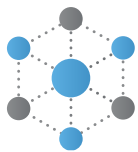




Alexion Supports Rapid Growth with Veeva Development Cloud

Regulatory, Clinical, and Quality Teams Enhance Efficiency and Collaboration



Improved collaboration with a single source of regulatory information



Control of clinical data, with real-time insights into trial status



Efficiency gains to scale quality document management



Flexible foundation to support a growing development pipeline

Alexion is a global biopharmaceutical company that develops life-changing medicines for rare diseases and disorders. After a period of intense growth, Alexion needed a way to work more efficiently and collaboratively in Regulatory, Clinical, and Quality. The company chose the Veeva Development Cloud to support and accelerate an expanding product pipeline and increased clinical trial activity. The unified platform will help Alexion transform patients' lives well into the future.

ALEXION – AT A GLANCE

- Corporate Headquarters: Boston, MA
- Employees: 3,000+
- Therapeutic Focus: Rare diseases and devastating conditions
- Veeva Solutions: Vault RIM, Vault Clinical Suite, and Vault Quality Suite

Consolidating Regulatory Information

First, Alexion's global regulatory organization identified the need to replace siloed systems and manual processes to keep up with rapid growth. Submission content and approvals were stored in separate systems and the team used spreadsheets to track registrations across 80 markets. Understanding the full picture of a product's approval status—which is crucial for coordinating regulatory, clinical, quality, and supply chain functions—required piecing together information from multiple places.

To manage an increasing volume and diversity of products, Alexion leveraged Veeva Vault RIM to standardize and centralize regulatory data and documents. Regulatory is phasing out manual tracking processes, increasing the efficiency of submissions management, and gaining the visibility and control needed to handle the surge in regulatory activity.

Vault RIM is quickly becoming the global organization's collaboration hub. After aligning multiple data sources, Regulatory now sees more cross-functional interest in using data to drive business outcomes. According to Michael Sauter, Senior Director of Global Regulatory Operations, "Stakeholders are starting to realize the advantage of having a single system where everything is located."

Taking Control of Clinical Data

On the clinical side, Alexion was challenged by a fourfold increase in clinical trials over a three-year period. With even more studies on the horizon, Alexion wanted to evolve its clinical model and relationship with CRO partners. They realized that owning Alexion's clinical operations data and processes was critical to increasing capacity and accelerating the delivery of new medicines.

To make the transition, Clinical implemented the Veeva Vault Clinical Operations Suite to plan and monitor studies, manage TMF documents, and unify clinical data and processes. Now, Alexion can have CROs use the Veeva system, which allows Alexion to work within their own processes and be more efficient. Most importantly, they also have real-time oversight and intelligence on trial status and risk. "We can get quick answers rather than being dependent on CROs to get us reports and hoping things are accurate," explains Jim Cronin, Director of R&D Development IT.

Gaining Efficiency in Quality

Alexion's quality team had its own business case for change. An aging document management system struggled to keep up with fast-changing business needs, so updating the system became a top priority to scale operations and mitigate risk.

Quality rolled out Veeva Vault QualityDocs as its foundation for the future. Veeva's intuitive user experience has increased adoption and efficiency, leading to improvements in both compliance and capacity. Kari Borroel, Director of Quality Learning, Documentation and Training Services, says, "Veeva has allowed us to take on more volume and to support the organization better as a whole."

Process visibility is another big win. With Veeva, Quality knows exactly where documents are in the authoring, review, and approval process and can monitor demand for the team's documentation services. This deeper level of insight drives better metrics and reporting on the needs of the organization. "It's been a significant change and a significant improvement for us all the way around," states Borroel.

Different Paths to Success

Alexion's regulatory, clinical, and quality organizations took different approaches to transforming operations. Regulatory and Clinical established new processes in parallel with system implementation. Their strategy was to move fast, leveraging Veeva's built-in best practices and automated workflows. This allowed the organizations to gain efficiency and control as quickly as possible, and then refine and grow from there.

“With the Veeva model of three upgrades a year, we have multiple opportunities to adjust things when we have to,” explains Sauter.

In contrast, Quality had engaged in a multiyear project to harmonize and streamline documentation processes before deploying Veeva. Still, the team challenged themselves to apply new learnings and capabilities during the Veeva implementation. “There were so many more things that the system could help us do that we weren’t able to do before,” says Borroel. “We pretty much overhauled our way of working for the better.”

Foundation for Growth

Alexion is on a rapid growth trajectory that shows no signs of slowing. With help from Veeva, they are expanding development activities without overwhelming their people, processes, or systems. The deployment of Veeva Development Cloud applications in Clinical, Regulatory, and Quality has also helped Alexion achieve greater alignment across product development and manufacturing. Looking ahead, the company sees an opportunity to use Vault Connections to streamline information flow between Vaults, further promoting cross-functional collaboration. “We’re looking at Veeva as an enterprise partner within the R&D and GxP spaces and thinking through where we might extend this partnership in the future,” Cronin concludes.

About Veeva Systems

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