astrix
TECHNOLOGY GROUP

CASE STUDY:

Labware Implementation

OVERVIEW: A global contract research organization (CRO) specializing in clinical research was faced with a 25-year-old laboratory informatics system (LIMS) that was central to running their core business. This legacy system had been designed in-house, primarily by the business user community, in an ad hoc manner. The system processed around 10,000 samples per day, serving about 200 users in five lab groups spanning three geographic sites. The client had tried to replace this system on two prior occasions, but these projects had failed. A decision was made to purchase Labware LIMS and try once again to replace the legacy system.

The LIMS processed about 10,000 samples per day, serving 200 users in five laboratory groups across three geographic regions.

BUSINESS CHALLENGE: The legacy system was expensive to maintain and rigid in nature. Due to the inherent inflexibility of the platform, it was very difficult to modify the system as the business processes grew in complexity. While the client was very motivated to make the switch to the new system, the Labware implementation project faced an enormously complex operational environment. Some of the challenges that the implementation team faced included:

- **Instrument integration** – Dozens of instruments needed to be integrated with the system across multiple laboratories.

- **Running dual systems** – Due to the long-term nature of clinical trials, and the difficulty in translating data from the legacy system, the decision was made to run the new Labware and legacy systems in parallel until they could fully transition off the old system. The team was faced with making sure the two co-existing systems were in-sync and communicated adequately to prevent errors or rework.

- **System validation** – The Labware system had to be fully validated for intended use and compliant with CFR Part 11.

- **Performance and latency** – Due to the high throughput, latency and performance were issues that needed to be addressed. In previous systems, this had been a problem, and the team needed a technical design that would minimize these issues.

- **Configuration complexity** – Samples from different studies and research sites around the world were coming

into the labs to be tested. These samples had to be associated with the proper instruments, and the test results had to be cataloged by study and grouped by batch, and then communicated to the appropriate sponsor or principal investigator in the field. The configuration complexity required to accomplish these requirements was enormous.

- **Local labs** – There was also the concept of a local lab to be included in the Labware configuration. In this instance, a test kit was sent out to an investigator, and that investigator would send the samples to a local lab as opposed to the client. The local lab would do the testing and send a report detailing testing results to the client. The project team needed to automate this process in the system as much as possible, to make sure the data received was in a consistent format with the other data.

- **Security and roles** – Complex security requirements needed to be configured – many different layers of user permissions were required to determine who could do what at any given time in any of the various workflows that were operating.

SERVICES PROVIDED:

The Astrix team was involved in several aspects on the project, including:

- **Static Data Management**

    ▶ Interviewed appropriate users and other client stakeholders to gather information on the legacy data requirements.

    ▶ Automated the import of large, complex data sets from spreadsheets. This saved time and resource overhead, while avoiding possibility of human error.

- **Security** – Labware did not have the necessary security capability (layered user permissions) at the time of the implementation.

    ▶ Worked with the Labware development team to design and implement the required security framework in the program.

- **Sample Batching** – For auditing purposes, it was important to know which samples were run together as part of a sample batch on a particular instrument. Depending on the instrument, it was not always clear from the data set output which batch the data was associated with.

    ▶ Worked with the Labware development team to design the mechanism through which Labware would process all of the data from all the instruments in a way that maintained batch identity, while avoiding performance issues. This process required many validation steps and needed to happen very soon after the testing was done due to down-stream considerations.

- **User Requirements**

    ▶ Led discussions around defining user requirements and workflows.

    ▶ Participated in many meetings with system users in the business in order to demonstrate functionality as it was developed to receive real-time feedback and ensure requirements were being met.

- **Validation**

    ▶ Contributed to creation and execution of validation scripts.

- **Integration of Instruments & Third Party Apps**
Worked on several different methods of integrating third party applications:

    ▶ Configuring Labware to monitor and process database tables created by external instrument

    ▶ Web services

    ▶ XML data mapped to specific fields in Labware, or to an XSD provided by external applications

Worked on integration of Labware with several different instruments (Roche Cobras and others)

RESULTS DELIVERED: As of early 2017, all client labs were successfully transitioned to the Labware platform. The resulting solution has delivered numerous benefits to the laboratory staff, including:

- Simplified workflows in the lab.
- Better insight into laboratory workflows and supporting data.
- Real-time visibility into production issues with the instruments.
- Ability to spot potential bottlenecks in the capacity for throughput.
- Enhanced reporting capabilities, providing better traceability of the samples across the business process workflows. Better laboratory performance. Due to the enhanced data management capabilities, the throughput of laboratory samples was improved by almost 50%. This has allowed the client to process a greater number of samples at a time.
- Fewer systems to manage. As a result of this project, the client was able to consolidate 5-6 different legacy systems being utilized in the laboratory domain into one.

Due to the enhanced data management capabilities, the throughput of laboratory samples was improved by almost 50%.

LESSONS LEARNED

This project represented a large, highly complex effort which ran over a ten-year period. The eventual solution pushed the boundaries of the vendor solution, including its integration capabilities, performance and configurability. Finding success involved partnering closely, not only with the client, but also the software vendor. In contributing to this effort, our team members learned a number of valuable lessons:

- A complex laboratory informatics project will most likely take longer than it seems at first glance, as there are always challenges to be dealt with that you don't see initially.

- User requirements need to be specific, and the business users need to sign off on the designs before configuration starts. This means that workflows should be mocked up in advance and documented screen by screen if necessary.

- Getting disparate systems to talk to each other is never easy – this must be something that is focused on early and often. Sometimes the tendency here is to wait till the end, but this is a mistake.

- Performance as scale must be thought about during the design phase and must also be tested prior to go live.

During this project, everything was tested thoroughly and validated, but there were serious issues on day one of operation, as no one thought to run the system with true high throughput before deployment.

- Collaboration with the vendor is essential for success. Due to the complexity of this project, every aspect and capability of the Labware software was explored and tested, and new functionality was added in collaboration with the Labware development team. Though you may be tempted to build your own integrations and code, it is always best to collaborate closely with the vendor early to align on best practices and limits of the system. You may be better served in the long run to wait for functions that can be incorporated as part of the supported product.

Though you may be tempted to build your own integrations and code, it is always best to collaborate closely with the vendor early to align on best practices and limits of the system. You may be better served in the long run to wait for functions that can be incorporated as part of the supported product.

ABOUT ASTRIX TECHNOLOGY GROUP

Scientific resources and technology solutions delivered on demand

Astrix Technology Group is an informatics consulting, professional services and staffing company dedicated to servicing the scientific community for over 20 years. We shape our clients' future, combining deep scientific insight with the understanding of how technology and people will impact the scientific industries. Our focus on issues related to value engineered solutions, on demand resource and domain requirements, flexible and scalable operating and business models helps our clients find future value and growth in scientific domains. Whether focused on strategies for Laboratories, IT or Staffing, Astrix has the people, skills and experience to effectively shape client value. We offer highly objective points of view on Enterprise Informatics, Laboratory Operations, Healthcare IT and Scientific Staffing with an emphasis on business and technology, leveraging our deep industry experience.