Life Sciences Case Study

PROJECT OVERVIEW

clarkston CONSULTING

Assessing LIMS Quality Control for a Pre-Commercial Biopharmaceutical Company

The client is a pre-commercial biopharmaceutical company focused on curing gut disorders through microbiome therapeutics. As they prepare for the launch of their first commercial product, they have invested in a Laboratory Information Management System (LIMS) that they hope will cover all laboratory processes, from research and development through the various Quality Control (QC) processes. This new LIMS would replace an aging Software-as-a-Service (SaaS) LIMS, which had not been validated by industry best practices and would not pass FDA inspection. The selected platform, however, was designed for R&D operations, and the QC business owners were concerned about the fit of the system to the business needs.

Clarkston Consulting was engaged to gather requirements for the QC processes in the future state LIMS and evaluate the new LIMS platform for its ability to meet the requirements. For requirements not currently met by the platform, Clarkston assessed the vendor's feature roadmap and the proposed customizations that the vendor would make to meet them.

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INDUSTRY:

Biopharmaceuticals

PRODUCTS AND SERVICES :

Biologics/
Cell Therapy

PRIMARY OBJECTIVES:

- Elicit and draft user requirements for the Quality Control LIMS
- Evaluate the LIMS as a solution for the Quality Control LIMS user requirements
- Recommend a roadmap to meeting Quality Control LIMS user requirements based on the outcome of the Benchling evaluation

RESOLUTION:

- Elicited user requirements for the Quality Control LIMS in nine process areas: Environmental Monitoring, Instrument Management, Laboratory Investigations, Lot Management, Method Execution, Sample Management, Standards and Reagents Management, Stability Management, and Reports and Trending
- Performed a detailed review of the vendor's ability to meet user requirements, including the vendor's timeline to develop functionality not currently available in the platform, and the level of customization required to meet requirements
- Reviewed the vendor's architecture and implementation against industry-standard LIMS
- Developed a roadmap for the future of the Quality Control LIMS, including a recommendation to perform a vendor selection and timeline for implementation

KEY BENEFITS:

- Fully documented and approved set of user requirements for the Quality Control LIMS
- Detailed breakdown of the gaps between the vendor and the user requirements
- Roadmap to meeting Quality Control LIMS user requirements

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