Life Sciences Case Study

PROJECT OVERVIEW

Reimagining Quality Management for a CRO

The client was recently spun off from a large clinical research and development organization into a newly formed independent Contract Research Organization (CRO) that provides Phase I-IV clinical trial management, patient access, and technology solutions to pharmaceutical and biotechnology organizations around the world.

As a separate organization, the client wanted to reimagine how quality is managed across the organization. The objectives for the engagement were to:

- Increase quality management activities and ownership in the individual departments while enhancing efficiencies and reducing redundancies in lower value activities in Quality Assurance (QA).
- Make recommendations on how to resolve issues faster, more efficiently, with a right-sized organization and systems, and closer to the operational level.
- Provide advice on how to retain an audit offering and respond to audits as needed, including exploring the potential for outsourcing audits.
- Reinforce customer perception of the organization and its quality capabilities.

Clarkston was engaged to review the company's strategy and provide recommendations for a new operating model to help achieve the goal of enhancing efficiencies, improving quality, and reducing costs. This involved assessing the current quality organization using both quantitative and qualitative methods.

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clarkston CONSULTING

INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES:

CRO for Pharmaceutical and Biotechnology Organizations

PRIMARY OBJECTIVES

- Conducted an organizational and operational review to identify opportunities for improvement (OFI) and cost reduction while maintaining the highest degrees of quality standards
- Performed a deep dive into the Quality Management System's (QMS) construct to understand quality culture and context
- Assessed ability for operations to absorb Quality Assurance (QA) work
- Evaluated Veeva as an enabling technology for QMS and documented the rationale to support a decision with keeping Veeva as the quality system for the organization
- Developed options for new organizational structures and provided details on the strategic considerations, risks, and implications of each
- Provided a final recommendation on a new operating model that enhances efficiency and reduces costs
- Worked side-by-side with the executive leadership team to review and fine-tune findings and recommendations

SOLUTION

- Reviewed existing ways of working to understand departmental functional alignment and responsibilities
- Identified gaps in the current operating model and organizational structure compared to the desired end-state
- Performed selected deep dives with QA and operations leadership to evaluate the potential for shifting quality responsibility into operations
- Reviewed previous QA consulting engagement findings
- Assessed a sample of existing open quality issues to understand non-conformances: investigations, CAPA processes, and the effectiveness of current roles and responsibilities (i.e., RACI)
- Benchmarked CAPA process against industry standards
- Provided recommendations for restructuring the organization, working side-by-side with the executive leadership team

KEY BENEFITS

- Delivered recommendations for the client to reduce costs by restructuring roles while still maintaining customer quality
- Provided the rationale for continuing the use of Veeva as the QMS based on the current cost structure and the high costs of switching to a different application
- Supplied a list of key activities and the roadmap for next steps

KPIs

- Drove significant cost efficiencies in the organization, resulting in eight-figure cost savings
- Assessed and streamlined technology licensing requirements to ensure fit-for-purpose investments
- Implement risk mitigation plans to reduce potential risks to ensure global support of quality and evaluate on a regular cadence

CONTACT US

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