CASE STUDY:

Driving Enterprise Transformation Through a Best-In-Class Sapio LIMS Implementation

PROJECT OVERVIEW

A global laboratory solutions partner providing support services for clinical trials worldwide was managing its **80+ global lab partners** with a fractured legacy ecosystem. This patchwork infrastructure was creating a number of operational inefficiencies, as well as compliance and data integrity risks.

The company decided to harmonize its operating environment by implementing a 100% integrated Laboratory Information Management System (LIMS) to manage all its global lab partners and automate critical clinical trial workflows. Initially, the company hired Kalleid to manage the GxP validation workstream for the new Sapio LIMS due to our extensive experience with the platform and the fact that we had several certified Sapio Engineers on staff.

Eight months into the Sapio LIMS implementation, it became clear to the company that the project was in danger of failure due to poor execution on the part of the external partner hired to oversee project management and other key workstreams. A decision was made at that time to give Kalleid leadership of the entire implementation program, which included managing all high-level workstreams and coordinating technical delivery for multiple versions of the platform and the associated client portal.

BUSINESS CASE

Prior to the transformation, the customer faced significant operational risks within its legacy environment. The primary drivers for the project included:

- **System Fragmentation:** Data was siloed across eight different systems, leading to fractured study design workflows.
- **Manual Inefficiency:** Resource allocation relied on manual spreadsheets, and supply chain syncing suffered from manual unit-of-measure (UOM) delays.
- **Compliance Risks:** Clinical trial participant unblinding risks were high, audit trails were fragmented across paper and email.
- **Data Integrity:** Inconsistent raw lab data required manual Bill of Materials (BOM) entry into the Enterprise Resource Planning (ERP) system.

These challenges necessitated a shift from a fragmented, siloed digital environment that often relied on manual, paper-based processes to a **100% integrated ecosystem** capable of supporting complex clinical operations.

SERVICES PROVIDED

Kalleid's leadership role in the project encompassed several critical workstreams to support successful implementation:

1 Program Management and Technical Leadership

Kalleid assumed leadership of the entire implementation project, providing the following:

- **Project Planning:** Created and managed the project plan for the release.
- **Technical Delivery:** Coordinated the delivery of the LIMS, client portal, and associated system updates.
- **Resource Coordination:** Providing a team of specialists including validation experts, technical writers, training developers, and organizational change management (OCM) leads.

2 GxP Validation and Compliance

Kalleid implemented a risk-based approach to computer system validation (CSV) in compliance with **21 CFR Part 11** and industry best practices. Key deliverables included:

- **Validation:** Developed a comprehensive validation plan, testing strategies, and PQ testing scripts. Provided ad-hoc testing for all system integrations and dry-runs.
- **Requirement Tracking:** Managed User/Functional Requirements (URS/FRS) and the Traceability Matrix to ensure all functional requirements were met and tested.
- **Documentation:** Provided a Validation Summary Report and managed deviations.

3 Mass Client Study Migration

Kalleid directed a four-wave migration strategy to transition **364 studies** into the new platform:

- **Wave 1:** Low-complexity storage and US-based labs.
- **Waves 2 and 3:** SGS/Import labs and high-complexity automations.
- **Wave 4:** Ship codes and outliers.

4 System Hardening, Documentation, and Change Management

To ensure a smooth transition, Kalleid focused on hardening the software and preparing the organization:

- **System Hardening:** Executed regression testing, security audits, and environment preparation to ensure the LIMS was "Production Ready."
- **SOP and Training:** Fine-tuned nearly 70 Standard Operating Procedures (SOPs) and created custom training for the customer's staff.
- **Communication:** Established internal and external communication plans to manage stakeholder expectations and create a smooth transition.

RESULTS DELIVERED

What began as a targeted **GxP validation** engagement for the Client evolved into a full-scale program management and strategic leadership initiative. Over nine months, the partnership shifted from foundational software verification to enterprise-grade validation and mass client study migration.

The program achieved a major advance in the Client's operational maturity. Significant impacts included:

- **Operational Efficiency:** The move to a 100% integrated ecosystem eliminated manual data silos and automated clinical trial workflows.
- **Quality and Compliance Gains:** Rigorous enforcement of ALCOA+ principles maintained GxP compliance and reduced regulatory risk.
- **Advanced Features:** The implementation delivered complex functionality, including analyte-level blinding, dynamic harmonization, and advanced sample tracking.
- **Stabilized Environment:** A dedicated hardening period ensured that the system was stable and secure prior to mass migration.

By evolving from a validation partner to a strategic leader, Kalleid provided a robust, compliant, and scalable infrastructure designed for modern clinical trial management.

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