

Conducting a Quality Systems and Quality Culture Assessment

This client is a leading global pharmaceutical company specializing in the discovery, development, and commercialization of prescription medicines. With operations in multiple countries across the globe, the client is at the forefront of breakthrough treatments in multiple therapeutic areas. The company was looking to improve their quality culture and processes at a key manufacturing site.

Clarkston was engaged to assess the organization's processes at this site as they related to their quality system and culture. To do so, Clarkston performed in-depth evaluations of relevant processes by conducting site surveys and interviews with key stakeholders. This culminated in Clarkston providing a necessary external viewpoint on the current procedures governing the responsibilities of the quality control unit. Through this initiative, the organization's leadership obtained a holistic view of quality. This project also served as a foundation for further improvements to quality operations, training, and processes in the future.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Quality Systems and Quality Culture Assessment

PRIMARY OBJECTIVES:

- Assess the current procedures governing the responsibilities of the quality control unit
- Evaluate relevant aspects of the organization's quality systems and quality culture
- Provide an external viewpoint as a means of driving continuous improvement, particularly within personnel elements of the pharmaceutical quality system
- Conduct site survey and interviews
- Document policies and procedures
- Synthesize and summarize evaluation results
- Provide recommendations for enhancement and continuous improvement

RESOLUTION:

- Conducted quality process training review to develop and ensure cross department quality process training.
- Collaborated with the client training department to ensure the site was taking on the appropriate amount of change to develop technical writing training
- Guided operational best practices to set the quality goals at the site level, cascading these through other departments to ensure organizational alignment
- Performed an operational Change Control (CC) process review to examine and simplify the process
- Conducted site survey and interviews, from which the results were analyzed and presented to the site management
- Introduced a methodology to enhance training effectiveness
- Presented recommendations built from specific feedback, highlighting avenues to execute improvements with focused follow-ups

KEY BENEFITS:

- Enabled client's quality leadership to embrace a holistic view of quality processes and their impact on product quality
- Provided detailed review of existing change control processes with specific recommendations to make corresponding updates to procedures, systems, and training
- Built a foundation for the site leadership to conduct a broad, in-person quality process training program that would elevate sitewide adoption of improved processes
- Provided the client with tools and resources to assess training effectiveness, with particular attention to new hire training and procedural training
- Enhanced communication through small quick win conversations with a few stakeholder groups based on survey feedback (e.g., closing the loop on a budget decision)

CLARKSTON CONSULTING



Conducted, analyzed, and presented data from 12 key stakeholder interviews



Collected, analyzed, and presented data for 224 survey responses



Uncovered continuous improvement quality culture themes through 207 survey comments



Surveyed 13 departments



Reviewed and analyzed 25 quality documents

