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## Going out on a LIMS

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*As laboratory environments continue to evolve, embracing the benefits of automation and efficient data management is becoming more critical, write Charles Hindbaugh and Christine Paszko*

Any laboratory that generates data, especially from an instrument run, that is stored and later used in some form of reporting or analysis will benefit from the use of a Laboratory Information Management System (LIMS). Using a LIMS system reduces the time it takes to turnaround sample results, improves internal communications, sample tracking, data retrieval, quality assurance and control, and secure archiving of data. Most importantly, laboratories find that their relationships with customers are also improved.

Today's trend is to leave the process of data gathering, decision making, calculations and review and release to those who are closest to the actual analysis in the laboratory. The goal is to gain seamless integration with the laboratory, with results sent from the instrument with electronic data validation and approval. Reports and notifications are automatically sent, secure web access to sample status is available, and there is integration with electronic laboratory notebooks as well as enterprise systems such as accounting packages and chemical inventory systems.



Today, most commercial LIMS have exceeded the key requirements of the analytical laboratory and become more of a laboratory ERP (Enterprise Resource Planning) tool, taking into consideration such items as workload, chemical inventory, quoting, invoicing, asset management, time tracking, and customer relationship management functionality, in addition to the core LIMS functions.

Before selecting a LIMS, the laboratory will need to perform a 'needs assessment' or 'gap analysis' to determine the functions and features required. This can be done internally by the laboratory staff or via a hired consultant (Table 1). Secondly, the LIMS vendors and their product offerings will need to be examined to see which will best fit the lab's needs.

What should one look for in a LIMS product and vendor? Some of the criteria are obvious, such as a flexible product that will conform to the requirements of the laboratory, one that is based on standard technology, and a vendor that provides excellent support. It is important to make sure that customizations are preserved when the vendor updates the software, thus future-proofing the system. Also each vendor will excel in a specific market area; it is important that the vendor's product matches your industry.

Vendor stability is also critical as multiple LIMS firms have been bought and sold over the last decade, some multiple times. Certifications for LIMS vendors are also important, as many laboratories are ISO 17025 certified and will only purchase from other vendors that are also ISO Certified. Small LIMS firms often do not have the resources or capital to invest in the implementation of a quality management system or regular auditing by an ISO auditor.

### Getting started

A thorough assessment can provide a powerful roadmap to successful LIMS implementation. Focus should be placed on actual needs as opposed to laboratory's desires, typically separating the 'Must- Have' from the 'Nice-to-Have'.

When performing the needs assessment in-house, remember that the goal is to identify the gaps between what is currently used and where you would like to be with a new LIMS. Use surveys, questionnaires, interviews, observations and flow diagrams to understand both the way things are now and decide what improvements are needed. Identifying the different types and parts of your laboratory data that need to be tracked is key.

In-house	
Advantage	Disadvantage
Intimate knowledge of the laboratory	Sometimes, too close to see the real need
The assessment can be controlled, keeping all the information internal	Assessors may lack the experience necessary or may not be objective
Laboratory staff may be more comfortable	May not be familiar with the latest technologies
Consultant	
Advantage	Disadvantage
They can provide insight from similar projects	Busy schedules may not meet the time requirements of the laboratory.
Have the expertise in what is successful as well as cost effective	Some may lack real world experiences
Familiar with the latest technology, advancements, and potential limitations	Consultants may intimidate the staff, inadvertently causing them to hold back with information during the investigation

Once needs are identified, it is time to convey those needs to the LIMS vendor, preferably through a Request For Proposal (RFP) detailing each expectation and requirement.

When choosing a LIMS vendor keep in mind that you are really looking for a solutions partner that will be there with you for many years. It is important to select a partner that understands your lab needs and has expertise in your business segment. Be sure to check their references, and talk with colleagues. Ask about the installation process, continued support, cost of upgrades, and if the program has kept pace with regulatory changes in the industry.

### Implementation and setup

Preparing for the implementation is important. During this process you will likely examine parts of your laboratory in more detail than you first imagined. Begin by identifying your team who will set up and verify the information in the LIMS. During this process it is equally important that all key personnel in the laboratory are available for input. Some of the key points will be

having a complete customer list, including any special needs or projects they may have; and, also important, the list of tests you do; along with the various parameters reported, methods used, detection limits, reporting limits and QA/QC information.

Successful implementations are those that set and follow a defined implementation schedule, setting realistic milestones for the project and sticking to them. Your LIMS partner should be able to help you with these milestones and determining appropriate timelines.

Once setup has been completed, schedule a 'warm up' or parallel testing period. Take this opportunity to validate the processes and capabilities of your new system. At least a month should be set aside for the warm up period. The goal is to cover all the use case scenarios expected to provide confidence the new system will yield 'correct' output.

Now you have everything set up and tested/ verified, it is time for the cutover or 'go-live', when you begin using your new system exclusively. During the first few weeks, be prepared for the unexpected: occasional hiccups are common. Keep in mind that your old system was a continuous work in progress, as will your new system be.

### **A healthy LIMS**

Laboratory requirements are constantly changing. Selecting a LIMS that can change with the times is important but more important is keeping your LIMS up-to-date. Take advantage of service packs for the database engine, the LIMS and software updates. Companies will often forgo service contracts and maintenance plans. Before opting out of plans, it is important to take time and calculate their worth. As software is continuously changing, keeping up with laboratory needs, new products can become available in several months as opposed to years. A maintenance plan including updates and upgrades at a cost of 10-20% of the software cost each year can bring several updates for the cost of just one replacement. Frequently technical support plans also include user forums, knowledge bases and web training.

Proper database maintenance is also important; routine tasks must be performed on a database to keep it running at an optimal level.

Often overlooked is the continual training of the users. LIMS software is both powerful and complex; on many occasions users may learn a specific way of doing something not realizing there is other functionality. In many cases that is fine, but sometimes there are more efficient ways of doing these tasks. Having users attend formal training from your vendor can give very valuable keys to using the system. Ensuring that new users are fully trained also means the laboratory is gaining the most benefit from the system, using all key features and functions. If formal training from the vendor is not possible, laboratories should conduct regular in-house training so users can share and expand their skills.

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