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ASIA EDITION

Data management for the entire product lifecycle

08 November 2021 | Opinion | By Partner Content

Jacqueline Barberena, Sr. Director, Global Marketing and Product Management at STARLIMS Corporationdiscusses the vast benefits of implementing and deploying a LIMS in the pharma sector.

Today's pharma manufacturers are finding they need more robust tools to meet modern regulatory expectations around data integrity.

Pharma requires a data management infrastructure that allows labs to work faster and more productively, with greater transparency. This digital transformation will allow the industry to derive more intelligence from their data, ultimately improving product and process safety, and enabling faster regulatory audits and approval timelines.

In the pharma industry, Laboratory Information Management Systems (LIMS) have become a mission critical application that supports this digital transformation from the ground up.

PM recently spoke with Jacqueline Barberena, Sr. Director, Global Marketing and Product Management at STARLIMS Corporation to get a better understanding of the vast benefits of implementing and deploying a LIMS in the pharma sector.

Q: The term "Laboratory Information Management System" can be misleading because in practice, these systems help manage data beyond laboratory testing. How does a LIMS improve day-to-day operations across the entire enterprise?

A: You are correct, a Laboratory Information Management System typically expands beyond laboratory data management. It is a comprehensive solution that not only manages data but helps with quality, regulatory compliance and safety throughout the entire product lifecycle.

LIMS solutions have the ability to integrate with existing systems, while also identifying opportunities to improve processes so that organizations can bring high quality and safe products to market faster. For a pharma/biotech organization, this means automation and secure data management for the entire product lifecycle, from R&D to production to quality assurance.

Q: What are some common barriers to implementing a LIMS in pharma, and how can they be overcome?

A: There's never a great time to implement sophisticated software in any industry, particularly industries that are as highly regulated as pharma and require intricate workflows. It takes proper planning, an excellent roadmap, resources to take time away from their day to day responsibilities, and funding. It's a big undertaking, but it's well worth it especially if an organization is still paper based. Two of the most significant barriers to innovation are outdated informatics tools and inefficient manual workflows. Moving from paper-based and outdated methodologies to automated digital solutions can breathe new life into the day to day operations of a lab.

The success of a LIMS project depends on several factors. One of the most important factors is creating accurate and useful laboratory workflows within the LIMS, ensuring that staff is involved, understand the benefits of the system, and will therefore work with and not against the system. Overcoming barriers and successfully implementing and deploying a LIMS requires:

- A clear understanding of the business and user requirements.
- A user-friendly interface that ensures a high-level of user adoption.
- LIMS workflows that match, or improve on, the existing laboratory workflows, enhancing efficiency and productivity.
- A clear understanding of the role of the laboratory and proper data management to the success of the overall organization, to name a few.

Q: What type of infrastructure is needed to ensure the success of a data management solution such as a LIMS within an organization?

A: I don't believe a specific type of infrastructure needs to be in place for a LIMS to help an organization. We have customers now that range from start-ups who were completely paper-based in their operations to mid-sized organizations who were partially paper-based and utilizing a combination of legacy informatics systems, to large global enterprises who were fairly automated but whose systems did not have the latest informatics innovations. All of these types of organizations with different infrastructures can benefit from a LIMS if it is properly implemented with the correct functionality and requirements to address the needs of the business.

Q: As companies continue their digital transformation journey, they often run into an issue referred to as "technical debt." What does this mean and how does STARLIMS address this problem?

A: The term technical debt can have a few different interpretations, however, essentially it means that as a lab's instruments, platforms and software are updated and replaced, outdated systems are retired from use, but many will still need to be maintained at significant cost in order to access data held in proprietary formats. It's a fact of laboratory life that has existed within the LIMS industry for decades.

As labs are chasing the latest revolutionary technologies, some may promise to support digital transformation in the short term but may result in technical debt five or ten years down the line. STARLIMS, however, is an application that supports this digital transformation from the ground up, while addressing the issues of technical debt.

As a corporation, we have taken an evolutionary approach to technological development, so that it can grow and adapt in parallel with the data requirements, formats and needs of labs taking on new analytical technologies and workflows. It's about empowering manufacturing, R&D and testing labs with the ability to stay ahead of the rapidly evolving technological and data landscape, so that they can protect their investment and derive maximum insight from data, enterprise wide. STARLIMS aims to constantly innovate. In the world of technology especially data management, staying ahead of the innovation curve and anticipating future customer needs is key to staying in business.

Q: What is on the horizon for STARLIMS and what does the future hold for LIMS?

A: This year has been an exciting one for STARLIMS and now as a standalone software organization, we are uniquely positioned to innovate faster than ever.

In July we announced the latest release of our Technology Platform V12.2. This highly anticipated release was a major step forward in the modernization of STARLIMS. The new technology platform features a powerful Electronic Lab Notebook (ELN) system, which allows for the execution of test workflows without interruption, using modern HTML5 technologies. HTML 5 is a more modern-looking, flexible, powerful, and efficient application which improves the performance, integration, and usability of STARLIMS.

On the business application layer, in 2018, STARLIMS released its first 100% HTML5 systems for clinical and quality manufacturing customers such as pharma and biotech. HTML5 is also most compatible with newer web browsers such as Google Chrome, which is key as older browsers such as Internet Explorer are becoming un-supported.

This year, STARLIMS also launched a new SDMS product (Standalone Scientific Data Management System) and STARLIMS LES (Lab Execution System). With STARLIMS LES, customers can ensure standard operating procedures are being followed and tasks are being developed in a compliant manner for regulated labs.

Looking ahead, to support customers on their journey, futuristic technologies are essential, including IoT, AI/AR etc. For STARLIMS, an example of this is the Digital Assistant. This technology provides the ability to interact with the STARLIMS HTML5 solution using user voice. Customers can utter commands using the microphone, launch applications and KPIs, conduct hands-free workflows while away from their desks and build their own skills to meet individual business needs. The tool leverages advancements in AI and NLP (Natural Language Processing), allowing the user to interact with the system using only voice. With continual and consistent product releases and innovations, STARLIMS will stay ahead of the technology curve.

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Original Source : Pharma Manufacturing