Case Study

Sapio Sciences ELN Helps Leader in Commercial Laboratory Services Coordinate Workflow Across 20 Countries

The Sapio ELN integrates seamlessly into digital workflows, supports a diverse spectrum of sample analysis platforms, complies with global GLP standards, and provides unsurpassed data privacy and security.

About the Project

Client Application
Global commercial laboratory services for basic research, drug discovery and development, manufacturing, and commercialization

Product
Sapio ELN

Snapshot

When you operate over 150 facilities in over 20 countries with a mission to deliver the fastest, most reliable pathway for your clients to get compounds to market, the integrity, compliance, and security of your digital laboratory operations are critical. Regardless of location, your scientists' electronic laboratory notebook must integrate seamlessly into digital workflows, support a diverse spectrum of sample analysis platforms, comply with global good laboratory practice (GLP) standards, and provide unsurpassed data privacy and security. That's why you partner with Sapio Sciences to equip your laboratory scientists worldwide with Sapio ELN℠ and help connect and secure your global informatics network.

The Challenge

Sustaining a leadership position in commercial laboratory services for decades requires continuous process improvement to consistently deliver the fastest, most reliable pathway for clients to get compounds to market—year after year after year. This includes continually adapting and adhering to stringent, dynamic standards that ensure the quality and integrity of global lab operations. It requires modern informatics that connects thousands of scientists in labs worldwide in a secure, paperless operating environment that integrates digital data collection and reporting systems.

Commercial laboratories in different countries operate in accordance with GLP standards compliant with the U.S. Food and Drug Administration (FDA), the Organisation for Economic Co-operation and Development (OECD), and the European Medicines Agency (EMA), depending on the location and nature of the tests performed (i.e., discovery, preclinical, and clinical). Multiple laboratory analysis platforms include a wide range of instruments to meet clients' diverse needs for analytical chemistry, immunology, genomics, LC/MS bioanalysis, and LBA bioanalysis and biomarkers. Within this framework, the laboratory services organization aimed to integrate a cloud-based ELN into an established GLP-compliant system to digitize sample management and associated workflows.

The unique requirements of a geographically dispersed, digitally unified GLP lab operation present demanding validation and implementation challenges, including:

- A highly configurable system with interconnectivity.
- Meeting regulatory requirements for all governing agencies.
- System operation across 9 time zones with different system outputs.
- 17 sites all want something slightly different, each with a different implementation timeline.
- Pre-loading the system with inventory items, storage locations, equipment, and other critical workflow information.

The Solution

The commercial laboratory services organization began evaluating ELNs following GLP requirements for laboratory software, especially electronic records, electronic signatures, controls for closed systems, quality system regulation of automated processes, and secure cloud computing. Beyond just a vendor, it wanted a partner that could provide an advanced ELN and a collaborative team to help meet its demanding customization, validation, and implementation challenges. It chose Sapio Sciences.

The teams employed a "hybrid agile" methodology adapted from software development for system design, agile implementation, integration testing, and deployment. Agile software development involves self-organizing, cross-functional teams to develop and deliver solutions to end users — in this case, 17 laboratory sites. Agile development requires adaptive planning, evolutionary development, early delivery, continual improvement, and flexible responses to change.

The Results

The "hybrid agile" methodology employed by the two teams enabled them to meet the demanding validation and implementation challenges of a geographically dispersed, digitally unified GLP lab operation by:

- Developing a minimum viable product (MVP) structure with checkpoints to ensure a new feature did not disrupt current functionality.
- Ensuring validation processes met regulatory requirements, including system operation across different time zones.
- Using feedback and focus groups to ensure all stakeholder voices were heard and clear direction from global leadership regarding what was and wasn't negotiable.
- Gradually migrating changes at each site's required pace.

Within the flexible implementation framework, sample management, instrument maintenance, and inventory modules for the Sapio ELN were validated. In addition, LC/MS bioanalysis, analytical chemistry large molecule bioanalysis, and immunogenicity workflows were validated for method development, sample dilution, and GLP sample analysis. Cloud hosting was validated for data privacy and security.

Through its partnership with Sapio Sciences, the commercial laboratory services organization can continue to improve its digital informatics network and help sustain its global leadership position.