Life Sciences Case Study

PROJECT OVERVIEW

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Modernizing Quality with Veeva Vault for a Global Biotech

This leading global biotechnology company focuses on developing treatments for cancer, autoimmune, and inflammatory diseases. Its product roster now includes a best-selling monoclonal antibody used to treat non-Hodgkin's lymphoma (NHL), a psoriasis drug, a treatment for relapsing multiple sclerosis, and royalties from alpha intron and other licensing deals and arrangements. The company hopes the combined pipelines of its predecessors will yield the next breakthrough in autoimmune therapies.

The client has embarked on a major transformation initiative to replace their quality systems with Veeva over several years. The initial phase of the transformation focuses on Learning Management (Training) and Document Management. They will be migrating from a legacy document management and learning management system as well as harmonizing business processes across the commercial and research organizations.

The client engaged the Clarkston team based on our familiarity with the business context and a proven history of delivering repeated success in similar transformation efforts across the industry.

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INDUSTRY

Biotechnology

PRODUCTS AND SERVICES

Pharmaceutical

PRIMARY OBJECTIVES

- Create simplified and harmonized processes across clinical, regulatory, quality, and safety management by replacing the client's quality management, clinical trial and data management, clinical safety, and regulatory IT systems with a single, industry-standard IT platform – Veeva Vault
- Deliver new processes, functionality, seamless integration with existing IT systems, and full data migration
- Implement quality document management, station manager, and Veeva training functionality
- Finalize the technical architecture and build the solution for the subsequent waves of the client's QMS transformation

RESOLUTION

- Supported the harmonization of business processes across Commercial and R&D
- Successfully enabled all GxP assets related to Training and Documents in Veeva Vault
- Executed a global end-user training plan spanning three continents
- Delivered External Collaboration, allowing third-party review and Part 11 compliant signature for Quality documents
- Conducted an enterprise-wide migration of documents and training records
- Maintained legacy document continuity by migrating quality library to new solution

KEY BENEFITS

- Enabled manufacturing to run disruption free due to the precision of execution and the quality of data migration and integrations, completing cutover and go live in the timeline outlined
- Harmonized and aligned GxP document management processes and enabled technology across Pharma Operations & Technology (PO&T) and Research, Development & Medical (RD&M)
- Allowed data to pass seamlessly throughout the organization by successfully integrating both up and downstream systems including MES and Oracle
- Reduced reliance on manual processes for third-party reviews of Quality documents
- Implemented streamlined GxP Training Program processes and enabled technology across PO&T and RD&M
- Achieved successful migration of documentation from legacy systems to Veeva Vault and provided continuity to critical business operations
- Delivered a fully validated Veeva Vault solution aligned with best practices and designed for sustainable release management
- Ensured measurable process and technology for end-user adoption

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KPIs

- Migration of more than 250,000 documents and over 1 million training records from client's legacy systems
- Improved quality and compliance metrics related to timeliness of GxP training
- Organizational adoption of Quality documents and Vault Training for more than 15k users in 30 countries
- Established a group of more than 40 cross-functional change champions who can be leveraged for future knowledge

CONTACT US

