

How Do I Find the Right LIMS— And How Much Will It Cost?

So...great, you say. LIMS are getting more affordable. Now where do I start?
I know my lab but I sure don't know LIMS and...it's a jungle out there!



Well, take heart. We have compiled a shortlist of the major players—and some minor ones—to help you make some initial comparisons.

You'll need to size up your lab's needs informatics-wise as well, in order to figure out which of them are worth investigating further. You can do that by using the Lab Questionnaire (LQ) included in the chapter titled "*How Do I Define My Lab's Needs?*"

LIMS vary a great deal in a number of ways. Of course your lab's requirements in terms of the types of analysis you do, reporting and data sharing constraints, instrument interfacing, barcoding, QA and on and on all are very important factors. But there are other factors. Price is certainly one (although it is as well to remember that value is ultimately what you seek rather than just a low price). Some other considerations that are just as important:

- **Should** we purchase licenses or "rent"

through subscription?

- **Does** it need to be onsite or is a SaaS (Software as a Service) hosted option better for us?
- **Is** a modular or complete system better for us?
- **What** is the best licensing/rental scheme for us? Site? Named User? Concurrent User? CPU? Workstations?
- **What** about the company? Can I trust them? Are they qualified?

Purchase vs. Subscribe

This didn't used to be an option. But much like the recent trend toward leasing cars rather than finding a large amount of money for up-front purchasing, labs can choose to pay only the cost of services (setup, training, report configuration, instrument interfaces, data migration, custom functions, etc.) and get started on a monthly subscription rather than buy licenses outright.

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When does this make sense?

Subscriptions make sense primarily:

- **...If** a large lump sum is hard to get budgeted. If your business cash flow will support the regular subscription fee but finding license fees is more problematic, then subscription may be right for you. But do the math. Project costs over a reasonable period, say, five years, to make sure it is a value proposition. Be sure to include maintenance and support in your figures—this is often included in a subscription but not in a license.
- **...If** you may need to reduce the number of users. Once you buy licenses, they are yours. You can't "un-buy" them. But with a subscription you can raise and lower the number of users or workstations, etc. as you need to.
- **...If** you may need to bail. Business decisions often need to be dynamic. Your lab may decide to go into another area of analysis and if your LIMS isn't versatile enough to support that you have wasted a lot of money and the LIMS becomes an albatross.

On the other hand, it may be important to you to have the LIMS source code. Some subscriptions allow you just as much access to it as if you had purchased licenses, while others may not give you the access you seek. Check with the vendor to make sure. Ask whether you get to keep an image of the database should you decide to end your subscription.

Onsite vs. SaaS

A small but growing number of LIMS vendors will actually host your system on their servers for you, or offer it "cloud"-hosted. When software is provided on the Internet for you rather than having it loaded on your workstation or server, that is called "SaaS", or Software as a Service. Most of us already make copious use of SaaS whenever we "Google" something. Cloud-hosted SaaS is characterized by multiples of servers that are load balanced so that resources are strategically used, and virtualized servers are employed to create discrete custom environments.

To decide if SaaS is for you or if you should go the traditional route, here are some points to consider:

- **IT Department.** If you have a small or overworked IT department, or none at all, then it may well make sense to let the LIMS provider take care of those functions, rather than invest in additional hardware, personnel and/or other resources just to support your LIMS. If you are a large company with an extensive and capable IT department, then they may prefer the LIMS and its database to reside physically on premises.
- **Security.** This is often cited as a reason to keep a LIMS on lab premises. The truth is, if the vendor uses a SAS-70 or SAS 70 Type II data center to host, with GxP SOPs, your system and data are probably a lot safer

than on a typical business infrastructure! Check with the vendor to make sure.

- **Vendor Stability.** If you decide to have your system hosted, make sure it's not by Bob and his buddy in their basement. They need to have been around awhile and have solid references and good customer service, or you may not sleep too soundly knowing your business is in their hands!
- **Guarantee.** A reputable SaaS host will guarantee you high availability, approaching 100% up time, with quick and responsive catastrophe response. Their great degree of redundant components and infrastructure (power, cooling etc.) allows them to do that.

Modular vs. Complete

Some LIMS are offered as a collection of modules for you to select from to constitute your completed system, while others come complete with all the functionality available. Those whose LIMS are modular espouse the benefit of only paying for the functionality you need. Those whose LIMS come as a single complete package say labs won't need to pay extra for any add-ons. Who's right? Well, it depends. If buying modules means you need one module for sample tracking and another for data entry and still another to generate reports, etc....then it may not be long before you have run up a sizable bill just to get basic standard functionality. That is especially true if the modules require hourly services

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to implement. Modules tend to be industry-specific and pretty much complete for each, then they may make sense.

The bottom line is...the bottom line. Make sure you compare apples to apples and identify all costs associated with getting all the functionality you need.

Named Users vs. Concurrent Users

It's important to be clear when comparing license fees. One distinction that should be made is the difference between *named* users and *concurrent* users. If a vendor charges by *named* users, then if you have 30 people who will ever use the LIMS at any time you will need 30 licenses. If the vendor charges by *concurrent* users, then you only need enough licenses to cover the number of users who are likely to be on the system at the same time. Typically in a lab with 30 staff, you might need a maximum of 20 concurrent user licenses. This is reduced even further if you have sites in other parts of the world whose work days are different.

The Company

As important as the LIMS and its functions are to you, the company is at least as important. Make no mistake, this is a relationship you are entering into. This is not like selecting a piece of furniture. A LIMS is a living, breathing, dynamic entity, and you'll need to interact with the vendor from time to time even with the most trouble-free system. Of course that interaction will be particularly intense in the beginning as they provide installation

or provisioning, training and all the other services to get things set up for you. Take your cue from your initial dealings with them. Of course you will want references, but also consider how you are treated during the sales "courtship". Just like in any relationship, they will be presenting their best side to you then. If that isn't very impressive (slow to return calls or emails, not following through with what they say, etc.) then you can bet it will be much worse once you are their customer.

So yes, do the usual things in researching their years in business, size and qualifications of their staff, references, etc. But ask yourself if you would be comfortable doing business with the person on the end of the telephone in the long term.

The Functionality

And now we come to what probably has weighed most on your mind since you had the first idea you might need a LIMS (other than price): functions and features. The functionality of what the LIMS can do is paramount, so it is important that, first, you have an idea of LIMS can do, and then you can begin to decide which functions and features you need or want.

Use the LIMSspec

To be sure you assess correctly, use the LIMSspec forms that are included in the hard-copy version of the LIMSbook (<http://limsbook.com>). The System Questionnaire (SQ) includes an exhaustive collection of questions to ask a vendor about the system

itself, neatly categorized by general functional area. It also contains a Vendor Questionnaire (VQ) which does the same thing with regard to the vendor company. These and many more useful forms and templates are included in the LIMSbook's LIMSspec published by the Laboratory Informatics Institute, Inc.

The following are the functions you should expect to see demonstrated in a full-function LIMS.



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Basic/Core Functions and Features

(You should expect these to be available in your LIMS.)

- **Audit Trail:** The LIMS keeps track of all user activity and/or targeted activity. This is essential in highly regulated labs like those regulated by the EPA or subject to 21 CFR part 11 and most or all government labs.
- **Barcoding:** Tracking samples by barcode vastly reduces or eliminates transcribing errors, and helps in pulling up the right sample information when logging in. Barcode printers and scanners are inexpensive, and the benefits are significant. You may not really need it yet, but you'll want to have that option in the future at the very least.
- **Batching:** Most labs create analytical batches, independent of whether they have come in as particular groups or projects or not.
- **Chain Of Custody:** The Chain of Custody, or COC, is important in most labs. You need to track samples from the time they enter the lab, to the time they are completed and disposed of, and that goes for for stocks, standards and reagents as well. You should be able to print a COC anytime, with barcodes if used.
- **Configurable Setup:** If the LIMS is too rigid and forces you to conform to its ways of doing things, the change management

of its implementation can be over-stressful. A good LIMS lets you input and configure your users and passwords, job profiles, departments, contacts, picklists, etc., exactly as you need to. Even more importantly it should also allow for setting up tests/ methods, analytes, specifications, limits, alerts and the like exactly as you require.

- **Data Entry:** The LIMS should support the entering of all types of results you are likely to encounter, whether numeric, alphabetic (ND, Present, etc.), symbols/ operators (>.022, etc.) or photographic. You should be able to enter them directly off of instruments or by hand, choose whether they appear on reports, modify them if authorized, flag for review, etc.
- **Data Warehousing and Mining:** You may need to access historical data and perhaps identify and chart trends. It should be an easy and painless operation, and not require you to build SQL queries!
- **Document Management:** Management of methods, SOPs, MSDSs and other documents the lab needs to track and access should be a part of today's LIMS standard functions as well. In many labs it is also important that the LIMS control versioning and a review process including use of electronic signatures.
- **Electronic Data Exchange:** The transfer of information between the LIMS and outside entities is a standard function you

should expect. This includes instrument data (one or both directions), remote sample collection data, PDA/Tablet data, Excel import and export, interactions with other software or databases (e.g. accounting, ERP) and other file transfers.

- **Event-Driven Actions:** The LIMS should be able to take defined actions upon specified events. For instance, it may email someone to approve a set of results upon completion of data entry, or notify through an alert system when an analyst has samples that have come in and are ready to be processed. You should be able to configure your own in addition to any defaults.
- **Faxing & Emailing Reports:** This ability should be able to be manual, automatic or semi-automatic. Where required, it should be HIPAA-compliant.
- **Formulas:** Tests may require that calculations be performed on results, and these may need to factor in other results. The LIMS should support that so that these are done automatically, and also allow you to create new formulas and modify existing ones, checking that the formula is valid.
- **Instrument Calibration & Maintenance:** The LIMS should keep track of all of your instrument information, which tests it is assigned to, who can use it, etc., helping you keep them in service and used properly, even alerting you when

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maintenance is coming due.

- **Instrument Interfacing:** Different LIMS have different methods for interfacing with your analytical instruments. It's important to ask how a prospective LIMS goes about it—and how it is priced and how much it costs.
- **Inventory:** Expect the LIMS to be able to keep track of your stocks, standards and reagents, as well as samples themselves. You should be able to define storage locations and track their movements as well as levels. You may even be able to set alerts or emails for when stocks get low.
- **Login/Accession:** Of course logging in samples is a basic function in any LIMS. However, you'll want to make sure of some features. Some of these are:
 1. *Simple and quick*—whether it's a single sample or two hundred.
 2. *Includes the right info*—All the fields you need when you need them—and ONLY the ones you need!
 3. *Flexible*—If your needs change over time you may need to adjust the way login works.
 4. *Intelligent*—If you enter a sample type of "bread" it shouldn't ask you how many liters...Additionally, it should support your ways of processing samples: by lot, project, case, etc. or as single samples or specimens.

- **Multiple Locations/Departments:** The defining of different locations and/or departments should be supported. You should have the ability to separate access between them strategically.
- **Regulatory Compliance:** There are quite a few regulations and standards that apply to various types of labs, and you'll need to make sure the LIMS supports the ones important to you. Although it is always the lab and its practices that are regulated, the LIMS must support that compliance.
- **Reporting:** At the end of the day this is the whole point of a lab. You should be able to generate internal, informal reports as well as formal COAs, etc. They should be able to be generated automatically, semi-automatically or on demand, and only be accessible to permitted parties. The LIMS should be smart enough to let you decide what to report and what not to.
- **Review/Approval:** You should be able to define as many stages of review or approval as necessary, and specify those authorized to do so. They should be able to designate samples for re-run, approval or cancellation (start over), and log any notes.
- **Sample Management and Tracking:** Of course this is central to the LIMS. It should have a configurable sample ID numbering scheme, support barcoding, track whereabouts and status, assign analysis and personnel, allow for grouping,

batching and aliquots or sub-samples, etc. You should be able to look up a given sample and its status easily.

- **Scheduling/Calendar:** Whether or not you receive samples on a regular basis, the scheduling function can help you with allocating resources, tracking equipment maintenance, shelf life and other time-sensitive items. It should contain alert functionality as well to let you know when something is coming up.
- **Training Tracking:** Keeping track of analyst certifications is important. The LIMS should help you do that, and help make sure that only those qualified for a given test are assigned to that test.
- **Trending/Control Charting:** Although Statistical Process Control (SPC) software is specifically designed to provide you with intense graphing and trending capabilities, a LIMS should offer you standard control charting and trending functionality. If not, see if it can come bundled with an SPC or interface with one in a cost-effective manner.
- **Version Control:** GxP and regulated environments require that you version not only documents, but tests/methods, analytes, limits, configuration changes, software upgrades, etc. Check that the LIMS is okay in that department.
- **Work Load Management:** Supervisory personnel need to be able to keep tabs on resource allocation. At a minimum the LIMS

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needs to provide quick and easy access to analyst worklists and lab or department-level worklists, to maximize efficiency.

- **Workflow:** Don't contort to what the software dictates. Once upon a time, LIMS were custom written for each lab, so the LIMS reflected exactly what they did. Unfortunately, any changes to that meant costly development to keep up. Nowadays any good quality LIMS is flexible enough to let you decide what your workflow is. In fact, you should be able to set up as many and different workflows as you like, change them whenever it suits you...and choose not to follow them if necessary.

Some Nice Things To Have

(Not for everybody, but great if you can get them!)

- **Case Management:** Not all LIMS are comfortable in the forensic or clinical arenas where information is managed by case. Many in these areas are more familiar with the term "LIS" as being vaguely more suited to those disciplines. The distinction has now largely disappeared, however, and a number of LIMS fully support comprehensive case-centric information management.
- **Complaints and Corrective Actions:** Some LIMS come equipped with a built-in Help Desk or Issue Management facility, which is a definite benefit for labs who deal with customers, whether internal or external.

- **Customer Relationship Management (CRM):** LIMS-based CRM especially helps in billing and inventory control, as well as just keeping track of which samples belong to whom.
- **Electronic Laboratory Notebook (ELN):** As LIMS and LIS have merged, many include an ELN. If so, you can avoid the need for a 3rd party application.
- **ERP/Accounting Interfaces:** Not all LIMS will link to other systems—or if they can it might not be pretty. If you require that, check out the details.



- **Invoicing:** If invoicing is important for your lab, check whether the LIMS has that function. You may need—or want—to use a 3rd party invoicing package, but you may not need to.
- **Product Specification Management:** In manufacturing or any kind of QA/QC you may need to manage specifications/limits. Some LIMS are able to provide that out of the box, some offer it as an add-on or alternative module and some may just not be up to the task. Check to be sure.
- **Project Management:** Some LIMS are good at tracking samples but not so good at handling projects. Make sure you communicate your needs in that area and find out whether the LIMS you are considering supports them.
- **RFID:** Radio Frequency Identification is an alternative to barcoding when identifying samples and other items. If you are interested in using it, check that the LIMS will support it.
- **Quoting:** A LIMS may even include an invoicing function but be unable to generate quotes—ask specifically.
- **Safety Tracking & Compliance:** If your lab needs to keep on top of safety compliance issues, you will have to ask about that function (it isn't standard).
- **SCADA Interfacing:** If you use SCADA (Supervisory Control And Data Acquisition), double-check that (a) the

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LIMS has the capability and (b) the vendor and/or consultant has the expertise to link them up.

- **Stability Management:** If you do stability studies, check that the LIMS supports it, as not all of them do.
- **Web Access:** Is the LIMS web browser based or web enabled? If you would like it to be able to support hyperlinks and web data exchange, be accessible from remote sites or home, etc., make sure you choose one that is comfortable with the web.
- **Web Portal:** Probably the most popular feature we at the LIMSInstitute are seeing labs ask for today is a client-facing web portal. Customers, whether internal or external, are demanding the functionality they see everywhere around them: the ability to log in to a web page and submit analysis requests, see reports and/or current status of their samples.

How Much Will It Cost?

OK, you have an idea about things to look for in the company and its products. What you probably don't know is what the price tag is likely to be. Heck, most of us don't even know how LIMS vendors price their products or what is involved, much less how much they actually cost!

Well, it's time to shed some light on all of that. Here's the deal:

There are three components to the

pricing for any LIMS. These are:

1. *Licenses*
2. *Subscriptions*
3. *Services*

The LIMS itself is never, ever, the entire cost. LIMS are complex creatures and your lab, even if it's small, is fairly complex too. If you think about it, you don't even use something as simple as Microsoft's Outlook mail program without some amount of setup. How much more is that true for a program designed to support all of your testing, sample tracking, results entry, etc. Let's go over what's involved and how much it's going to cost.

• Licenses

If the LIMS is a purchased license type (as opposed to rented/subscription), then you will of course have to pay for those. Keep in mind what we said earlier about named vs. concurrent user pricing. Other methods include by site, by CPU or server, by workstation or by unlimited user corporate level licensing. The lack of standardization in this area has probably contributed as much as anything to the vagueness that has surrounded LIMS pricing for so long. Ironically, of the three pricing components, this is the one that is simplest to figure out.

The vendor profiles in the next chapter bring you pricing information for licenses for the vendors included. In fact, that was the primary criterion for inclusion—their pricing had to be either publicly available

or they had to supply it to us. Review and compare, but make sure you factor in pricing method!

• Subscriptions

These include two possible items:

1. Rented or SaaS LIMS
2. Annual Maintenance, Support & Warranty (MSW)

The LIMS rental is equivalent to the license, but isn't a lump sum you have to come up with up front. These can run anywhere from a couple of hundred dollars a month for a single user up to maybe \$2000 or so for 20+ users. Just like purchased licenses, however, these can be priced by site, concurrent or named users, etc. so make sure you try your best to compare like with like or at least factor these considerations in as you shop. And your rental may be annual instead of monthly. In pretty much all cases it does include all IT services and maintenance, support and warranty, including updates, at a specified level.

The second type of subscription cost is annual MSW, and you need to factor that into your budgeting if you are buying LIMS licenses. Typically it is priced at around 15% of the license fee, and is available at graduated levels. A certain level may be standard for a certain number of licenses—say, 10 hours of support and additional services available at \$200 hr for a

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10-concurrent user LIMS—but you can buy a higher level of support (and cheaper rate for additional services) if you want to pay extra.

One thing to keep in mind: trying to avoid an MSW is a false economy. You will certainly need coverage as you go through your first year. If you think you can then drop it, think again. A modern LIMS should be built on technology that can give it a much longer life span than those in years past. That is dependent on staying updated. If you lose that update path your LIMS will expire prematurely. If you decide later to renew MSW you may find yourself liable for the missed years, before the vendor will bring you current.

• Services

Ah yes, services...here's where many a LIMS acquisition goes awry. Your LIMS is a function of both the cost of the LIMS itself, whether a subscription or license, *plus the services involved in its implementation plus, in the case of a licensed LIMS, annual MSW.* Many first-time LIMS buyers neglect to factor in the cost of services when budgeting.

As mentioned earlier, any LIMS will require services to get going, and you may want more if there are extras you need or want. Services break down more or less like this:

Basic Implementation Services:

- Kickoff Meeting (Planning, coordination, communication procedures, etc.)

- Training
- Setup (Enter users, configure profiles, departments, tests, screens, etc.)
- Create Main Report(s)
- Go Live Support

Additional or Optional Services:

- Instrument Interfaces
- Additional Reports
- Data migration from a previous system
- Interfaces to other systems or databases
- Special customizations
- Configure Web Portal
- Validation
- Standards Certification support

There may be other services you'll need. Rates for services vary from vendor to vendor, but a good rule of thumb for initial budgeting purposes is to figure service costs to be roughly equal to the licensing cost—or to a year's worth of LIMS subscription.

Now...Happy Hunting!

The information in this guide will give you a real head start as you cut a swath through the LIMS forest. For a full guide to everything LIMS, including templates for creating RFPs and documenting systems, doing validation (DQ, IQ, OQ, PQ etc.), as well as history, trends and more, you will find the LIMSbook (<http://lirmsbook.com>) invaluable, and as we mentioned, the LIMSspec it contains is an extremely detailed and useful tool for managing the LIMS process..

This guide, however, serves as a handy

aid to making sense of the current landscape. You will find useful profiles of some of the main LIMS vendors in the next section, the LIMS Directory, along with pricing information and examples. Use it as a reference point to get you started, then use the LIMSspec process to help you through as you research, select and maintain your LIMS. Good luck!

