

## CASE STUDY

# Implementing an Automated Document Management System at Red Cross Flanders Blood Services

## In Brief

**Customer Profile:** The Red Cross Flanders Blood Services is responsible for delivering safe, reliable and cost-effective blood services to blood product customers, namely the hospitals in Flanders, Belgium.

**Situation:** The company lacked document controls, resulting in no formal processes for SOP enforcement and inhibiting access to current documents. Local sites had their own procedures, which led to delayed implementations of SOP updates.

**Solution:** Red Cross Flanders selected SmartSolve to improve the accessibility and quality of critical documents and to create a collaborative environment that facilitates regulatory compliance. With SmartSolve, the company can easily track change revisions and manage annual document reviews.

**Business Type:** Blood Services

**Users:** More than 500 users across the organization.

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

- Document Management
- CAPA Management

Red Cross Flanders Blood Services is a geographically dispersed organization with administrative headquarters, four production sites, various fixed collection centers, mobile collection teams, and clinical labs located in hospitals. The organization is part of the Belgian Red Cross (BRC) — one of the more than 178 National Societies of the International Red Cross and Red Crescent Movement, a worldwide action-oriented relief organization. Red Cross Flanders operates in Flanders, the Flemish-speaking region of Belgium.

Red Cross Flanders manages volumes of critical data — both internal business information and blood product and processing documentation. On the product control side, Red Cross Flanders has used barcodes extensively for the identification of donor and product entities to minimize data entry errors. For internal management, whether local or corporate, controlled documents had been created in electronic format, primarily Word, based on pre-defined templates. Beyond those electronic files, the organization had a minimal electronic data management system.

The need to maintain compliance across all of these sites through a unified approach drove Red Cross Flanders Blood Services to seek an enterprise-wide solution for document management.

## Challenge

Under Red Cross Flanders Blood Services' previous document management system, the lack of control and efficiency were primary concerns for the organization's Quality Assurance department. All quality-related documents were made available to users throughout their network through an html-based interface, but networks were local to each site. This required corporate documents to be distributed annually on CD and copied by the local network document server.

As a result, access to information was not immediate for all locations, and global documents were forwarded to local sites for approval, leading to delayed implementation and decreased efficiency. Local procedures were allowed, approved, and implemented locally — leading to independent processes that resulted in uncontrolled and un-harmonized procedures across the enterprise.

In addition, Red Cross Flanders had no process to ensure SOPs were being followed at each site, no capabilities to quickly access the most recent and applicable documents or data, and no formal change request process. In short, the existing document management system was not compliant with industry regulatory requirements and was not standardized across the enterprise.

## Solution

Because of these un-harmonized processes and the need to meet regulatory requirements, Red Cross Flanders needed a document management solution to improve the accessibility and quality of critical documents and facilitate regulatory compliance.

The company selected SmartSolve® Document Management, from Pilgrim Quality Solutions because it met all their requirements. The solution would

formalize document controls, increase efficiencies, and harmonize procedures across all sites. And, of all the products considered, Document Management was best suited to continuously support Red Cross Flanders' compliance and quality objectives.

With the implementation of Document Management, a fully-automated, web-based solution, Red Cross Flanders created a collaborative environment where knowledge can be easily accessed and shared by connecting people, information and processes. The company can now:

- Completely track employee acknowledgement and sign-off of all new and revised documents, creating an accurate record of document knowledge among all employees.
- Manage all required changes revisions, and withdrawals with a closed-loop change order workflow.
- Manage initial and annual document review with a separate review type for each document.

The enterprise-wide SmartSolve implementation was completed within 12 months. Inge Buyse, Red Cross Flanders Blood Services' Quality Manager for Blood Services, explained that the process could not have gone more quickly or smoothly. Initially, a number of internal factors had to be addressed in preparation of implementation. Red Cross Flanders first needed to:

- Define the functional organization and role patterns from a high-level perspective.
- Define relevant document management processes.
- Migrate 800 existing documents to electronic format within the new structure.
- Bring all employees, approximately 450 organization-wide, on line with internal email.
- Completely overhaul the IT infrastructure and hardware.

Each challenge was swiftly overcome by the implementation team through focused problem-solving. Employees underwent intensive in-house training to ramp up on PC skills that would enable them to easily navigate the solution. Descriptive manuals, created by Red Cross Flanders Blood Services' QA staff and containing Document Management screen shots, supplemented hands-on training.

Document Management was implemented in phases, one site per week, at the four blood processing centers. The system was first introduced within the QA department, then rolled out to IT, Purchasing, and Facility Management. This rolling implementation allowed for sufficient user support by Red Cross Flanders' internal implementation team. Approximately 500 users were brought on-line by the conclusion.

Though it took nearly a year for Red Cross Flanders employees to be completely comfortable working with PCs on a fully automated system, Buyse said the organization achieved a satisfying return on its investment in rapid time.

Additionally, Red Cross Flanders began implementing SmartSolve CAPA Management for corrective and preventive action handling while Document Management was still being implemented. Together, these automated compliance and quality management solutions will further drive organizational harmonization, efficiencies, and overall success.

### **Business Benefits**

Since going live with Document Management, the organization experienced a broad ROI and ensured provision of a safe and effective blood supply throughout Flanders.

Key resulting benefits included:

- Improved quality and accessibility of documents. All relevant parties at all sites are now involved in approval processes.
- Boosted reliability for electronic document distribution and access. Documents are still distributed in a controlled manner for mobile collection teams that are not online.
- Improved the quality of documents with new, well-defined change request process that allows the organization to implement changes more quickly.
- Standardized formal document review process also improved document quality and prevents obsolete documents from remaining in circulation.
- Ensured compliance with regulatory requirements.

"By centralizing critical documents, we have gained enhanced visibility and collaboration between sites, allowing our organization to quickly identify and resolve discrepancies to continuously ensure the integrity of our blood products. SmartSolve has helped Red Cross Flanders Blood Services provide a safe blood supply to our customers."

**Inge Buyse, Ph.D.**  
**Quality Manager, Blood Services**  
**Red Cross Flanders**

Cumulatively, these benefits — efficiency, standardization, and visibility — have brought about the harmonization that Red Cross Flanders Blood Services sought across the enterprise, resulting in improved operational quality and full 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..

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