Business Sector: **BIOTECH**

CASE STUDY:

Business Process Analysis and LIMS Selection for a Global Life Sciences Company

OVERVIEW: A global life sciences company focused on providing products for emerging public health threats staffs eight laboratories for product manufacturing, quality control/testing, and research and development. These laboratories prepare and test a range of products for direct sale and distribution to governments and healthcare providers. Several of these laboratories performed commercial-scale contract manufacturing for external customers, creating a challenging environment to establish an IT infrastructure that supported both internal and external stakeholders.

The company was interested in improving the IT infrastructure in the eight laboratory sites by selecting and implementing an integrated laboratory information management system (LIMS) solution. The company chose Astrix Technology Group as their Laboratory Informatics Consulting Partner to assess current and planned laboratory/analytical processes and help select the LIMS solution that was best suited for their multi-site manufacturing, QC, and R&D facilities.

BUSINESS CHALLENGE:

The company was experiencing several issues in their laboratories that they hoped to remedy with this project:

- **The need to support both research and operations functions**
- **Laboratories with either paper-based processes or disparate existing commercial LIMS**
- **Continued company growth of 50% year over year – both organic and via acquisitions**

In order to address these business challenges, the company chose to select, implement and integrate a LIMS solution that would improve the overall reproducibility, traceability, and efficiency of its eight laboratory sites. Astrix was tasked with executing the assessment phase of the LIMS project, which included conducting Business Process Analysis and participating in the LIMS Selection Process. Applicable tasks for the assessment phase included:

- **Inventory of lab current state, including equipment and functions**
- **Draft end-user functional and non-functional requirements**
- **Develop recommended implementation roadmap of prioritized capabilities/functionality (i.e., "Phased Approach") of the LIMS Solution, including integrations with enterprise systems**
- **Facilitate the selection of the LIMS vendor best suited to meet the company's needs**

SERVICES PROVIDED:

The Astrix Approach™ is a proven methodology designed to ensure success in laboratory informatics projects. Astrix has developed and refined this methodology based on 25 years of researching best practices and implementing, observing and measuring results for scientific and laboratory-based organizations. In applying the Astrix Approach™ to the assessment phase of this project, Astrix performed the following services for the customer:

Project Management – The Astrix Team utilized a comprehensive and scalable project management methodology as the foundation for project delivery. Weekly status meetings were conducted to facilitate effective communication with key stakeholders, and the Astrix Team formulated a Risk Matrix document that was used to monitor and manage project risks.

Project Initiation and Kickoff Meeting – Prior to any site visits, the Astrix team reviewed available information about the customer's laboratory environment, processes and procedures in an effort to become familiar with the customer's operations. The kickoff meeting served to introduce Astrix team members and the customer's project team staff. In addition, the project approach was finalized with input from the customer to establish a shared project vision and focus.

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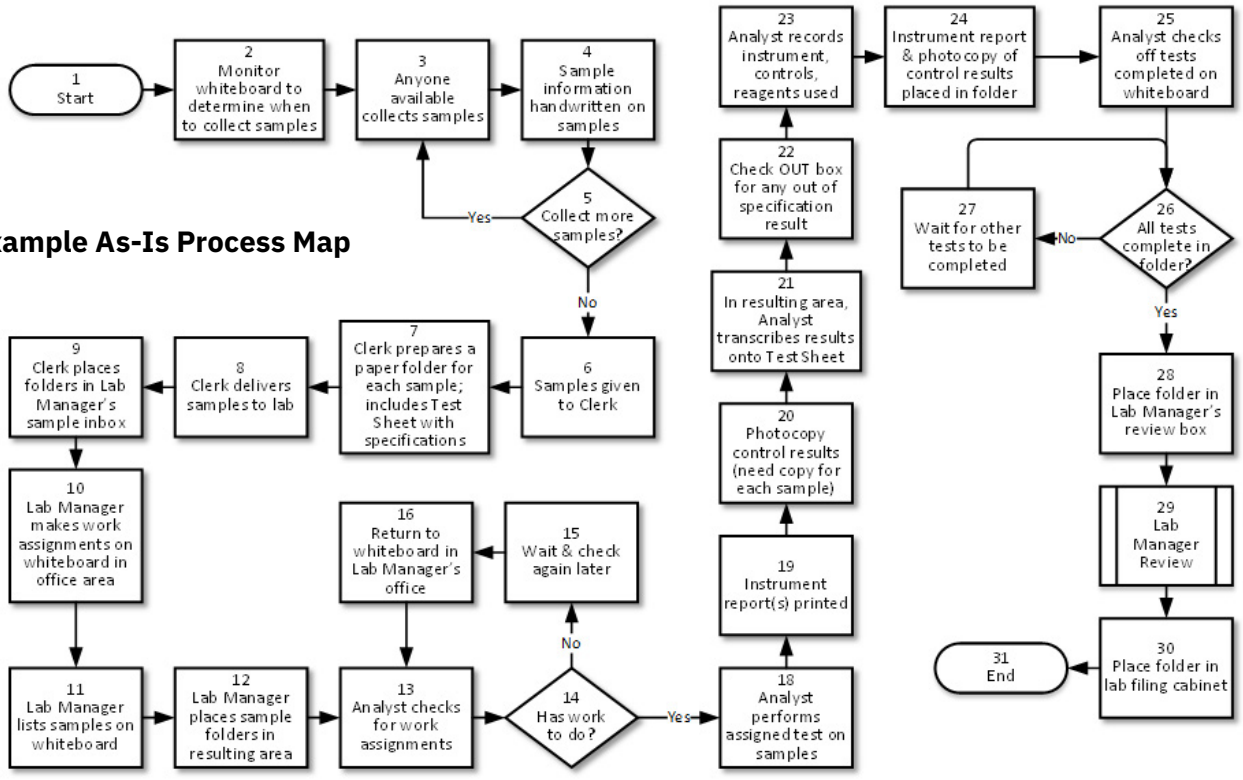
Current State Assessment – This phase was critical, as it established the foundation for the rest of the LIMS project. The Astrix team met with each stakeholder group to develop the current state or "As-Is" work process maps. This was accomplished in group workshops and individual interviews. The current state (As-Is) process maps served to identify inefficiencies and wait states and thus helped guide development of the optimized future (To-Be) state work processes that detailed process improvements. Both As-Is and To-Be process maps were provided to the customer's project team members for review and discussion before being finalized.

Example As-Is Process Map



Requirements Analysis – The Astrix team collected and documented the requirements of all the stakeholder groups (e.g., Laboratory Services, Information Technology, Management), modeling and analyzing these requirements as a basis for system configuration. Given that these requirements flowed from the To-Be process maps, they were constrained to business improvements.

The requirements were documented in a requirements matrix at the appropriate level of granularity, with each requirement containing a unique identifier and classified according to type (e.g. Business, Regulatory, Functional, Reporting, Interface, Security, Performance, and Technical). In addition, the Astrix team worked with the customer's project team to assign the appropriate priority level to each requirement according to the following scale:

1 = Required
2 = Improves work process, but not required
3 = Nice to have

Example Requirements Matrix

Reqt ID	Description	Cat.	Priority	Response
861	Technical Requirements.	TC		
862	The system should operate in a web-based architecture.	TC	2	
863	The system must support training, development (TEST), and production environments.	TC	1	
864	The system must store data in a relational database.	TC	1	
865	The system should operate on Microsoft SQL Server Standard 2012 R2 or Above .	TC	2	
866	The system should operate on Windows server 2012.	TC	2	
867	The system must support the ability to perform SQL queries directly against the database.	TC	1	
868	The system must support Microsoft Windows Client operating systems.	TC	1	
869	The system must support Windows 7 or above.	TC	1	
870	The system must support Microsoft Internet Explorer 11.0 and above.	TC	1	
871	The system may support data collection by PDA or electronic notebooks.	TC	3	
872	The system must support data collection by field devices.	TC	1	
873	The system must support Windows, Pagenation and scrolling capabilities (One screen).	TC	1	
874	The system must support TCP/IP protocol.	TC	1	
875	The system must support Microsoft Office 2013 or Above applications.	TC	1	
876	The system must support customization/configuration by standard tools.	TC	1	
877	The system may support Microsoft Visual Basic .Net.		3	
878	The system must interoperate with McAfee antivirus software or other antivirus as approved by the in-house IT Dept.	TC	1	
879	The system must support W3C XML (World Wide Web Consortium eXtended Markup Language).	TC	1	
880	The system may support W3C SOAP v1.2 (World Wide Web Consortium Simple Object Access Protocol).	TC	3	
881	The system must support W3C XML Schema 1.0 (World Wide Web Consortium eXtended Markup Language Schema).		1	
882	The system should expose information via web services.	TC	2	
883	The system may retrieve, via web services, sample data and metadata by ID, date or location.	TC	3	
884	The system may update, via web services, sample data and metadata.	TC	3	
885	The system shall provide RESTful API (REpresentational State Transfer API) services to support integration with other applications. .	TC	1	

Implementation Roadmap – The Astrix team formulated a roadmap that described the transition from the current state to the future state To-Be work processes that reflected the customer's priorities, funding and resource expectations, and that embraces industry best practices and trends. This roadmap included:

- **Analysis of the fit of the current state to the strategy**
- **Prioritized opportunities and high-level benefits**
- **Critical decision factors in considering paths**
- **Orchestration of the paths to address dependencies**
- **High-level risk factors**

Vendor List Development – After reviewing both the requirements and the project budget, the Astrix team developed a list of vendors for consideration by the customer, along with a rational for each vendor selected. In this process, all potential LIMS capable of supporting life science laboratories were considered to ensure a thorough evaluation.

Vendor Selection – The Astrix team served in an advisory capacity during all vendor selection activities. For purposes of scoping and cost estimation, Astrix participated in meetings and review of documents related to:

- **Request for proposal (RFP) development**
- **FP response scoring and review**
- **Vendor demonstration script/agenda preparation**
- **Vendor demonstrations**
- **Vendor selection discussions**

RESULTS DELIVERED

The customer was very pleased with the contribution of the Astrix team to their LIMS project. The results delivered to the customer included:

- **Due to the workflow assessment conducted by Astrix, work processes across all eight laboratories were able to be harmonized and improved significantly.**
- **The Implementation Plan was realistic and sequenced to avoid disruption to ongoing laboratory operations.**
- **Having gained intimate knowledge of the customer's laboratory operations from this project, Astrix is available to continue to partner with the customer for knowledge transfer and project implementation services**
- **Given that the requirements developed were constrained to business improvements, the customer is confident that their new LIMS will deliver significant business value for their organization.**
- **Astrix review of the vendor cost proposals based on our experience and expertise provided greater cost certainly for the customer, especially with regards to services to be provided by the LIMS vendor**