

CASE STUDY 

6 Months to Deploy and Validate an Enterprise Document Management System across 5 Departments

Based in France, HORIBA Medical designs, develops and distributes automated in vitro diagnostic instruments in the fields of Hematology and Clinical Chemistry. These instruments contribute today to the preparation of tomorrow's health. Founded in 1983, the French company ABX became a subsidiary of the HORIBA group in 1996. Today, HORIBA Medical is one of the world leaders in the hematology market.

With an increasing amount of data in the company, the need for a cross-functional document management system (DMS) became apparent. The overall goal for DMS implementation was to increase productivity by eliminating paper and reducing the time spent searching for the correct information.

A document management system was also an opportunity to strengthen collaboration between departments and reduce silos by creating shared workflows within a unified database.

HORIBA chose the Ennov document management platform to share information and standardize workflows for its 600 users and 60,000 documents.



HORIBA

About HORIBA

HORIBA is a global provider of a wide range of instruments and systems for applications such as: automotive R&D, environmental and process control, in vitro medical diagnostics, semiconductor manufacturing, metrology, and measurement systems for quality control and scientific R&D.

> More than 300 Life Sciences companies around the world are powered by **Ennov**

Selecting a Solution: Industry-Recognized Software with a Compelling Project Methodology

HORIBA Medical conducted a detailed analysis of their specific needs. Each department held workshops to clarify the current situation, expectations, and desired goals. These workshops resulted in a draft of specifications highlighting that document flows were closely linked to the product process. HORIBA then proceeded with the selection process with vendor presentations and practical work sessions with sample use cases. Ennov competed with two American companies, and won the bid based on 3 key criteria:

KEY CRITERIA

- › The software's highly configurable nature within a unified repository
- › Expertise in the regulatory sector
- › Proven project methodology, with a strong emphasis on user support

The project was launched immediately in order to meet Horiba's ambitious timelines. The initial launch required a 6-month deployment across 5 departments.

Deadline Management and Business Satisfaction

Ennov conducted a detailed analysis of the first 5 document collections. At the end of this phase, the design file specified the target configuration and the data recovery rules. The Ennov team used this file to configure the software, while managing the preparation of the import of existing documents. Ennov met the timelines, finalized the migration of 20,000 documents, and performed a complete validation of the system. Particular attention was paid to ergonomics: usability workshops gathered users from different departments to evaluate the ease of use and adjust the interface elements as needed. After 6 months, the steering committee was satisfied that the application was compliant and was approved to launch. In the following 2 years, four additional batches of documents were migrated, for a total of 60,000 documents.



"The Ennov project team adapted to our expectations and rolled up their sleeves to meet tight deadlines."

ROI and Results: Ennov Adopted as the Leading DMS

Ennov Doc is used by the Montpellier site for the entire product cycle: Marketing, R&D, Documentation, Engineering, Production, Monitoring, and Quality—each document collection is managed in a separate instance of the system. The user who connects automatically sees the interface and the content corresponding to their profile.

Training sessions are regularly organized and conducted by HORIBA Medical on specific topics: how to create a procedure, what is the best way to do a search, etc. User accessibility is a key element of success: the DMS has become an integral part of each employee's work environment.

Product file management is an emblematic case of the concrete improvements introduced by Ennov. Until now, each department separately managed product documentation, and file creation was tedious. Ennov Doc led to the harmonization of all departments around a central system, leading to efficiency and reliability gains.

Perspectives: Global Rollout to Adopt Ennov a Company-Wide Solution

Ennov Doc is currently used to manage different types of documents within HORIBA Medical, including composite files, scanned documents, emails, and more. Various expansions are being considered, including: incorporation of new document collections, integration with the intranet portal and ERP, workflow management, etc. Deployment in the United States and Asia is also on the horizon in order to maximize the exhaustive validation of the software performed during the first project (the FDA has made no remarks to date). Compliance and positive user feedback are critical factors that have influence the decision to make Ennov Doc a company-wide solution.



"Successfully integrating from such diverse sources was not a forgone conclusion. Ennov helped us manage this transition."

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About Ennov

Ennov offers a unified compliance platform to power solutions that span all regulated business areas (Regulatory, Quality, PV, Clinical, Commercial). From leading pharmaceutical companies to start-up biotechs, we proudly serve over 300 companies and 300,000 users worldwide.

For more than 20 years, we have been developing innovative, powerful and easy-to-use software for regulated content, data and process management. Our solutions are designed and built to support the entire Life Sciences R&D continuum. Ennov is ISO 9001:2015 certified for all software products and processes and we boast a 100% success rate in customer audits.

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