Life Sciences Case Study

PROJECT OVERVIEW

Operational Excellence in Quality for a Life Sciences Company

Clarkston was engaged by a life sciences client. This client is a leading developer of novel cancer therapeutics with the goal of significantly improving patient outcomes. As a fully integrated oncology drug research and development company, they have established a track record of accomplishments, including advancing the research and development of multiple compounds and clinical programs. A mock audit identified gaps in the current cGxP processes that would prevent the company from passing a PAI inspection. In support of their clinical pipeline and future product commercialization the client was looking for a partner to help them identify gaps and build compliant and sustainable business processes.

Clarkston Consulting was engaged to work with this client to design and support future capabilities, assess their QMS processes and define their Quality Management Systems (QMS). Additionally, Clarkston supported the mock PAI inspection. The client's partnership with Clarkston resulted in a defined quality organization role and responsibilities process and business strategy overall. They also benefitted from operational process flows put into place for support of revised and new processes, while still being flexible to be sustainable for future growth. The main resolution was a successful mock PAI inspection with no GMP findings.

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PROJECT OVERVIEW

COMPANY:

Life Sciences Company

INDUSTRY:

Biotech

EMPLOYEES:

Over 100

PRIMARY OBJECTIVES:

- Quality Organizational Design to support current and future capabilities
- Assessment of current QMS processes
- Compliance with current supporting SOP's
- Compliance with GMP regulations and best practices
- Operational efficiency
- Defined Quality Management Systems
- Addressed the gaps identified during the assessment
- Identified process owner and roles and responsibilities within the process
- Right sized for the current organizational size and future state
- Incorporated operational efficiency
- Supported the mock PAI inspection preformed by ex-FDA auditor

RESOLUTION:

- Defined the quality organizations roles and responsibilities – preparing the job descriptions and aligned responsibilities to current and future growth / product approval business strategy
- Operational Process flows to support revised and new processes
- Clearly defined inputs and outputs for the revised and new processes
- Roles and Responsibilities
- Supporting Standard Operating Procedures and Training
- Implementation of new processes with in-place reporting and process refinement
- Processes with the flexibility to support future growth and organizational changes
- Successful mock PAI inspection with no GMP findings

KEY BENEFITS:

- Completion of required training in MasterControl increased from 77% of users completing their training on time to 94% completing their training on time
- The number of days for a document to complete the Document Change Process in MasterControl decreased from an average of over 90 days to less than 30 days
- Successful Mock FDA GMP Inspection conducted

CLARKSTON CONSULTING

"The Clarkston team delivered a high-quality product that could be imbedded in any major biopharmaceutical company and stand up to the rigors of a Pre-Approval Inspection (PAI). Clarkston delivered a Quality Management System that is easy to defend, because it does need to be defended. The product included the appropriate content and level of detail expected for a PAI."

MANAGER OF QUALITY

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