



**CASE STUDY:**

**SAMPLEMANAGER LIMS  
IMPLEMENTATION AND INTEGRATION**

**Overview:** A global biopharmaceutical company with many different research and manufacturing facilities in multiple time zones around the world was using a number of different informatics systems in the laboratories across these facilities to collect, store and report data. These disparate systems from multiple vendors were configured to best meet the needs of the local operations in each laboratory.



The company made the decision to embark on a strategic, global initiative to transform, standardize and then optimize their Quality Operations Lab footprint. In order to implement this global standardized footprint, they looked for collaborative partners that could assist them with the implementation of SampleManager LIMS™ Version 11 (SM11), Empower 3 CDS, and NuGenesis SDMS in laboratories across the enterprise. Additionally, the project partners would work to harmonize key operational systems and implement standardized work-flows based on industry best practices.

The company chose Astrix Technology Group as one of its partners for this project due to Astrix’s extensive experience with defining and deploying common business processes for organizations with multiple global sites using a standard technology platform with shared master data. Specifically, Astrix assisted the customer with upgrading all of its research and manufacturing facilities to SampleManager LIMS version 11 and integrating this system with a number of other systems already in use in their facilities. Astrix also participated as a collaborative partner in the implementation of the Empower and NuGenesis systems.

This case study will examine how the global biopharmaceutical company, Astrix and Thermo Fisher Scientific collaborated to develop a plan that lead to the successful deployment and integration of SampleManager LIMS.

**Business Challenge:** The Quality Operations environment in the biopharmaceutical company’s different facilities was very diverse and non-standardized – many sites had different systems in use to accomplish the same thing, different sites had different configurations of the same system, multiple configurations of a site’s system for a given workflow were sometimes present, different nomenclature was used at different sites to describe the same data, different workflows and methods were in use, etc.

The company recognized that supporting multiple informatics systems with tailored configurations and workflows was highly inefficient for a global organization with dispersed laboratories.

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Additionally, the process of managing non-standard processes and procedures introduced significant regulatory compliance risk via potential data integrity issues.

With this project, the company's main goal was to establish a foundation for future growth by standardizing the Quality Operations environment to guarantee data integrity across all functional groups. To accomplish this, systems, system configurations, and workflows needed to be standardized and data and nomenclature needed to be harmonized across the enterprise. Facilitating consensus on what this standardization would look like in an organization of this size was anticipated to be a significant challenge.



### The scope of this project was immense:

- ◆ **Platforms:** LIMS Sample Manager 11, Common CDS Empower 3, SDMS (NuGenesis), ERP (SAP QM)
- ◆ **Business process mapping for the areas/processes within scope of the project, which included:** MEC (Microbial Environment Control), Analytical (Raw Materials, Manufacturing and Product Release) and Stability.
- ◆ **Overall project and program management:** Performed by Astrix on the initial phases of the project and transitioned to the customer as the project progressed.
- ◆ **Configuration of LIMS SampleManager 11 which was divided into different releases:**
  - Release 1 – MEC
  - Release 2 – Analytical
  - Release 3 – Stability
- ◆ **Phased rollout of the Releases on the different sites:** This strategy for a phased rollout, which also included static data migration and site-specific data load efforts, was a key factor on the overall project strategy.
- ◆ **SampleManager upgrade during the releases:** As the project progressed, key functionality and bug fixes were identified. The customer and Astrix teams worked closely with Thermo Fisher implementation, support and development teams in order to have key pieces of functionality either patched or prioritized for an upcoming release/service pack. The MEC Release 1 used SM11.1 while Analytical release SM11.2.1 and Stability release SM11.2.3.
- ◆ **System Integrations:** SM 11 interfaces with SAP QM, POMSnet (MES), and Cognos (BI).
- ◆ **Reporting:** A large number of reports were being generated from existing systems (Cognos, iStudyReporter, Discoverant) at the beginning of the project. The new LIMS/CDS/SDMS solution fed data to existing systems in support of those reports. The customer wanted these same reports, ideally without any changes to their structure, to be generated by the new system.
- ◆ **Customization:** With a project of this size, spanning many sites, several countries, thousands of methodologies, and interfacing with several external systems, a key strategy was to minimize customizations to the COTS systems being implemented. As the benefits of customizations outweighed the drawbacks in some cases at some sites, Astrix needed to deliver minimal customization in its least disruptive form.
- ◆ **Change Management:** Given all the different people in different cultures using the different systems in multiple facilities around the world, managing the people aspect of the transition to the new system, workflows and nomenclature was a significant undertaking. Stakeholder meetings, for example, often had hundreds of participants from all around the world.

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**Services Provided:** As the premier services partner for Thermo Fisher, Astrix collaborated with both the customer and Thermo Fisher on the implementation of the global LIMS platform for the customer's Operations.

A sample of the services provided by Astrix is listed below:

- ◆ **Business Process Mapping** – Focused on LIMS (SampleManager), Empower (CDS) and NuGenesis (SDMS)
- ◆ **Program and Project Management** – Initial program management, project management and project planning, setting the initial overall release approach and site go live strategy (which later was reviewed and adjusted as needed and transitioned to the customer's ownership).
- ◆ **Requirements Gathering and Documentation** – Gathered user and functional requirements through workflow process mapping in collaboration with the customer's personnel.
- ◆ **Installation of Multiple Environments** – Development, QA, PQ and Production on different versions of SM11+ (which included performing the upgrade of these environments).
- ◆ **Design and Configuration of the System** – Leveraged as much of the out-of-the-box (OOTB) functionality as possible. This often included negotiation with the customer's business representatives and IT to explain SM functionality and how their business process could work with the OOTB functionality.
- ◆ **Development of Customizations** – When no other alternative existed, customizations were developed on both C#, .Net, and VGL (VGL was used only when no other alternative was possible).
- ◆ **System Integration Support** – Support to SAP QM module (SMI-IDI) installation and configuration and SAP Master Data Harmonization.
- ◆ **Stability Module Configuration**
- ◆ **User Acceptance Testing (UAT) Support** – Supported the customer's team with UAT before releasing the system to be validated.
- ◆ **System Validation Support** – Supported the customer's Validation team during protocol execution and Incident resolution.
- ◆ **Data Management Support** – Supported site rollout and static data migration and site-specific data load activities.
- ◆ **SOP Modifications** – Supported the customer in creating SOP procedure modifications that were needed for the release of the new system.
- ◆ **Training of the Customer's IT Personnel** – Training was provided on the overall design, configuration and customization of the system so the system maintenance could be transferred to the customer.

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**Results Delivered:** Astrix is very proud of the work that has been done on this project, and the customer is pleased as well. This project is still ongoing, with the main achievements so far being successful rollouts of all three phases of SampleManager LIMS:

- **Rollout of Release 1 (MEC)** successfully completed on all the customer's sites (11 sites total) – Including all static data migration and site-specific data load.
- **Rollout of Release 2 (Analytical)**, including SAP QM module interface (SMI-IDI), on multiple sites. Some site rollouts still scheduled to be completed in Q4 2017.
- **Rollout of Release 3 (Stability)** successfully completed.

In addition to the technical aspects of these rollouts, hundreds of SOPs have been standardized, harmonized or decommissioned.

Astrix continues to support the remaining site rollouts of SampleManagers releases, as well as Dot releases and change requests for specific needs that could not be addressed on the initial rollout. Going forward, Astrix will also participate in SM11 interfaces to/from Empower and other laboratory instrumentation.

**Project Success Factors:** For any project of this size to succeed, protocols will need to evolve and lessons will need be learned as the project proceeds. There were a number of key principles that the collaborative partners in this project applied to achieve success:



**Flexibility:** If a process wasn't going to work for a site, management encouraged active discussion to find alternatives. Our team was able to provide the technical expertise and, as mentioned, training that lead to the solutions. The ability to pull team members in on an issue at a moment's notice, and management support of the focus change, was a key factor in the success of this project.

**Open communication:** The communication became more open with each release. With the stability release, the Astrix Team worked very hard to keep SMEs and management informed of what was happening with the project so they could provide immediate feedback. This allowed problems to be identified up front and fixed before they became larger. A "no blame" atmosphere allowed the team to be comfortable communicating issues and focus on the resolution.

**Trust:** The customer trusted Astrix's expertise and incorporated our advice. But furthermore, they trusted each other. When someone made a decision they stuck to it, unless it didn't work. We didn't spend time justifying suggestions or trying to "win someone over" to get things done. The time spent reworking things because someone changed their mind was reduced considerably.

**Responsiveness:** The Astrix team has a very fast turnaround time for fixes and updates on SampleManager thanks to our partnership with Thermo Fisher, but we can only provide that service on a project if management provides the environment to support it. For this project, the customer had backup people identified and empowered to make decisions when the key decision makers were out. The customer's project managers encouraged quick meetings with all stakeholders involved to resolve issues instead of having to communicate to one person, wait for them to talk to someone, wait for the second person to talk to a third, and then go back up the chain.

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