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# The Essential Guide to LIMS

Modern scientific laboratories generate an enormous amount of data from a wide variety of sources that are frequently not integrated. With the advent of high throughput technologies, both the complexity and quantity of information that scientific laboratories need to track and process is increasing dramatically. At the same time, many companies now operate globally with laboratories located around the world, and R&D partnerships continue to increase. As a result, laboratory data is increasingly flowing across organizational boundaries and between sites.

All these trends contribute to significant data management challenges for both small and large organizations alike. One of the most common methods for managing these challenges is to implement a Laboratory Information Management System (LIMS) to automate the business processes and data capture associated with laboratory workflows. Some of the capabilities inherent in modern LIMS include:

- **Provide centralized repository for accessing and storing quality control data**
- **Facilitate workflow automation and management**
- **Integrate with instruments, devices and other systems**
- **Perform instrument run monitoring**
- **Track and manage samples, lots, reagents and associated testing data**
- **Support regulatory compliance**
- **Initiate data analysis**
- **Create reports and facilitate audit trails**

While a good LIMS has the potential to dramatically enhance your organization's operational efficiency, regulatory compliance, collaboration and innovation, there are many factors involved in realizing that potential over the full lifecycle of the system. Some of these factors include:

- **Matching a specific LIMS to your organization's needs**
- **The system must be implemented, integrated and validated properly**
- **User adoption needs to be maximized**
- **A good system maintenance, upgrade and extension strategy needs to be developed**

In this white paper, we discuss key best practice recommendations in each of these areas to help ensure that you maximize the business value generated by your LIMS investment.

## LIMS Selection

With dozens of LIMS vendors now available, an increase in specialized LIMS designed for a particular industry or laboratory type, and increasing demands for cloud-based applications, selecting a LIMS has become more difficult than ever. In fact, these days there really is no such thing as "the best LIMS." The focus instead should be on selecting the LIMS that is the best match for your unique laboratory and organization.

One of the biggest mistakes that companies make in the LIMS selection process is NOT conducting a business process analysis (BPA) to help ensure that the LIMS selected will maximize value for your organization. If the main impetus to implement a LIMS is to simply speed up current work processes with a new informatics system, then you very well might end up with faster but still fundamentally inefficient work processes. Instead, why not invest the time to design optimized workflows that will maximize the business value of your new system and then select your LIMS based on this optimized future-state?

Towards this end, the first step in any LIMS selection process should always be a thorough business workflow analysis to develop an optimized set of future state system requirements. These requirements are developed through a series of interviews and process walk-throughs that a qualified business analyst conducts with laboratory stakeholders in the organization. The result of this collaborative process is a detailed Requirements Matrix that prioritizes the opportunities. It is important to note that the effort (and thus cost) that is required to implement and maintain the LIMS will also be significantly influenced by the quality and clarity of the requirements that are generated, so this effort will also be an important part of ensuring a successful implementation.

In addition, if the LIMS implementation will involve significant integration with instruments and other enterprise and laboratory systems, or if it will be deployed at multiple sites, it is wise to address how the LIMS will fit into the laboratory systems Architecture Roadmap as a part of selecting your LIMS. This effort should also identify significant technical risks in the deployment and potential approaches to mitigate those risks. Having an overall strategic vision for the laboratory informatics ecosystem architecture helps to narrow the LIMS selection process to systems that have the hosting option (see below) you require to maximize business value for your organization.

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With the Requirements Matrix and the Architecture Roadmap for the LIMS system available, the LIMS selection process can commence. A list of vendors should be developed that can meet the requirements, and an RFP (Request for Proposal) sent out to all vendors on the list. Once all proposals have been received and evaluated, the top vendors should be invited to demo their product. Demonstration scripts and score sheets should be developed, and each system should be thoroughly evaluated after demos are complete in order to determine which one is most suitable for your business.

## Hosting Options: On-Premise vs. Cloud

A variety of different hosting options are now available for modern LIMS, and these different architectures determine the way LIMS are installed, managed and utilized. A key factor to consider when selecting a LIMS is the hosting solution that is best aligned with your business goals, as well as standards your organization's IT group has established.

Each of the different architectures supported by commercial LIMS today has its own benefits and drawbacks in terms of data security, scalability, ease of customization and integration, IT resources required for system maintenance, etc. Let's take a more detailed look at the pros and cons of two of the more common hosting models: on-premise and cloud-based.

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### On-premise deployment

Traditionally, LIMS software has been purchased from a vendor and the server and database installed (either with a physical CD/DVD or downloading through a web link) directly on internally owned and deployed computers with a fixed licensing fee. This on-premise deployment architecture can be used as a thick client, where the user interface is also installed directly on an internally owned computer. However, many modern LIMS leverage web services to render the user interface in a web browser, requiring no installation of LIMS software directly on user computers, in what is known as thin client architecture.

#### Advantages:

- **Functionality** – thick client LIMS sometimes offer richer functionality compared to thin clients, and on-premise installed LIMS typically can offer higher performance.
- **Data Security** – on-premise installation allows for higher level of data security with tighter control over all the system components.
- **Customization** – on-premise installation can allow for higher degrees of customization and integration.

#### Disadvantages:

- **IT Resources** – requires a skilled IT team for system administration, maintenance, implementation, upgrades, patches, data backup, disaster recovery, etc.
- **Capital expense** – typically larger initial capital expense for infrastructure requirements, license(s) and labor for implementation.

## Cloud Hosted Fully Managed Deployment (SaaS)

While in an on-premise system the customer owns the software, a SaaS (software as a service) LIMS is typically licensed based on the demand (e.g., the number of users) on a monthly or annual basis. Typically, the SaaS model has many different users (customers) running on a single instance of the software and database in what is called a multi-tenant mode. To provide an option with improved data security, some SaaS vendors make their systems licensable in a single-tenant mode, where the customer has dedicated infrastructure for the application and/or the database, but usually at a substantially increased cost. In either SaaS model, the customer accesses the software application via a web browser.

### Advantages:

- **Pay-as-you-go** – You only pay for what you use.
- **Minimal IT Resources Required** – All of the administration and support of the underlying application infra-structure is the responsibility of the vendor.
- **Scalability** – The elasticity and resource pooling aspects of the cloud allows for more rapid and flexible scalability with increased use.
- **Reduced Deployment Time** – Since the application is deployed in the cloud by the vendor, your organization can be up and running on a SaaS LIMS very quickly.
- **Reliability** – The SaaS vendor is typically contractually responsible for system availability and communication of scheduled downtimes.

### Disadvantages:

- **Integration**– It can be challenging to integrate on-premise systems with a cloud-based application.
- **Customization** – Most SaaS systems have very limited or no ability to be customized.
- **Cost** - Monthly fees can add up over time.
- **Data Security**– With a SaaS system, data travels and is stored outside your company firewall, meaning that you must partner with the service provider to ensure data security.
- **Complexity of Validation** – System validation is a potentially more complex activity, requiring both the SaaS vendor and the customer to closely cooperate.
- **Limited Options** – There are fewer LIMS systems on the market that are capable of being delivered as SaaS, offering less choice of vendors.
- **Network Dependency** – You lose access to the system if your office loses the network connection to the external data center, and performance of the system will be dependent on this connection as well.

## System Implementation, Integration, Validation and Maintenance

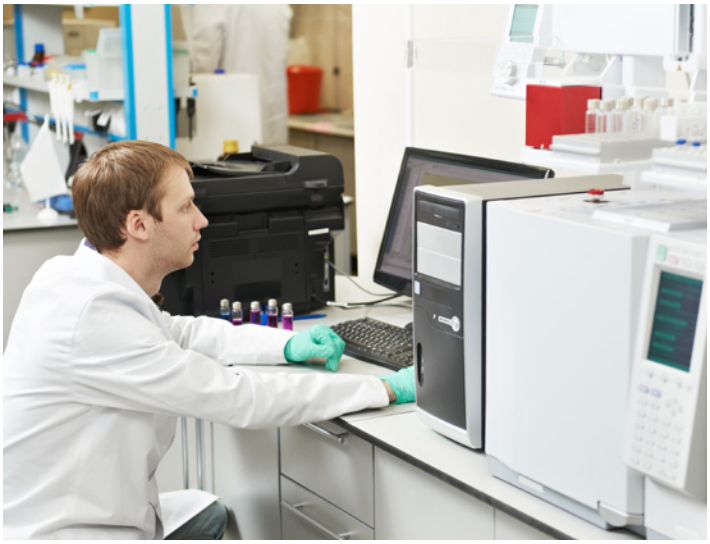
Once you have selected the LIMS for your organization, the next step is implementing it properly. While there are many factors to consider in ensuring you get a LIMS implementation right the first time, some key best practice recommendations include:

### Follow an Iterative Approach

The requirements developed in the workflow analysis conducted at the beginning of the project should be prioritized and implemented in an iterative approach with the "must haves" implemented first. Any technical risks identified in the Architecture Roadmap should also be prioritized and addressed early. Failure to follow this kind of methodical approach can cause the project to get bogged down in excessive customization to satisfy lower value requirements, leading to project time delays and cost overruns.

### Limit Customization

Customization increases the complexity of implementation, future maintenance, and testing and validation effort. The bottom line is that LIMS customization should be very carefully challenged, and only be done if doing so would provide your organization significant business value. It is often too convenient to "change the system to fit the current practice" instead of considering the full cost of that approach, as compared to considering making changes in the business practice to reduce the total cost of the system. Unnecessary customization can also occur if there is insufficient knowledge of the specific LIMS system capabilities in the project team.



### Plan for Data Loading and Migration

Data loading and migration is almost always a bigger job than anticipated during a LIMS implementation. Waiting until latter stages of the project to accomplish this can end up causing significant project delays in addition to impacting business continuity in the lab. It is wise to focus on data loading requirements early in the implementation process. Addressing the process of extracting, translating, loading, and testing the new system's required data is a significant and frequently underestimated effort. The actual migration is typically accomplished through a combination of automated programmable migration tools and manual processes. Dynamic data migration should be done last to make sure the new system contains the most up-to-date data.

### Select the Right Project Manager

A key factor for a successful LIMS implementation is a project manager (PM) with LIMS experience who is involved in both the planning and ongoing management of the effort. Strong project controls and governance are needed to implement a LIMS successfully, and a LIMS-experienced PM will help to drive triple constraints (on time, on scope and on budget), ensure value realization and help to avoid common people-based challenges. The communication skills of the PM are paramount: the ability to work across key laboratory personnel, the technical implementation team, software vendors, and executive stakeholders require a clear understanding of these audience's perspectives and experience.

## Approach Integration Deliberately

For organizations implementing LIMS, requirements usually include laboratory devices and instruments that need to be connected for automated data transfer. In addition, LIMS systems have increasing integration requirements with enterprise systems to meet master and reference data quality and reporting needs. As with data migration, integration is one of those areas that can contribute to significant project cost and time overruns if not managed properly. Some best practice recommendations include:

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- Ensure all integrations are structured with an overall comprehensive architectural view to avoid a point-to-point expansion of the complexity of the implementation as well as the testing and support. Point-to-point integrations may meet the business requirements but often result in extremely fragile systems in operation, and long-term challenges managing the technical risks of change of both the LIMS and the other systems.
- Investigate the overall cost-benefit of an investment in an integration architecture that provides a platform with re-usable integration components and centralized operational and administrative management.
- Conduct a site survey of instruments and devices and prioritize which instruments to integrate based on critical path and high ROI.

## Apply Risk-Based Validation

Once the system is successfully installed, it must also be validated to ensure it is working as expected. Validation of computer systems is required by most regulatory agencies around the world in order to confirm data accuracy and integrity in systems so that product safety and effectiveness is ensured. Computer System Validation (CSV) is required when either making a change in a validated system (upgrades, patches, extensions, etc.), or configuring a new system. Some best practice recommendations for CSV include:

- Follow a flexible GAMP 5 approach that utilizes a risk-based assessment on the system to determine required test cases and the optimal level of testing for each.
- Create a good validation plan before the project starts that defines the validation objectives and the approach for maintaining validation status over the full software development lifecycle (SDLC).
- As described above, it is important to develop precise system requirements, as precise requirements lead to precise validation testing that confirms the system is fulfilling its intended use.
- Create good documentation that fulfills regulatory compliance.
- Audit third-party service providers to ensure regulatory compliance.

## Explicitly Plan for System Maintenance and Upgrades

As described above, both customization and point-to-point integrations can significantly increase complexity and cost of future maintenance and upgrades, as well as adding risk to any necessary extensions/enhancements when business requirements change. Designing your system solutions with scalability and maintainability in mind needs to be a top priority. Additionally, in order to maximize ROI on your new LIMS, it is important to create a strategy to accomplish system maintenance and upgrades in an efficient manner once the system is implemented. Not having a plan, or having a plan that isn't thorough, is a recipe for a costly, non-compliant system. Frequent (quarterly or bi-annual) reviews of the system are also recommended, as they help to keep documentation up to date, build organizational knowledge of the system, and ensure the most effective testing scenarios for any future validation efforts.

## Maximizing User Adoption

A major source of project failures is the lack of utilization of new systems in favor of reverting to pre-deployment systems and methodologies. A newly implemented LIMS cannot add business value to your organization unless people use it. A good plan based on BPA facilitates user adoption through effective engagement with users. Users buy-in to the future state being implemented because they are consulted throughout the process and help to shape the future state workflows. This collaborative approach ensures the implementation will address user needs and thereby facilitate user adoption.

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In addition to communication with users during the requirements development process, clear and frequent communication with all stakeholders during each phase of the project is imperative so they feel part of the process. It is vitally important to create and implement a comprehensive project communication plan as part of your LIMS project. Along with providing critical information necessary to keep the project on track, the communication plan helps convey the ways in which the project will provide business value to your organization. This helps users feel motivated to use the new system.

The people facilitating communications between stakeholders in your organization will play key roles in the communication plan. Different aspects of organizations often speak "different languages" and may have trouble communicating with each other effectively (e.g., IT and lab personnel). It is important to have someone who is well-versed in all the different stakeholder domains facilitating communications in order to avoid misunderstandings.

Another key aspect of facilitating user adoption is an effective LIMS training program. Training on the new system needs to be conducted for all stakeholders that will be using the system – system administrators, super users, managers, lab technicians, scientists, information consumers, report generators, etc. Since each of these users' training needs will be different, different role-based trainings should be developed. Otherwise, you will have a lot of unsatisfied users on your hands, as they are forced to sit through training on system features that they will never use. Ideally, the training given to each of these users will reflect the parts of the new system (features and functions) that are relevant for their individual jobs. Designing modular, role-based training materials will allow you to easily create/adjust individual trainings so that they are most appropriate for an individual user.

In order to minimize user frustration, user training also needs to be customized to reflect the specific configuration of the system that has been implemented. Many organizations rely on generic training materials from vendors that have been designed for standard COTS functionality only, but this material will be of limited value in the training of personnel. Instead, for maximum user adoption, training materials should be customized and optimized by professionals that are intimately familiar with the unique features of your implementation and possess industry, domain and laboratory knowledge and experience.

## Conclusion

The digital revolution is rapidly changing the laboratory environment. Large amounts of data generated in modern laboratories, along with high throughput requirements, are necessitating the use of informatics solutions such LIMS to improve laboratory automation. Success in LIMS implementation projects can be particularly difficult to achieve, however, due to the complex processes and technologies utilized in labs, and the many different aspects of the enterprise that laboratory systems touch.

LIMS projects often require significant investments of money, resources and time. A LIMS implementation, for example, can cost a company hundreds of thousands to millions of dollars, and require hundreds of labor hours to implement. As such, failure in LIMS implementation projects are simply not an option. Equally important is to get the implementation right the first time. In order to ensure that your LIMS implementation optimizes laboratory productivity and efficiency and maximizes business value for your organization, it is important to follow a comprehensive and proven methodology. We have presented several key aspects that should be a part of your methodology when implementing a new LIMS in this White Paper. The bottom line: In any LIMS implementation, a combination of project management skills, good resources (both internal and external), and methodologies are vital to ensure success.

### About Astrix:

Astrix Technology Group is a full-service global laboratory informatics consulting, regulatory advisory and professional staffing firm focused on serving the scientific community since 1995. Our experienced professionals help organizations implement innovative informatics solutions that turn data into knowledge, increase organizational efficiency, improve quality and facilitate regulatory compliance.

If you would like to discuss your organization's LIMS project and/or overall informatics strategy with one of our experts, please contact us at **www.astrixinc.com** for a free, no obligations consultation.