

CASE STUDY

Global Document Lifecycle Management: Structured Lifecycle and Change Order Management for Controlled Documents

In Brief

Customer Profile: This global health care company manufactures 1,500 medical products and equipment. The company employs more than 12,000 people and markets its products in more than 150 countries worldwide.

Situation: The lack of efficiency in document handling contributed to insufficient visibility of critical documents and complicated change control management. Ideally, they would replace manual processes, eliminate non-value added activities, and improve compliance with global regulatory requirements.

Solution: The company implemented Document Management to replace its paper-based procedures. The solution ensures the most accurate, up-to-date information is available within any of the company's global sites on demand.

Business Type: Medical Device Manufacturer

Users: 800+ total document viewers, 100+ document owners/approvers at the company's headquarters as well as six sales branches and five business units

Pilgrim Quality's SmartSolve® Solutions:

- Document Management
- Change Management

With state-of-the-art manufacturing facilities making extensive use of automated processes and systems, this company takes enterprise quality management software (EQMS) seriously across its other plant sites and sales offices. Its Quality System is certified to ISO 13485 and ISO 9001 standards, and its superior manufacturing processes are a vivid example of the success that can be attained when an entire enterprise focuses on quality. As a manufacturer of products within a highly regulated industry, it is critical that the entire operation maintains 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

Throughout the past decade, this medical products manufacturer has continued to expand its product portfolio, manufacturing sites, and workforce. With each step along the way, the challenge to maintain operational efficiencies in an ever-increasing regulatory environment has spiraled.

Until 2009, this company had been managing internal documentation and change control through disparate and primarily manual processes. On the manufacturing floor, a binder of printed, controlled documents was literally hand-delivered to employees every week, and approvals were signed off on paper. As the manufacturing company was

expanding into the U.S. market, it needed to comply with FDA regulations including 21 CFR Part 11 for electronic records and signatures. Further, in today's highly regulated industries, accuracy of data and real-time access to quality records are critical to a company's compliance to operational and regulatory requirements.

To combat these challenge, the company would need to:

- Increase efficiencies across departments
- Improve compliance and audit results
- Match growth of quality system with increasing consumer demand
- Reduce risk of damage to brand and maintain consumer trust

Anticipating the upward trajectory of its portfolio and reach, the company began seriously considering its automation options. The selected solution would need to be flexible enough to allow for beginning with a small investment and growing over time.

After evaluating various automated EQMS solutions, including other solutions within its parent portfolio of companies, the company selected Pilgrim Quality Solutions' fully integrated, out-of-the-box, enterprise compliance and quality management as the most effective solution for addressing its quality and compliance concerns. The solution would satisfy the company's user requirements, its quality standards, and critical U.S. and global regulatory requirements. The initial focus would, however, be on the Document Management capability of Pilgrim's EQMS platform, SmartSolve.

Solution

Pilgrim was selected both for its ability to support this global manufacturer's quality and compliance management processes, and for the industry best practices that they have built into the solution. The

100% Web-based SmartSolve Document Management has helped the company cost-effectively create, manage, and share critical documents and best practices throughout the entire enterprise.

Prior to implementation, Pilgrim supported this company in migrating its current documents, including SOPs and forms, into Document Management. All forms used by local sales offices throughout Europe were also migrated into the system, allowing the remote sales staff to locate, retrieve, and use the latest version of the required form.

Since going live, Document Management has provided the company a document control framework to meet industry and regulatory requirements with these integral features: creation, versioning, collaboration, approval, release, change control, training and certification management, and periodic review processes. By connecting this company's people, processes, and documents, Document Management has improved the organization's effectiveness, agility, and competitiveness.

One company administrator stated that SmartSolve provides a solid, unified framework of quality and compliance solutions to meet industry and regulatory requirements: "We are pleased that we have fully leveraged SmartSolve Document Management to automate our document control and change request needs. We're also pleased with the inherent flexibility and scalability of each of Pilgrim's integrated products, knowing those characteristics will become critical as our infrastructure, processes, and production continue to grow."

He also said the company looked at numerous software packages and most importantly, challenged the products through numerous demonstrations and use-case presentations. "The more we challenged the products, the more Pilgrim applications stood out. The depth, the breadth, and the relative simplicity

in configuring and using the products became very evident.”

Looking ahead into the next decade, Document Management will help ensure this company's ability to meet expected future demand, while remaining in full compliance with industry and regulatory requirements. The solution provides a consistent approach for enterprise-wide visibility of the document status globally, and in real time, contributing to both process efficiency and, subsequently, an enhanced bottom line. This company also intends to implement the remainder of SmartSolve's EQMS solutions and derive the same level of benefits for increased operational efficiencies and a higher degree of predictable regulatory compliance.

Business Benefits

With the implementation of Document Management, this medical products manufacturer is earning a rapid return on its investment with these key business benefits:

- **Accelerated Document Review Cycles:** Document templates and automated workflows shorten the time it takes to create documents, route them for approval, and make revisions. When bottlenecks occur, the solution's escalation capabilities redirect work to ensure that tasks are completed on time.
- **Change Management:** With review schedules, workflows, and change notification capabilities, this solution ensures that the most accurate, up-to-date information is available on demand. This helps enforce SOPs by providing instant access to the latest revisions.
- **Increased Visibility Across the Value Chain:** Powerful, customizable reporting capabilities enable the creation of critical reports such as approval cycle times, time-to-close-out on changes, and master document reports to help align to Key Performance Indicators (KPIs) and monitor the progress and status of a document.

- **Facilitates Compliance & Validation:** With role-based document security, powerful password authentication, a complete audit trail, and an easy, automated validation process, Document Management facilitates compliance with internal and industry standards and regulatory requirements such as: 21 CFR Part 11, FDA standards; ISO 13485, 14001, and 9000; GMP, GLP, and GCP; Environmental and Workforce Safety; EU, International Health Ministries; and more.

Additional “soft cost” benefits include:

- 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
- Best Practices forms and workflow for Change Management
- Ability to identify change categories and impacts
- Automated notification triggers, task assignments, and escalations for overdue tasks
- Highly configurable review and approval processes throughout Change Management workflow
- Unlimited file attachments for references/supporting documents
- Scalable, configurable solution to accommodate company growth
- Consistency through automated management
- Better facilitation of continuous improvement through capture of key process data

Pilgrim's quality management system provides this globally respected company a highly automated, high-visibility, lean, real-time, cGMP-compliant system that effectively minimizes 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.

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