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CASE STUDY

Out of the Box, ENSUR Helps Ortho Molecular Products Manage Critical Documents Affordably, Reliably

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Introduction

For over 25 years, Ortho Molecular Products has partnered exclusively with health care providers to deliver nutritional solutions of the highest efficacy. The company's commitment to science, careful raw ingredient selection, and strict quality standards goes into every supplement. With its continued growth and in accordance with FDA (21CFR Part 11 Electronic Records and Signatures and 111 Dietary Supplements) requirements, the company sought to upgrade to a fully electronic document management system (DMS).

The Problem: Document Storage is Not Document Management

Previously the company was using SharePoint, which was not a validated system. "SharePoint is great if you have a development team to build and maintain it," said Albert Webster, Computer Software Validation Coordinator at Ortho Molecular Products. "It's not a good tool if you try to customize it using limited resources."

Even though SharePoint was used for document storage, the company had to route and sign hard copies for approval. SharePoint was only the finished repository for scanned documents. Retrieving documents wasn't intuitive. "We experienced issues finding what we needed and finding the most current version. This is why you get a DMS and validate it," added Webster.

The Evaluation: Customization vs. COTS

The company looked at different options. One suggestion was to validate SharePoint. But SharePoint wasn't designed, out of the box, to manage approvals of documents and policies and procedures. The evaluation team determined that customizing SharePoint would be expensive and time consuming. It would require additional development expertise to make it do what the company needed it to do.

The other choice was to move to a document management system (DMS). A consultant suggested a (commercial off-the-shelf) COTS DMS—specifically, ENSUR.

"SharePoint is a great, general-purpose tool. But we liked that the DMS approach gave us options for expansion," said Webster. "We could build out at our own pace. We could add electronic forms, deviations, corrective action/preventative action (CAPA), training management, incident reporting, change requests, and more." Best of all, the build-outs are standard functionality and would not require development expertise.

The Solution: ENSUR Meets Current and Future Document Management Needs

Ortho Molecular Products chose ENSUR and immediately started with critical functionality: Document management and storage validation. "We did a 10-Step Validation Process to determine our requirements and needs and make sure that we built the system correctly at its core," recalls Webster.

10-Step Validation Process
✓ Scope user requirements from 10,000 foot level
✓ Implement project team and plan
✓ Install the system and environments through a protocol (2 steps)
○ Installation Protocol (steps to prove accurate installation)
○ Installation Report (proof of correct installation)
✓ Define specific needs and extent of validation for processes, modules, and system configurations (any module or function not being used was not validated for launch)
✓ Risk assessment of specifics
✓ User testing of the specifics (2 steps)
✓ Release and review of the system (2 steps)

Because of thorough work done up-front, the team at Ortho Molecular Products was confident they captured all current needs *and* anticipated the future needs of all stakeholders. Such proactive work can prevent painting the project into a corner and greatly reduce the number of changes required down the road.

The Outcome: "Before Anything Else, Preparation is the Key to Success" – Alexander Graham Bell

Ortho Molecular Products implemented the configuration in July 2016. The team is proud to say that it was the most successful IT project they had completed! Certainly, this was the direct result of extensive cross-departmental collaboration including quality assurance (QA), information technology (IT), manufacturing, laboratory, and other users.

Unlike the company's SharePoint deployment, the release of ENSUR included large-group general training, training videos on performing certain processes and roles, and one-on-one training. Also, as new employees came on board, they underwent the same training everyone else had. This helped adoption by users, even those who struggled with SharePoint use and acceptance.

"DocXellent provided administrator training specific to system configuration and usage," said Webster. Beyond the one-on-one training, online materials were provided (tutorial walkthrough videos, short informational videos on a process, and a very thorough system manual). "Overall, DocXellent support was great," said Webster. "I actually enjoyed calling them. Even prior to being a customer, DocXellent was very helpful."

Given their thorough preparation, the team quickly realized the increased benefits of their new implementation. Document management has been eliminated from the old SharePoint system and they are now operating much more efficiently. They now have the peace of mind that they can guarantee compliance of the new system. "A critical piece is sheer compliance," said Webster. "We no longer have to question content integrity. We know we have status tracking. With ENSUR we can't lose a paper version of a document." This is especially important before audits and inspections.

"To do what we did in six months in ENSUR would have taken four years and cost between $250k to $300k in consulting costs and our own developer payroll. ENSUR had all the functionality we needed right out of the box," said Webster. Additionally, Ortho Molecular Products could run ENSUR with fewer people. "We eliminated one FTE role that was responsible for maintaining our hybrid system, and dedicated this role to more important projects."

Best Practices: Invest Time on Data Migration and System Scope

Reflecting on the successful rollout, the team identified two areas of improvement on future projects: data migration and system scope.

Migrating data from their old hybrid system to ENSUR was challenging. Ortho Molecular Products had different types of data and lacked content owners for some forms and procedures. "We didn't have a way to determine what should be archived and what should be kept," recalls Webster. The company's phased data transition made it challenging to find data and format how each document is used. "We didn't plan this part as well as we could have, because we underestimated the time required to fix preexisting poor data and transition content into consistent templates." The ENSUR overlay (header/footer master that can be applied to documents) is easily customizable to accommodate different template structures. However, since the team didn't anticipate templates, they had to adjust the formatting on each form and procedure.

After implementing the system, the team learned two crucial aspects of a project: (1) know the current process, and (2) know how the new system can manage that process. Beyond the project, the system will need to be maintained and modified. Having a well-defined and documented structure and process only helps future maintenance and modifications.

"We could have better planned and mapped the workflow on how user groups, associations, and people interact (administrative structure and process structure for users)," said Webster. "For example, should a document go to Doc Control first, before a department or QA?"

The team also realized that knowing the system structure is easy with one or two people. But when more people become involved in the administration of the system, naming conventions, properties, and how elements are associated, things start to get complicated. Ortho Molecular Products was working with 1,000 general documents, 2,000 laboratory documents, and a plethora of additional content added to the system. "DocXellent provided valuable guidance through this migration process," said Webster.

User groups needed to be named well and made easy to identify for all users and editors on the system. The system administrator is not the only one impacted by how a user group is named. User groups are used for permissions, training, routing, and many other features general users come in contact with. For example, while department names and area groups are easily recognizable by all employees, role-specific user groups are also needed, but are not always easily identifiable. It can be hard to determine what users are associated to what role group. There are multiple facets to consider when implementing a naming convention:

- Department
- Job Role
- System role (editor, approver, viewer)
- Responsibility
- Permissions
- Folder assignment

More recently, Ortho Molecular Products validated and released CAPA incident and training modules. This functionality has helped the company improve incident workflow: They can quickly detect, investigate, review and respond to incidents; information is more readily available to users; and this is a much better way to collaborate and address incidents more effectively. The modules, which provide one unified incident report, have been live for two months. The company estimates Deviation Incident tracking has saved manufacturing supervisors about five hours per week, and that's just for two supervisors in a single department.

Thank you to Albert Webster, Computer Software Validation Coordinator at Ortho Molecular Products, for participating in this case study.