrective and Preventive Action (CAPA) Management has been similarly successful, leading to operational improvement and cost savings on the manufacturing side. The company can now track the source of a nonconformance, including which product, which supplier, and again, cycle time. Pilgrim's solution manages internal nonconformances, inter-company complaints, systemic CAPAs (process, not product-related), and supplier nonconformances.

"This has been the biggest eye-opener," said one manager. "We have sites that share suppliers, and having one system for CAPA management reduces variability and enhances visibility and identification of supplier problems. Together with Pilgrim's Audit Management, we can discover, for example, that one vendor is the source of a widespread problem, and we'll then reconsider our partnership with that particular supplier," he said.

In addition to supplier audits, this manufacturer's global organization uses Audit Management for customer and third-party audits. Its largest Life Sciences site is divided into two areas — Medical and Biologics — but their operations are harmonized through Pilgrim's platform. The site is typically audited by customers 1-2 times per week. Audit Management helps drive efficiency and improvement at the site level.

In addition, having this global view better prepares their multiple sites to handle audits. For example, if one site gets audited by a customer or supplier, and a second site is scheduled for a future audit, they can preview and evaluate what type of information the auditors were seeking and what they noted at the first site in order to prepare for their own audit.

The implementation of Pilgrim's Document Management at the corporate site has driven a major reduction in cycle time for completing new SOPs. Previously, the process could take up to a year, but

now, from initiation to effectiveness, it takes just one month. Management reports that the most beneficial features of the solution have been the proposed changes, references, and repositories capabilities.

Overall, in just one short year, this global enterprise has seen a vast improvement in the cost of quality — a perfect FDA audit (zero observations), a reduction in shipping costs related to customer complaints, and a reduction in overhead through streamlined documentation, tracking, and reporting in quality management operations.

Business Benefits

Within the two years since all the enterprise solutions went live, this corporation has realized many benefits in hard costs, including a 10-15% reduction in the cost of quality. Major soft costs savings have included:

- Reduction of audit observations
- More robust CAPA system for tracking product and process nonconformances
- Electronic reporting capability for improved metrics gathering
- Real-time global view, eliminating 13 separate views through multiple reports every 2 weeks
- Elimination of 30 old databases
- Harmonized and standardized business processes, resulting in the retirement of 8,000 documents
- Improved accountability of employees
- Enhanced site-level productivity
- Decreased overhead
- Improved visibility of supplier problems
- Improved on-time product delivery, resulting in as much as a 60% decrease in complaints
- Timely reporting submissions from all sites
- Meets or exceeds customer expectations for product quality
- Meets or exceeds overall customer satisfaction through rapid resolution of complaints

In the short-term, this company will implement Pilgrim's training and electronic change control

management solutions to improve the efficiency and robustness of its training processes and expedite introduction of new SOPs across the organization. In the future, thanks to SmartSolve's integrated design and scalability, the company will be able to seamlessly harmonize the systems of any future sites or functions it may engage.

With Pilgrim's cost-effective, value-added solution, the company has successfully met its objectives for harmonizing its multiple Life Sciences divisions, thereby reducing risk, ensuring compliance with current industry regulations, strengthening overall quality and customer satisfaction, and increasing efficiency and productivity.

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.

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