

## CASE STUDY

# Integrated Document and Training Management Software: Providing Synchronized Personnel Knowledge Management within a Life Science Enterprise

## In Brief

**Customer Profile:** This medical device company manufactures minimally invasive equipment used to treat vascular diseases. Headquartered in the United States, with additional offices in Europe, it is a respected leader in the growing neurointerventional market.

**Situation:** This manufacturer sought a robust, closed-loop electronic document and training management solution to structure and automate document, change, and training and to provide visibility into newly created documents and SOPs.

**Solution:** SmartSolve® improves accessibility and quality of critical documents, automates employee training records and certifications, and harmonizes the company's change control processes to address day-to-day changes.

**Business Type:** Medical Device Manufacturer

**Users:** All employees can check training status and sign off on documents as part of their daily job function.

**Pilgrim Quality's SmartSolve® Solutions:**

- Document Management
- Training Management
- Change Management

For over a decade, this medical device manufacturer has been developing proprietary interventional neuroradiology devices. The company, headquartered in the United States, with additional operations in Europe, is considered a globally recognized leader in its industry.

## Challenge

Throughout the decade, this company has been growing as its proprietary technology has been gaining a stronger global foothold. As the acceptance of its products has spread, so, too, has its pursuit for enhanced operational efficiencies.

Until recently, the company had been managing its training and certification processes and their related documents on disparate internal servers. This often complicated processes and impeded version control. Document change order (DCO) processing times were lengthy since the Document Control Group spent time on related activities such as administration and tracking down documents. As such, it was difficult to handle certain complex requirements where simply reading documents was not sufficient.

The company wanted to improve automation and streamline its training and certification and document management procedures. They needed a solution to generate substantial benefits for improving process efficiency and process results. Most importantly, an automated document solution would improve cycle

times for document review and approval, which in turn, would automatically make those documents available to employees for more rapid training and certification.

An additional underlying force driving this manufacturer's quest for process quality improvement was the looming compliance requirements of global regulatory bodies. With adherence to industry standards enforced by the FDA, it was already operating at high levels of compliance. However, as the company expanded its production and distribution globally, management understood the critical need to adopt integrated electronic solutions to support quality, safety, and compliance with CFR 21 Part 11 and the Medical Device industry-specific Part 820 requirements. Complicated, disjointed systems leave an organization vulnerable to not only regulatory scrutiny, but can also lead to failed audits, potential recalls, harmed reputation, loss of customer trust, and loss of profits.

## **Solution**

Pilgrim Quality Solutions' Enterprise Quality Management Solution (EQMS) SmartSolve was ultimately selected. SmartSolve enhances this company's document and training management efficiencies and ensures its compliance with regulatory requirements and international standards. The two systems have been deployed within the quality, regulatory, and clinical functions of the company.

SmartSolve Document Management replaces the previous manual systems and now enables trending and analytics of various metrics involved with document release and revision timelines, training requirements, and training performance. It provides centralized storage and access; review processes with a pre-built signature matrix; and access control with the abilities to add or remove approvers, protect confidentiality among viewers and editors, and secure electronic signatures, all in real-time. The company has moved from a file server-based document storage control solution, an unreliable approach, to

[www.pilgrimquality.com](http://www.pilgrimquality.com)

an enterprise solution that consolidates information and brings robust security controls to the forefront, ensuring that the right people have access to the right information at the right time.

From a change control perspective, SmartSolve automates the entire lifecycle of a document change. The robust change control system can track changes to multiple documents from a single record. Users are notified when changes are made to documents that affect their training requirements. In addition, the real-time capabilities can disable document accessibility (for viewing or printing) during a major change.

With SmartSolve Training Management, training events are triggered by the release or revision of documents. Notifications are sent via email, and email notification escalations are sent to supervisors for any delinquent training records. Because Document Management integrates directly with Training Management, this medical device manufacturer eliminated the cost of integration between two disparate systems — something that would have needed to be manually integrated otherwise. In the future, the company can easily deploy other SmartSolve quality and compliance management solutions, including Audit, Complaint, and CAPA Management for a fully integrated, closed-loop quality process.

## **Business Benefits**

In addition to the day-to-day benefits of these two solutions, on a broader level, better, formal change management practices have led to substantial compliance improvements and operational risk reductions — including potential product recalls and litigation. With role-based security, powerful password authentication, a complete audit trail, and an easy, automated validation process, SmartSolve helps this company maintain compliance with internal and industry standards and the regulatory requirements of: 21 CFR Part 11 and Part 820; ISO 13485, 14001, and 9000; GMP, GLP, and GCP; Sarbanes-Oxley (SOX); OSHA; EU, International Health Ministries; and more.

By automating these business processes and strengthening its change control, this company has successfully streamlined its overall operating environment and realized a significant return on its investment. In hard costs, it estimates the annual reduction in labor and materials costs to be approximately 5,000 man-hours, translating to a budget savings of \$400,000 annually.

Breaking it down by solution:

**Training Management** — Annual Savings: \$198,750

- Eliminated SOP-related manual training, preparation, and grading of quizzes by training and department coordinators.  
**Hours: 400 Dollars: \$30,000**
- Eliminated work-practice-related manual training, preparation, and grading of quizzes by training and department coordinators.  
**Hours: 250 Dollars: \$18,750**
- Eliminated manual entry of training records, class registrations, management of delinquent training, reminder emails, and documenting re-training for failed quizzes.  
**Hours: 2,000 Dollars: \$150,000**

**Document Management** — Annual Savings: \$178,125

- Eliminated manual routing of change controls.  
**Hours: 650 Dollars: \$48,750**
- Provides ability to attach source documents in the system.  
**Hours: 375 Dollars: \$28,125**
- Generates automatic notifications and escalations for tasks pending.  
**Hours: 375 Dollars: \$28,125**
- Provides real-time automatic metrics.  
**Hours: 375 Dollars: \$28,125**
- Grants customer access for review and approval.  
**Hours: 600 Dollars: \$45,000**

Major soft costs savings have included:

- Increased efficiency and productivity
- Integrated systems that “talk” to each other

- Reduced volume of paperwork
- Accurate database tracking and real-time metrics
- Increased document security
- Harmonized and standardized business processes
- Regulatory compliance

“With a total investment outlay of approximately \$250,000 to purchase and implement SmartSolve, this medical device company realized its investments — in just 8 months — and continues to benefit from the on-going savings obtained through automation.”

## 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.

### U.S. Headquarters

2807 W. Busch Blvd.  
Tampa, FL 33618

Tel. (813) 915-1663  
Fax (813) 915-1948

### European Headquarters

Hilversum  
The Netherlands

Tel. +31 (0)35 6950959  
Fax +31 (0)35 6783856

[sales@pilgrimquality.com](mailto:sales@pilgrimquality.com)

[emea@pilgrimquality.com](mailto:emea@pilgrimquality.com)