Life Sciences Case Study

PROJECT OVERVIEW

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Enhancing LIMS Master Data Management for a Global CDMO

The client has operated in the Contract Development and Manufacturing Organization (CDMO) for more than 30 years, building deep expertise in biologics manufacturing and world-class mammalian protein production. The company has produced more than 250 commercial batches and supported five commercial products marketed in over 90 countries. For over a decade, the client has maintained an impeccable quality record, guided by a commitment to doing things right the first time to reduce rework, save time, and control costs.

As the organization grew, increasing operational and regulatory complexity created an opportunity to strengthen its foundational data and quality systems. To support this evolution, the client engaged Clarkston Consulting to provide project management, master data governance, and LabWare expertise to establish a robust master data structure within its LabWare 8 Laboratory Information Management System (LIMS) platform.

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INDUSTRY

Life Sciences

PRODUCTS AND SERVICES

Biologics

PRIMARY OBJECTIVES

- Provide project management support to guide the LabWare 8 LIMS master data initiative
- Bring LabWare expertise to help design and establish a stronger master data structure
- Support the client in strengthening foundational data and quality systems to address increasing operational and regulatory complexity as the organization grows
- Develop master data governance best practices to improve consistency and control
- Establish and configure the master data structure in Labware 8 LIMS for Drug Formulations and Substances

RESOLUTION

- Reviewed core documentation for 22 Formulations and 18 Drug Substances, including Batch Production Records (BPRs), In-Process Material Specifications (IPMSs), Certificates of Analysis (CoAs), and test methods, to define detailed master data configuration requirements
- Consolidated findings into a structured requirements workbook for validation with the client's Business Lead and Quality Control (QC) team, ensuring alignment, completeness, and traceability before the master data build
- Translated validated requirements into macro-enabled configuration templates that served as controlled inputs for the build process.
- Configured key LIMS master data objects across tables (*sample plans, specification types, item codes, analyses, components, units, products*) to establish a standardized and scalable data framework
- Deployed configurations in the Development environment, supported business validation testing, and remediated identified issues
- Managed structured promotion from Development to Quality Assurance (QA) and ultimately to Production, with formal QC approval at each stage to ensure data integrity and regulatory compliance
- Identified improvement opportunities across visibility, coordination, analysis, and testing to increase cross-functional alignment and improve requirement readiness as the project progressed
- Provided recommendations to optimize Crystal Reports in alignment with the new data structure
- Managed project timelines and deliverables through a cloud-based solution, accessible by the full team to ensure accountability, transparency, and on-time execution

KEY BENEFITS

- Master data configuration for 22 formulations and 18 drug substances in client's LIMS
- Formulations and Drug Substances can now be actively tested and marketed
- New Formulations and Drug Substances will follow a similar master data configuration, enabling a more seamless setup process and saving the client time and resources

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KPIs

- 50% reduction in testing cycles
- Two-thirds reduction in the number of collaboration applications used for delivery
- Reduced end-to-end delivery time by 50%

CONTACT US

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