

User Training and OCM Support for a LabWare Implementation for a Global Biopharmaceutical Company



PROJECT OVERVIEW

A global biopharmaceutical company was struggling with a fragmented and inefficient technology environment. Their processes and legacy systems were siloed, relying heavily on manual entry of data from external partners. This led to frequent transcription errors, data integrity issues, and compliance problems. To address these challenges, the company aimed to implement digital technologies that would enhance efficiency and ensure compliance.

After undergoing a technology selection process, the customer decided to create a global, cloud-based instance of LabWare LIMS as the platform's comprehensive features can

manage multiple aspects of operations in different types of laboratories. The goal was to support externalization and efficient internal tech transfer for therapies as they progressed from pilot and clinical manufacturing stages to regulatory commercial manufacturing.

Based on Kalleid's experience with the LabWare platform and our track record of success with similar projects in other biopharmaceutical companies, the customer chose us to run the Organizational Change Management (OCM) workstream for the project. This encompassed user communications as well as training for sites located in the United States, Germany, and Japan.



BUSINESS CASE

The customer intended to eliminate several operational issues through implementation of the global GxP LabWare instance:

- **Data integrity and regulatory compliance risks**
- **Ongoing costs of supporting manual processes**
- **Inconsistent business processes across sites**
- **Lack of effective data-driven decision tools for planners**
- **Inability to share data and projects globally**
- **Inability to address data initiatives and leverage new emerging technologies**
- **Business continuity risks with legacy, site-specific, end-of-life systems on company data centers**

The expectation was that this project would deliver a number of important business improvements for the organization:

- **ESTABLISH DATA INTEGRITY** with a single source of truth for master data and end-to-end sample traceability through a centralized solution
- **REDUCE COMPLIANCE RISKS** through the creation of standardized reports, audit trails, and digitized workflows
- **PROMOTE DATA DRIVEN DECISIONS** utilizing a harmonized data model, providing business synergies and outcomes through analytics, shared metrics, and KPIs
- **IMPROVE OPERATIONAL EFFICIENCY AND PRODUCTIVITY** by reducing manual processes and enabling internal data sharing
- **LOWER COSTS AND INCREASE REVENUE** by facilitating accelerated pipeline progression
- **ELIMINATE BUSINESS CONTINUITY RISKS** by retiring legacy end-of-life systems

Providing an effective user training and communication program to support stakeholder transition and user adoption of this global system was essential to capitalize on these potential business benefits.

SERVICES PROVIDED

The services provided by the Kalleid Team to the customer within the contracted workstreams included:

- **Change Management Assessment.** The Kalleid Team conducted interviews with key business stakeholders to assess current experience and identify opportunities to support stakeholders. A business-led OCM approach was developed to support impacted stakeholders with the tools and messaging they needed to maximize and sustain user adoption of the new system and processes. A final plan with recommendations was delivered to the customer for review and sign-off.
- **Communications Plan.** A Communication Plan was developed to keep stakeholders and users informed on relevant aspects of the project. The Kalleid Team implemented this plan with regular newsletters, awareness sessions to deliver site-specific information, intranet blog updates, socialization materials for town halls, strategic material development for leadership, FAQ creation and maintenance, deployment notifications, and more.
- **Intranet Communication Site.** A SharePoint communication site was built that was accessible to all internal and external users of the system. The site was used to communicate all relevant information to users that kept them informed and engaged with the project.
- **Training Strategy and Plan.** The Kalleid Team interviewed business leads to collect training requirements and develop an effective training strategy. A Training Plan with recommendations was delivered to the customer for review and sign-off. This document contained training strategy and approach, role-based curriculum, team roles and responsibilities, course descriptions, training schedule, training process for new hires, etc.
- **Training Materials Development.** Role-based slide decks were developed to support instructor-led training for 6 different courses, as well as a series of hands-on practice exercises focused on each of the roles created in the system.
- **Live-Session Instructor Lead Training.** The Kalleid Training Lead delivered each of the 6 courses using Microsoft Teams and recorded each of them for future training of new hires
- **Hypercare Sessions.** The Kalleid Training Lead participated in Office Hours that were held for each site over a 30-day period post go-live with users attending as needed.

RESULTS DELIVERED

As a result of successful implementation of the first iteration of the system as a Minimum Viable Product (MVP), the customer now has one global system that provides standardized reports, audit trails, digitized workflows, and sample tracking for both lot lifecycle and stability study workflows for multiple sites. The customer was extremely pleased with the user response to the new capabilities (100% enthusiastic user adoption) and has contracted Kalleid to work on subsequent Continuous Improvement phases (currently on Phase 5) of the project.

5 years after the initial MVP implementation, Kalleid continues to provide user communication and training support for the project. In addition, our role has been expanded to provide training and communication support for Project Team members to optimize collaboration and efficiency within the Team, enable new Project Team members to be brought up to speed quickly on the project, and facilitate seamless adoption of new technologies and tools to optimize system development and testing.



Corporate Headquarters
245 Main St., Cambridge, MA 02142
617-366-2656 | info@kalleid.com | www.kalleid.com