Life Sciences Case Study

PROJECT OVERVIEW

Veeva Vault QualityDocs and RIMS Implementation

Founded in 2015, this client is a pre-commercial genetic medicines company dedicated to transforming the lives of patients suffering from rare genetic diseases by curing the underlying cause of the disease. As the client moved toward clinical development and eventual commercialization of innovative gene therapies, they realized the need for new IT systems to support both quality and regulatory document creation and management. Specifically, the client needed to manage expanding content generated by its engineering, facilities, manufacturing, research, product development, regulatory, and quality organizations.

Currently lacking any centralized content management systems, the client realized that a platform for sustainable growth was critical in this period of development and expansion. After leading a requirements-gathering and vendor selection project, Clarkston worked with this client to implement two Veeva softwares – the Veeva QualityDocs and Veeva RIMS solutions. Clarkston provided oversight and execution of governance document updates, system validation, user training, and cutover.

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PROJECT OVERVIEW

HQ LOCATION:

Bedford, MA

INDUSTRY:

Biotechnology

PRODUCTS + SERVICES

Gene Therapy and Gene Editing
Biologic Medicines

PRIMARY OBJECTIVES:

- Establish sustainable and scalable content management and regulatory information management capabilities
- Control the distribution of each system's data and content, including automated workflows and electronic storage
- Streamline processes around submission organization, and and data included in the application were substantiated by the appropriate documentation
- Reduce inefficiencies in document creation, revision, review, and approval

RESOLUTION:

- Provided project management oversight for both implementation phases, guiding the core client team and the external vendor partner, including all cutover activities and ensuring successful go-lives
- Developed and documented new processes to govern electronic record systems
- Validated each of the out-of-the-box Veeva Vault solutions, including documentation of client-specific user requirements and execution of new test scripts
- Produced training materials, job aids, and delivered initial training to ensure business adoption, while empowering the client to perform ongoing training efforts post go-live

KEY BENEFITS:

- Embedded critical capabilities to contain cost associated with managing and handling content management
- Enhanced access to information through the implementation of a secure, compliant, reliable, and sustainable system
- Enabled security controls to critical content including clinical and non-clinical study information, audit reports, and engineering drawings
- Created a platform for growth that can expand as the client grows, and be updated to future technologies based on industry best practices

CLARKSTON CONSULTING

Enhanced efficiencies through elimination of unnecessary steps during document creation, review, and approval

Increased document accessibility through the creation of the single source of truth document and data repository

Improved data integrity through audit-trail control

Increased visibility into training progress and completion

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