

DocXellent™

ENSUR✓™ CASE STUDY



ENSUR Helps Pharmaceutical Contract Manufacturer
Work Smarter and Build Their Business

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Introduction

In order to maintain their policy of strict customer confidentiality, the rapidly growing pharmaceutical company featured in this case study has requested to have their name withheld. The company is, however, excited about sharing their valuable experiences and best practices with other customers.

This Northeastern pharmaceutical contract manufacturer (“the CMO”) prides itself in investing in its business to provide the highest level of efficiency and quality to its clients. Yet, the “manual” document management process that previously supported its R&D, manufacturing and packaging services wasn’t exactly a model of efficiency. As the company grew, it also anticipated increasing challenges associated with data security and FDA regulations. So, the company decided to invest in ENSUR. Within a month of going live, the CMO believes it earned a full return on that investment.

The Problem: Manually Managing Documents is Time-Consuming and Risky

In the early days, the CMO’s document management system was an elaborate, paper-based process. Documents were manually routed for review and approval. When signatures were obtained, documents were scanned, and files were copied to a network drive. What might seem like a straightforward process actually consumed hours of non-direct, value-added time as employees were physically trafficking documents every step of the way.

Like all pharmaceutical companies, this CMO’s operations are regulated by the Food and Drug Administration (FDA) to ensure products are manufactured, tested and released in compliance with Good Manufacturing Practice (GMP) regulations. Inspections by the FDA and audits by the CMO clients are conducted to ensure processes and documentation meet federal codes and client quality and regulatory requirements.

The manual, paper-based system used by the CMO to manage and retrieve documents and records during inspection/audits required enormous personnel resources such as document request coordinator, document runners and administrative personnel. In addition, the manual document management system was prone to generating discrepancies within standard operating procedure (SOP) content and records that were easily overlooked by employees thereby creating unforeseen compliance challenges during inspections.

Training on new and revised SOPs was a hard task that required the maintenance updates of numerous SOP binders across all departments. Tracking the training activities and ensuring that the proper documentation of training events was completed required dedicated resources and human error was a common variable.

The Evaluation: Are There No Alternatives to Free or Expensive?

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As the CMO considered different solutions, it leveraged the Quality Management System (QMS) experience of their Principal Scientist. The small but growing company first considered free DMS platforms. But these all lacked the necessary security. Accessibility was also very limited. So, the CMO

turned to licensed and subscription-based systems. Many of these offered much more functionality than the company needed, and they cost much more (\$30k - \$50k per year) than the company budgeted.

The Solution: A DMS That's Right-Sized to The CMO's Needs and Budget

In the end, the CMO chose ENSUR because it met critical requirements, including the ability to:

- Organize, code and securely store documents, testing plans, procedures
- Reliably and quickly route documents for approval
- Link documents to quickly find related materials
- Provide auditors with any report or procedure, of any version, at any time
- Give transparency to auditors at any stage, even if a project not completed
- Provide overall control and traceability

Overall, ENSUR offered more functionality and security than free DMS options. Compared to other licensed systems, ENSUR was right-sized for the CMO—both in terms of features and cost.

The Outcome: Stop Managing Documents, Go Build the Business!

The principal scientist says that life is a thousand times better since moving to ENSUR. Everything flows much better. Electronic signatures obtained internally are now centralized. The CMO even set up external clients as approvers for their products. Clients visit a protocol and method folder to sign, approve and complete documents.

ENSUR has allowed the CMO to take on more projects. They work smarter than before. He believes the CMO could not support as many clients as it does today, without ENSUR. The DMS has freed up several employees who were previously required to support the manual process. Lab managers also gained back several months of time and can now focus on priorities such as researching, testing and developing new products.

According to the principal scientist, his company made its money back in the first month of switching to ENSUR! But, having the ability to quickly and confidently provide information to auditors is priceless. One observation too many by auditors could shut an operation down.

The quality team is now behind ENSUR. The CMO is confident they can realize similar benefits, by expanding to other departments. Manufacturing could store bill of materials (BOMs). Accounting could maintain purchase orders (POs). Human Resources could catalog SOPs. Even if those departments are not audited, a DMS still makes good business sense. Back in the lab, the CMO is expanding the use of ENSUR, too. Recently, scientists began using ENSUR as an electronic laboratory notebook (ELN) to

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document research, experiments, tests, and procedures. ENSUR's security and search functionality is far superior to its paper-based predecessor. In short, if it needs to be documented, there is a place for ENSUR.

Best Practices: Super-Users Ensure Consistency

Given the CMO's unfamiliarity with document management systems, there was a natural and understandable resistance to learning a new system. People in different pockets of the company were comfortable with their own, existing processes. Even though the CMO appointed admins in different areas to help with the rollout, they still ended up with different content types and naming conventions. It was not standardized. It was not unlike the shared server situation they were trying to abandon.

Other departments weren't working towards GMP standards. So, documentation skills may have been lacking a bit. In hindsight, the principal scientist believes the company could have coordinated itself better and maintained some controls at a higher level. Implementation should have been thought-out ahead of time, across the organization to ensure consistency.

If he were to do it all over again, he would demand a single administrator for the entire company. An ENSUR super-user would consider stakeholder input then develop a structure and process that could be replicated consistently throughout the company. Providing best practices and guidance, DocXellent consulting services might also help the super-user map the company's current processes to ENSUR. This individual would also be responsible for staying current on ENSUR and helping the company take advantage of new functionality and features.

Thank you to the Principal Scientist at the CMO for participating in this case study.