Life Sciences Case Study

PROJECT OVERVIEW

CLARKSTON CONSULTING

Global Quality Management System Process Redesign

The client is a multi-national, research-based biopharmaceutical company. Founded over 30 years ago, this client's medicines and pipeline are designed to help patients with a number of life altering diseases.

The organization faced significant challenges with its quality management system (QMS) and automation platform used to support and optimize ongoing quality change controls. The client's rapid organizational growth and global expansion led to an extremely complex change management process, and system instability for performance and reliability. These were disruptive to the business and caused the stakeholders to have reduced confidence in their QMS.

Clarkston Consulting collaborated with the client to redesign and streamline the client's global change management system to be a compliant, collaborative, and scalable process that increases stakeholder's usability and confidence, improves compliance, and proactively eliminates regulatory exposure.

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COMPANY:

A researched-based biopharmaceutical company

INDUSTRY:

Biopharmaceuticals

EMPLOYEES:

Over 6,000

REVENUE:

$5 B

PRIMARY OBJECTIVES:

- Identify, collect, and collate User Requirement Specifications (URS) from stakeholders in multiple functions that are impacted by the following GxP change types:
  - A) Internal CMC;
  - B) External CMC;
  - C) Supplier Change Notification;
  - D) IT & Automation;
  - E) Internal Documentation
- Summarize and present the final URS and industry best practices to be used for generation of formal request for proposal (RFP), QMS solution selection, and vendor onboarding
- Streamline and develop future state process map and vendor demo scenarios

RESOLUTION:

- Designed a single foundational process for all changes with a workflow creation and requirements driven by selection criteria
- Executed SME-led global change management workshops and individual interviews to develop URS
- Developed URS to be leveraged for QMS vendor identification, demonstration, and system solution selection
- Developed a stage-gate framework to divide the process into distinct phases with management approval
- Established a change notification model to drive change impact assessment management prior to initiating a full change control
- Created a parent-child structure to develop hierarchical relationships for changes
- Defined and strengthened roles and responsibilities within the quality function
- Established seamless connectivity with other GxP systems

KEY BENEFITS:

- Cross-functional clarity on what and when actions are required throughout the process
- Stage-gate process model increased the focus on the change's content
- Enhanced communication, eliminated errors, and provided defined RACI and clear deliverables
- Two (2) phases change management model, change notification phase and change control phase, minimizes the optics of open change controls
- High-level visibility on a change's status in the process and transparent indication of a change's category
- Robust and structured cross-functional impact assessment mitigates improper work from being executed if the classification is incorrect
- A clear understanding of which function defines the change classification
- Cross-functional alignment on the change's content
- Quality function oversight and decision authority to review all GxP change classifications to ensure compliance
- Reduction in paper-based documentation, non-value repetition, and complex data analysis
- Seamless connectivity with other GxP systems to increase data availability & accessibility, and facilitate the decision-making process
- Cost savings due to increased efficiencies and enhanced quality compliance
- Increased user confidence and usability of the QMS process
- Reduction in the number of opened, unrestricted, and abandoned change controls
- Enhanced right first-time change control assessment and reduced repetition of non-value activities among users
- Enhanced data integrity, data & metric availability & accessibility, and compliant audit trail.

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