

Implementing Benchling Validated Cloud for a Biotherapeutic Company

This client is a clinical stage biotherapeutic company focused on discovering and developing microbiome therapeutics to treat diseases by modulating the underlying biology of microbes that naturally reside in the human body. The company currently produces one FDA-approved treatment and operates several research programs.

The client had been implementing Benchling LIMS to support their research & development (R&D), Quality Control (QC), Chemistry, Manufacturing, and Control (CMC), and Clinical Operations across multiple sites in preparation for a Pre-approval Inspection. However, the lack of implementation experience has led to significant delays in achieving project milestones. Deliverables weren't clearly identified, and documentation was insufficient and disorganized. Additionally, cross-team collaboration efforts had been minimal due to the absence of proper project management.

The client engaged Clarkston Consulting's program management and LIMS experts to realign their ongoing LIMS implementation initiatives and effectively manage and execute implementation activities using industry-recognized software implementation methodology.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Microbiome
therapeutics to treat
human diseases

PRIMARY OBJECTIVES:

- Establish overall program methodology to ensure a timely and compliant implementation process
- Ensure the program requirements meet business needs through properly structured requirements and alignment of sprints to requirements backlog
- Deploy a validated LIMS solution to replace existing non-compliant processes
- Optimize data management processes by transitioning several systems, Excel/Google sheets, and manual processes into one LIMS solution
- Build a foundation for overseeing and maintaining a validated LIMS to sustain long-term compliance

RESOLUTION:

- Established, managed, and executed project plan and scope using the proven Clarkston methodology
- Aligned laboratory systems strategy with their newly developing data practice, working hand in hand to establish best practices that would be used company-wide
- Gathered and built data models, requirements, and process flows for entirety of the LIMS scope
- Developed and executed overall project validation plan for initial implementation and successive software updates
- Created, reviewed, and updated standard operating procedures (SOPs)/Work Instructions (WIs) related to LIMS implementation
- Achieved migration of historical paper and third-party system-based data into LIMS
- Developed mid-term and long-term support models to ensure current needs were met while future proofing for additional growth and system scope

KEY BENEFITS:

- Migration to one compliant LIMS with a clear data structure from uncontrolled systems and spreadsheets to reinstate regulatory compliance
- Enhanced data integrity by eliminating paper-based processes and applying digital traceability
- Simplified laboratory processes by standardizing workflows within LIMS
- Prompt data analysis for investigations and trending via dashboard query searches.
- Enabled data sharing and visibility across multiple sites with site and role-specific access control
- Established LIMS management plan to sustain long-term regulatory compliance



KPIs

- One LIMS solution that replaced paper and uncontrolled systems
- Process standardization with data analysis and tracking capabilities
- Clear data structure and sharing across multiple sites

"Very, very much appreciate what you have done for [us]...I'm sure we will end up working together again."

-CIO

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