

Project Management for Veeva eQMS Implementation

This client is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines designed to alleviate patient suffering from debilitating diseases with significant unmet medical need.

In late 2020, the company was moving from a paper quality management system to an electronic quality management system as they prepared for launch of their first commercial product. The organization engaged Clarkston to provide project management services for implementation of Veeva eQMS modules for Change Control, CAPA, Deviation, Laboratory Investigation, and Product Complaints.

Clarkston worked with the organization to define and implement requirements for the system and configuration. Multiple workshops were held with key users and subject matter experts to optimize the QMS processes and ensure that the Veeva system modules would work with the client's processes.

Life Sciences Case Study

PROJECT OVERVIEW

COMPANY:



A biopharmaceutical company

PRODUCTS & SERVICES:



Therapeutic medicines

PRIMARY OBJECTIVES:

- Implement Veeva eQMS modules
- Identify key functionalities needed for each module
- Lead workshops with subject matter experts and key stakeholders to review each module and demonstrate key functionalities and use cases
- Identify procedural documentation needed for training and implementation
- Manage review of validation documentation to ensure timely and thorough completion of specification documents.

RESOLUTION:

- Management of the timeline, risk mitigation, organizational communication, and resource management
- Led workshop sessions and process exercises with functional areas to identify requirements and configure these requirements in the new systems
- Managed configuration documentation to provide input to final validation documents.
- Identified and documented SOPs and Work Instructions needed to ensure appropriate guidance for implementation of the new systems.

KEY BENEFITS:

- Aggressive timeline for simultaneous review and development of 5 eQMS modules was met
- Managed feedback and implementation of comments from multiple workshops and process exercise sessions for each of the modules
- Managed interface with Veeva technical team to ensure understanding of comments and feedback so that all were incorporated into the final configuration.
- Managed update of configuration documentation to provide input to final validation documents.

CLARKSTON CONSULTING



All workshops were completed with valuable feedback provided to Veeva in a timely manner.



Managed all comments and feedback from multiple process exercises and workshops for each of the 5 modules.



Managed update of configuration documentation to provide input to final validation documents.

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