LIMS vs. LMS

Defining the Future of Laboratory Informatics

The concept of the Laboratory Information Management System (LIMS) has been with us for more than 30 years, born at a time when minicomputers and networking were making dedicated departmental IT systems possible. The first commercial LIMS systems were intended for sample management which, until that point, had been tracked with pencils and paper. From that simple beginning, the scope and definition of LIMS have continuously expanded, with new capabilities and modules being added regularly.

As a tool for linking the laboratory to the business, LIMS has served a useful role in the operations of many corporations, even as it has placed a burden on users to key in data. After three decades in the marketplace, one might expect that LIMS solutions would be as widely and fully deployed as Enterprise Resource Planning systems (ERP).

However, that is not generally the case. Primarily for reasons of cost and complexity, many organizations have been unable to undertake a full-scale LIMS implementation.

Meanwhile, considerable progress has been made in the development of non-LIMS software products that offer varying amounts of LIMS functionality. At the top of that list is the Laboratory Management System (LMS), the first solution to offer a real alternative to LIMS.

Because of their similar-sounding names, abbreviations and overlaps in capabilities, LIMS and LMS can be challenging to differentiate in people's minds. This white paper was created to make those differences more clear, and to help laboratories of all kinds better understand the technologies and determine which solution is best suited to meeting their current and future needs.

THE GROWING CHALLENGES OF THE MODERN LABORATORY

Analytical laboratories across all industries are facing increasing pressure to perform at their peak while simultaneously managing a growing number of challenges, including:

- **The rising volume and variety of laboratory data** – As workloads grow and analytical instruments have become increasingly sophisticated, laboratories are producing more data – in file size, volume, and variety – than ever before. Files of 1 GB to 1 TB are not uncommon. This data needs to be gathered, shared, stored, analyzed, and reported seamlessly and efficiently.
- **The transition from manual processes and spreadsheet-based records** – Many laboratories still maintain records on paper or with simple spreadsheets, both of which are labor-intensive, susceptible to human error, and difficult to share. They need a way to move to digital record-keeping and workflow tools that automate and simplify business processes and reporting requirements.
- **The pressure to accomplish more faster** – Whether it's the competitive pressures of the pharmaceutical industry, tightened budgets due to reduced government spending, or the demand for innovative new products in the chemical industry, most analytical laboratories are being pushed to be more productive – often with fewer resources.
- **The need to fully leverage analysis data** – Being more productive also means deriving more usable data from each analysis. While searching for answers to one question, scientists invariably gather other insights that may be useful for the current project, other work, co-workers' related explorations, or future projects. When organizations are able to store, access, and share that information more readily, they can support the business better and reduce the number of unnecessary repeat analyses.
- **Increasing regulatory compliance requirements** – According to a 2014 report by the Progressive Policy Institute, **"the amount of regulation on the pharmaceutical industry has increased 40% since 2000."**[1] That trend is mirrored in other industries, from cosmetics to food, as government health organizations work to limit adverse reactions and limit exposure to potentially harmful substances. The burden goes beyond simply managing and reporting data; regulatory agencies are now requiring more in-depth information about the integrity of the data. That trend is expected to continue as regulations such as the European Union's Identification of Medicinal Products (IDMP) prepare to go into effect. ***Effective July 2016, companies that are not compliant with IDMP could potentially be fined 5% of their products' revenue.*** This is increasing the time, expense, and effort all companies have to expend for testing and reporting.
- **Mergers and acquisitions** – According to Bloomberg, there were more than $118 billion worth of Pharma deals proposed or announced in the month of April 2014 – not much less than the $174 billion spent on mergers and acquisitions in all of 2013.[2] As these and similar deals in other industries take effect, companies must move quickly to integrate their laboratory operations for maximum productivity, efficiency, and seamless data sharing. Many organizations are responding to these needs by standardizing processes and workflows across all laboratories.

- **The growth in outsourced testing** – In recent years, more companies have discovered that they can save resource costs and handle fluctuating laboratory volume by using third-party testing laboratories to perform at least a portion of their routine analytical needs. To work effectively with contract laboratories, these companies need to be able to track samples closely and quickly incorporate outsourced test results from third parties into their existing databases.
- **The need to provide management visibility into the laboratory** – Every corporate laboratory is part of a larger business with its own enterprise systems for finance, supply chain, manufacturing, and other functions. Department managers need to depend on consistent and predictable workflows to minimize any negative impact to profitability, market share, and feed resource planning activities that are required to stay competitive in today's business world.

Both LIMS and LMS are intended to support these needs.

WHAT DO LIMS AND LMS HAVE IN COMMON?

For someone new to laboratory informatics, LIMS and LMS may appear to share a lot of functionality. For example, both LIMS and LMS support:

- Sample registration
- Test tracking
- Labeling and barcodes
- Workflow
- Stability study management
- SAP integration
- Calculations
- Electronic Laboratory Notebook (ELN)
- Management of reagents and instruments
- Training records

At first glance, it may seem that there is little difference, but there is more to the story. To understand where LIMS and LMS diverge and their respective strengths, it's necessary to take a closer look.

WHAT IS A LIMS?

It's challenging to provide a precise definition of a LIMS because the components and functionality that comprise a LIMS have evolved steadily over the past three decades.

The first-generation LIMS of the early 1980s were stand-alone systems that handled sample management and offered automated reporting tools. By the end of the decade, as relational databases grew in popularity, LIMS functionality grew to include application-specific modules, such as specification management, sample tracking, inventory and equipment management, and time tracking. A third generation of LIMS arrived in the 1990s, based on personal computer software and client/server architecture. The first web-enabled LIMS arrived in the mid-1990s, followed by XML support and georeferencing of samples.

In recent years, LIMS have expanded to include clinical and ELN functionality, and many LIMS now include modules for:

- Corrective And Preventive Action (CAPA) management
- Customer Relationship Management (CRM)
- Chain of custody
- Environmental monitoring
- Investigation management
- Trend analysis
- Certificates of Analysis (CoA) generation
- Formulation and recipe management
- Plate management
- Audit management

At the same time that capabilities have been added, LIMS implementations have become more operationally specific; many are geared more to biology, chemistry, Quality Assurance/Quality Control (QA/QC), or Research and Development (R&D) departments.

LIMS strengths

Customers typically choose a LIMS because they want a comprehensive solution – or at least one that they are confident will be able to support more comprehensive needs as they require them. This spares the customer any worry about having to integrate additional, non-supported software, now or in the future.

LIMS are also strong in offering industry- and application-

specific functionality, particularly for Drug Metabolism and Pharmacokinetics (DMPK), Bioanalytical, Clinical, Food, Research, and QA/QC operations. This can reduce the need for customization and allow for better alignment with operational workflows.

LIMS are also fully customizable. Since it is unlikely that any laboratory could use a commercial software product as-is, right out of the box, the ability to customize it and get exactly what you want is attractive to many.

Finally, most LIMS can link well to the ERP systems upon which the day-to-day business operations and supply chains of many corporations depend.

LIMS challenges

For many customers, the major strengths of LIMS – the comprehensive breadth and depth of functionality, the sophistication of the software, the customizability – also constitute some of its biggest drawbacks.

Some of the most-often cited frustrations include:

- **Deployment time, effort, and cost** – It is not unusual for a LIMS deployment to take two to three years to complete. In fact, many customers say that their LIMS deployment has never been fully completed. The expertise required is also specialized and costly.
- **Customization is always necessary** – Every laboratory wants software that will work with its unique business processes and workflows. However, there is a big difference between configurability and customization. Too often, LIMS require customization at the software-coding level to meet specific needs. Again, this adds time and cost and delays a return on investment.
- **Maintenance and updating require resources** – Customized software is never easily updated. A new software revision may require further coding.
- **An inability to integrate quickly and easily with updated technologies** – Because many LIMS deployments include custom code, they may not mesh smoothly with new system software revisions, new analytical techniques and instruments, or new analytical software products as they become available. This can hinder productivity and require custom testing for validation, delaying any expected benefits.
- **Global deployment challenges** – With increasing globalization and consolidation within industries, more companies are operating multiple laboratories on several continents. Their preferred LIMS may not be supported in all locations or offer the language version required for some sites.
- **Unused functionality** – A common complaint among LIMS customers is that their LIMS provides unnecessary functionality that contributes little if anything to their productivity while adding to the testing, validation, and deployment burden.
- **A greater focus on operational vs. laboratory functionality** – To many scientists, the LIMS is a good tool for automating the operational functions of the laboratory, but less so for supporting their analytical work. If the goal of the laboratory is, for example, faster drug discovery throughput, simplifying operational tasks alone will not be enough.
- **Data management is an issue** – Most LIMS have limited data management capabilities, so they have little functional ability to link the numeric results data entered into the LIMS system to the original report or raw data file that generated it. Data is less available, so organizations must deploy another data management system or keep complex paper-based records.
- **Upgrading is difficult** – The more customized a system is, the more difficult the transition to the next version of software. Customized systems require customized upgrade paths, which are often expensive. This in turn stifles the use of new equipment and systems in the laboratory which are not compatible with the in-place LIMS.
- **Personnel turnovers can affect lengthy projects** – A LIMS project requires a long-term effort. The technology industry has one of the lowest employee tenure rates – about three years on average, according to published estimates. If a key contributor leaves for another opportunity, it could increase the risk of additional cost, delays, and errors.

WHAT IS AN LMS?

A Laboratory Management Systems (LMS) is different from a LIMS because it evolved differently to meet different needs. Unlike LIMS, LMS emerged from the world of laboratory data management software in support of the analytical work of scientists. This "scientist-centric" orientation of LMS is reflected in its components, which include:

- Sample management
- Scientific data management
- Management of reagents and instruments
- Workflow tools
- Analytical instrument integration
- ELN
- Stability management and testing
- Laboratory test execution
- Simplified workflow creation tools
- Scientific search

As this list of components indicates, LMS supports all of the essential laboratory functions across the product lifecycle, from discovery to manufacturing, as well as seamlessly linking data from the lab to the business operations of the enterprise.

How does LMS differ from LIMS?

Unlike LIMS, LMS puts the needs of laboratory scientists and managers first. Because it began as a solution for managing and tracking laboratory data, LMS excels at capturing, indexing, and cataloguing all laboratory report data generated by the broadest range of laboratory instruments in their native formats. By providing a centralized repository for all relevant laboratory data, LMS makes it easier to retrieve, view, and reuse information, and share it with others across servers, projects, and data types.

The additional components of the LMS – such as ELN and Sample Management – are available as add-on modules. This means that customers can deploy an LMS more incrementally and affordably than a LIMS. Even smaller independent laboratories can afford to deploy Scientific Data Management as a starting point and add modules and capabilities as their needs grow.

As a more lightweight and modular solution, LMS is easier than LIMS to deploy globally at smaller laboratories. This gives companies the means to standardize their informatics software across all laboratories at all locations. For global companies seeking to implement best practices, drive process improvement, streamline regulatory compliance, and support quality programs, LMS makes software standardization a more practical and achievable goal.

LMS also differs from LIMS in the additional helpful tools it provides laboratory scientists and managers, including preconfigured statistics reports for Stability, automated reports for Sample Management, and integrated Scientific Search that makes it faster and easier to find vital information.

How can LMS complement LIMS?

Although LMS is often seen as a competitor to LIMS, it can actually coexist effectively with LIMS in an enterprise environment. This enables larger organizations with significant LIMS investments to take advantage of LMS capabilities without sacrificing their LIMS.

Many of these organizations have deployed LMS in addition to LIMS because:

- LMS can feed data directly to a LIMS with no transcription required.
- Companies can link major LIMS operations to smaller and/or remote laboratories by deploying LMS at those sites.
- LMS makes it easier than LIMS to add new instruments to the laboratory informatics environment.
- Unlike LIMS, LMS gives organizations the ability to capture and share entire reports instead of just results. All users can link to the raw data.
- Because LMS provides easy-to-use Lab Execution tools, organizations can ensure "right the first time" initiatives more quickly and confidently than with a LIMS.
- LMS can enhance an incumbent LIMS.

LIMS AND/OR LMS?

Ultimately, only you can determine which is best for your organization – LIMS, LMS, or a combination of both. However, here are some general guidelines:

Choose LIMS if:

- **You need all the functionality that a LIMS offers.** Your business requires Project Management, Chain of Custody, Plate Management, Analytical Batch Management, Environmental Monitoring, Quotations and Invoicing, Formulation and Recipe Management, trend analysis outside of Stability, Analysis and Retest rules, CAPA management, KPI reporting, investigation management, Storage Location Management, Contact Management, CRM capabilities, and DMPK (Animal Models).
- **You can justify customized applications to manage your business processes.**
- **You are willing to undertake the extensive, up-front data gathering and planning that a LIMS requires.** This necessitates upper-level buy in from all of the groups that will use the system. As with any automated system, the process of developing user and functional requirements combined with gathering the associated master data is an extensive process. This is a function of the number of groups that will use the system and the number of processes each of those groups plug into the system. The level of functionality already built into a system directly correlates to the level of master data gathering that will be required. Ask the key questions: is reporting built in or will you need to develop reports? Are analytics and statistics built in or will you need to develop them?
- **You are willing to engage consultants for a prolonged period of time for implementation and potentially over the lifetime of the application.**

Choose LMS if:

- **Your primary interest is increasing laboratory productivity.** An LMS will have a more immediate, direct, and significant impact on laboratory operations, while still providing visibility and integration with business systems, such as ERP.
- **You're a growing company with limited resources and budget.** An LMS does not require large capital investments or a sophisticated IT team to deploy and maintain it. Many features are built in and do not require you to design and develop your own interfaces, reports, and statistics. At the same time, it can scale readily from a small number of users to hundreds without incurring performance issues.
- **You don't need extra functionality.** The modular design of LMS makes it possible to select and use only the functionality you really need. Additional capabilities can be added at any time in the future without business disruption.

Making your own decision

There is no shortage of systems in the market today that promise to solve bottlenecks and inefficiencies in laboratory-based businesses. Unfortunately, some of these systems are the source of the bottlenecks and inefficiencies. Navigating these choices can be a challenge. Ultimately, the best path is one that begins by evaluating what you really need. Identify the processes that will benefit from automation and bring value to your business. Once you have done that, you will be able to determine which tools you need or do not need. LIMS or LMS? In the end, the choice is yours.

FOR MORE INFORMATION

To find out more about the features and benefits of NuGenesis® LMS, please go to www.waters.com/nugenesis

References

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