Life Sciences Case Study

PROJECT OVERVIEW

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Implementing LabVantage LIMS for a Seamless TSA Exit Strategy for a Biopharmaceutical CDMO

The client, a unique technology, biopharmaceutical, and contract development and manufacturing organization (CDMO), is dedicated to building sustainable end-to-end manufacturing solutions for complex medicines and providing increased access while ensuring the biopharmaceutical supply chain maintains efficiency. The client aims to transform biomanufacturing with advanced technologies to innovate how they are produced, funded, and scaled.

Recently, the client acquired a biologics manufacturing site as part of their mission to establish a robust network of biopharmaceutical manufacturing facilities. To successfully integrate and optimize this new site, the client engaged Clarkston, looking for LIMS experts for a Transition Service Agreement (TSA) exit strategy and LIMS implementation.

This collaboration aimed to implement a new LabVantage LIMS solution in a timely manner to ensure a successful go-live prior to the exit from their legacy LIMS. Clarkston provided essential project management, functional, and business analysis support, supplementing the client site, digital, and quality resources while enabling a seamless transition and operational excellence at the facility.

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INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES :

Contract Development and Manufacturing Organization (CDMO) for biomanufacturing

PRIMARY OBJECTIVES:

- Align on the strategy needed to transition from the current legacy LIMS to a new LIMS for the new organization
- Understand lab processes to ensure the LIMS would meet workflow operations
- Provide technical and master data configuration of LabVantage 8.8 and hypercare support
- Train users and administrators on the new system and help bridge knowledge gaps from the legacy system to the new system

RESOLUTION:

- Made significant configurations in LabVantage to suit specific needs
- Built release master data for products, product variants, specifications, sampling plans, test methods, and parameter lists
- Delivered ongoing support after go-live, addressing issues and offering guidance to ensure continued success and performance
- Provided and drove training curriculum for end-users and admins of the system

KEY BENEFITS:

- Ensured a successful and on time exit from the legacy system, preventing additional usage charges from the legacy organization
- Established confidence in the knowledge and usage of the new system through proper hands-on training

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KPIs

- Conducted an in-depth evaluation of the client's existing lab processes and developed 13 Process Maps for lab operations, including pre- and post-go-live scenarios
- Managed system validation by developing and executing 7 OPQ test scripts to confirm functionality
- Designed tailored training programs and workshops, as well as facilitated 7 "Train the Trainer" sessions and supported 18 on-site training sessions

"Your hard work, collaboration, and commitment have been truly commendable. Your perseverance and teamwork have not only met but exceeded everyone's expectations, demonstrating your collective strength and capability as a team. Your contributions have made a significant impact on how [the client] supports Quality Control operations. I am proud to work alongside such a talented and driven group of individuals. Your professionalism and positive attitude have been instrumental in our success."

- Head of Quality Systems & CSV

CONTACT US

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