

CASE STUDY

A Quality Management System for Contract Manufacturing: Minimize cGMP Compliance Risk and Improve Customer Service

In Brief

Customer Profile: This CMO offers state-of-the-art packaging design and development services for the pharmaceutical and health care industries and operates laboratory and testing facilities to satisfy the product requirements.

Situation: This company was seeking a Quality Management System (QMS) solution to improve and expedite operational processes by eliminating manual, non-value added activities.

Solution: This CMO selected Pilgrim's SmartSolve® quality and compliance management system to accommodate the company's growth and protect its customers' product.

Business Type: Contract Manufacturing

Users: More than 1,100 employees among seven pharmaceutical and specialty packaging manufacturing facilities increased productivity resulting from the implementation of Pilgrim's document, training, and corrective/preventive action management solutions.

Pilgrim Quality's SmartSolve® Solutions:

- Document Management
- Training Management
- CAPA Management
- Nonconformance Management

As a rapidly growing contract pharmaceutical package manufacturer, this enterprise operates one of the most progressive process, facilities, and validation programs in the CMO industry, upholding a consistent reputation for best-in-class quality and unparalleled customer service. It employs more than 1,100 at its U.S.-based headquarters and multiple manufacturing facilities. As a contract manufacturer of products within a highly regulated industry, it is critical that the entire operation maintain a fully integrated quality and compliance management system to both ensure its own sustainability and to secure confidence among its customers who have entrusted it with the care of their assets.

Challenge

Until 2009, this company had been managing internal documentation and change control, training, customer complaints, nonconformances, CAPAs, and audit preparations through disparate and primarily manual processes. As a result, there have been multiple non-value added action items required of various departments, and a growing need to improve compliance in those areas.

The lack of integration among those areas' respective systems contributed to regulatory vulnerability regarding training completion and periodic reviews of SOPs and documents. These limitations were visible during customer audits. Likewise, without integration, visibility between departments had been extremely limited. The lack of visibility made notification,

tracking, and deployment of CAPAs difficult. Both processing and completion time would need to be improved to ensure that quality and compliance standards would be consistently met.

Employee training had been a highly manual system requiring time-consuming maintenance of matrices for training event requests, notifications, proficiency testing distribution and grading, and tracking metrics — all tracked in spreadsheets. The company's document, content management, and change control systems were also not consistently effective due to frequent variations in data input and management. Additionally, without built-in security controls, the manual system could not be accessed by customers — resulting in added manual steps that increased the processing time for customer review and approval of documents.

This CMO was also engaging a variety of manual, semi-automated, and homegrown systems for CAPA, complaints, investigations, and audits. Managing those events involved steps built into different systems. Complicating this process, the company's multiple divisions were not all engaged on the same system software, and there was limited access and visibility among them.

After evaluating various automated EQMS solutions, they selected Pilgrim's fully integrated, prebuilt SmartSolve as the most effective solution. It addresses the company's quality and compliance concerns and satisfies their user requirements, its Lean Six Sigma standards, and U.S. and global regulatory requirements.

Solution

Pilgrim Quality Solutions was chosen as the provider both for its ability to support the contract manufacturer's quality and compliance management processes, as well as for the industry best practices that Pilgrim has built into the 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.

SmartSolve Document Management helped this business cost-effectively create, manage, and share critical documents and best practices through the entire enterprise. It provided a framework of document control to meet industry and regulatory requirements by offering these integral features: creation, versioning, approval, change, training, and review processes. And, it gave them a means to allow secure access for customer and vendor review and approval.

By connecting the company's people, processes, and documents in a single system, Document Management improved the organization's effectiveness, agility, and regulatory compliance — resulting in annual labor savings of \$71,000.

SmartSolve Nonconformance (NC) and CAPA Management helped this CMO overcome risks through closed-loop processes, allowing users in any department to initiate an investigation to quickly resolve an issue and prevent recurrence. This proactive approach to event management ensures corporate well-being and industry and regulatory compliance.

Training Management ensures the CMO sustains an educated and proactive workforce, superior job quality, and industry and regulatory compliance throughout the enterprise. It simplified the management of skills sets and certification requirements, streamlined classroom and on-line course activities, and drove annual labor savings of \$79,000.

And, with SmartSolve, this company reduced its 24-step/6-system event management process down to a 6-step single system. This effectively

centralized change controls and thereby expedites audit observations, internal investigations, customer complaints, and laboratory out-of-spec (OOS) situations. In addition, SmartSolve displays all QMS tasks on one screen. With this increased efficiency and visibility, the company saved more than \$80,000 annually in labor costs.

Business Benefits

With the implementation of these integrated solutions from Pilgrim, the CMO achieved a rapid return on its investment by realizing these key business benefits:

- Real-time data for improved decision making
- Reduced process time
- Reduced inefficiency due to variation
- Reduced non-value added manual activities prone to error
- Minimized IT support due to common integrated platform
- Reduced physical storage efforts and space
- Eliminated hard copy filing and retrieval efforts
- Increased inter-departmental and cross-functional communication
- Centralized oversight of company-wide projects and built-in metrics
- Scalable, configurable solution to accommodate company growth
- **Year over year, a 5-year savings of nearly \$1.2 million**

The key regulatory benefits include:

- Part 11 and cGMP compliance
- Centralized change control
- Risk reduction through improved compliance
- Consistency through automated management
- Better facilitation of continuous improvement through capture of key process data
- Increased visibility and access to users, various departments, divisions, management, and customers

Pilgrim Quality's quality and compliance management system will provide this globally respected company a highly automated, visible, lean, real-time, cGMP-compliant system that will effectively minimize the potential for cGMP non-compliance, while boosting customer satisfaction and its bottom line.

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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