



Advanced Clinical Streamlines Quality Management to Ensure Clinical Success

A fast-growing CRO sees investment in a unified cloud solution as key to improving efficiency and compliance

As clinical outsourcing continues to grow and competition intensifies, improving clinical trial quality, speed, and agility are often prerequisites for any contract research organization (CRO) that aspires to grow its business. Modernizing the way that GxP quality content and data are stored and used is critical to improving efficiency and compliance while ensuring risk-based quality management.

ADVANCED CLINICAL – AT A GLANCE

- Headquarters: Deerfield, IL
- Number of Employees: 1,000

Advanced Clinical, a full-service global CRO, turned to Veeva Vault Quality Suite to streamline quality content, processes, and training. Named one of Inc.'s fastest growing privately owned businesses in the US in 2019, Advanced Clinical has expanded rapidly over the past few years, opening new offices in Asia Pacific and Eastern Europe to complement the company's North American and Western European locations. The investment in modern quality solutions was part of an overarching effort to scale while improving the speed and efficiency of its quality and overall clinical operations.



Reduced paper-based quality documentation processes by 95%.



Improved training management efficiency, documentation, and compliance including the ability to manage online training programs.



Minimized the time required to find and use historical audit and other quality data.

The Pitfalls of Paper

Previously, the CRO handled most quality processes manually. Updating and maintaining training content, standard operating procedures (SOPs), audit reports, deviations, and corrective and preventive actions (CAPAs) involved tedious and error-prone steps. The company relied mainly on email for exchanging controlled documents and Microsoft Excel for tracking workflows. "At the time we were still using SharePoint for document storage and tracking," recalled James Kalemis, senior director of information technology, governance, risk, and compliance at Advanced Clinical. These tools and manual processes increased compliance risk and diverted staff from value-added work.

Another challenge was the company's existing learning management system (LMS), which did not support online training or address variability in training documentation, requiring manual efforts. When the company's contract with the vendor ended in 2019, Kalemis and his team had to find an advanced LMS solution—and install and implement the solution in nine weeks. "Some people doubted this could even be done in such a short time," he recalled.

Unifying Documentation and Learning Management

Kalemis had led the company's validation effort for Veeva Vault eTMF seven years earlier and was already familiar with the Vault platform. After evaluating several solutions, he and his team selected Veeva Vault QualityDocs and Veeva Vault Training to streamline document and training management in a single system. Part of the Veeva Vault Quality Suite, the combined solution automated the content management and the design and delivery of training assignments for improved efficiency and effectiveness.

The SCORM (Sharable Content Object Reference Model) capability within Vault Training facilitated the sharing of online training programs with Advanced Clinical's customers.

The single environment for both content and training management streamlined quality workflows, simplified administrative tasks, and improved productivity. "The connectivity, useability, and efficiencies gained from having Vault Training and QualityDocs running on a single platform have been great. Now we can create, review, and approve quality documentation in QualityDocs and deliver training assignments in the same system, which has resulted in huge compliance and productivity increases," said Kalemis.

Eventually, convinced by the savings and efficiency achieved by the initial rollout, Kalemis and his team decided to implement Vault QMS to achieve better control and visibility into quality processes. "The addition of Vault QMS complemented the full Vault Quality Suite, increasing transparency and streamlining quality processes across the company," said Kalemis.

Reduced Integration Risk and Centralized Data Access

The benefits of a unified system for quality management system content, training, and processes have continued to accrue. Vault Quality Suite has eliminated the need to integrate multiple systems from different vendors. It has also dramatically simplified tracking and pulling historical quality data for reports, meetings, recurring qualification audits, and CAPAs. "In the past, it could take two weeks just to locate the data required for quarterly management review meetings. Even preparing for biweekly status meetings with customers could take 60 to 90 minutes per auditor. Now, this time can be spent on value-added activities that improve quality and compliance," said Kalemis.

Strategic Partnership and Sharing Best Practices

Advanced Clinical wanted more than an effective solution; rather a strategic vendor partner that would collaborate on ways to improve entrenched work processes. Veeva's implementation team invested the time to learn Advanced Clinical's day-to-day quality operations to identify areas for improvement. "We wanted best practices, and to see what we needed to change in order to gain the greatest efficiencies," Kalemis stated. "We've since updated some SOPs to leverage more of the benefits that Veeva's systems brought us and have eliminated 95% of manual processes so far."

To learn more about Vault Quality Suite, visit veeva.com/quality.