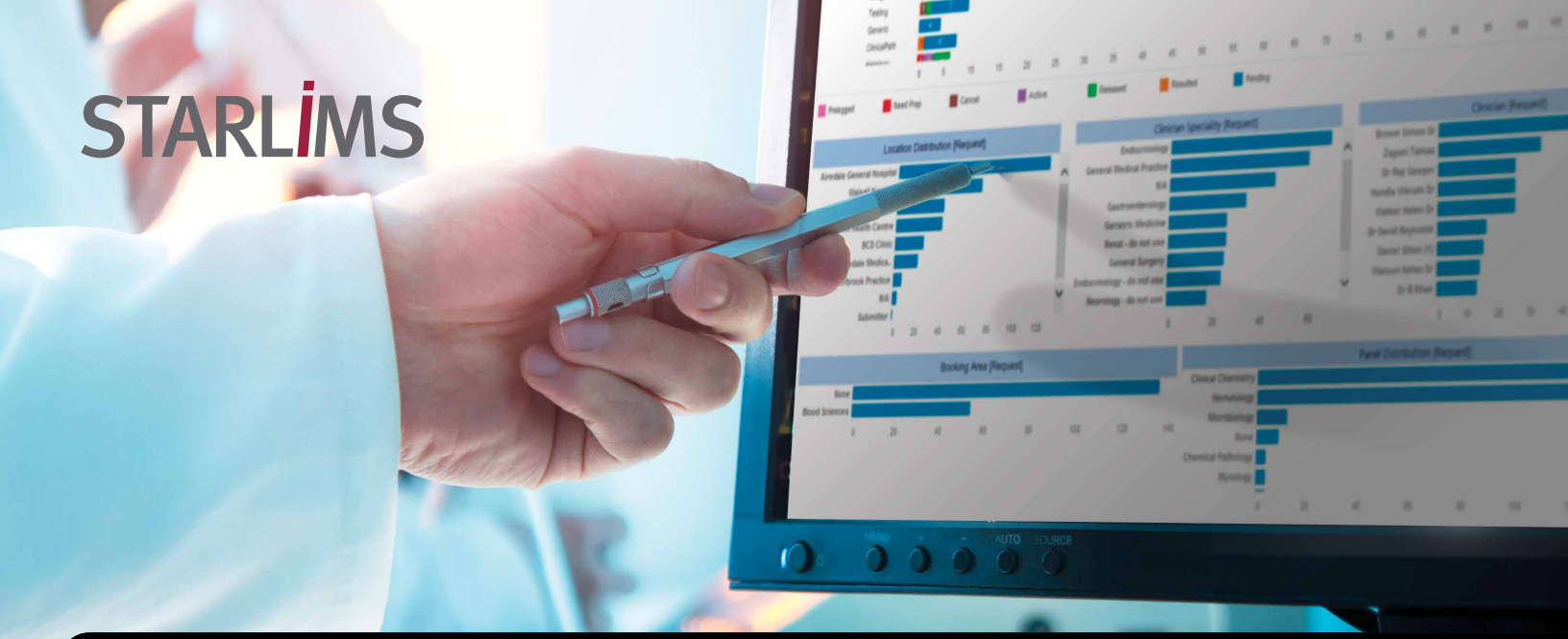
STARLIMS



Considerations in Purchasing a LIMS

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INTRODUCTION

Many scientific enterprises find themselves in need of a Laboratory Information Management System (LIMS) to replace an incumbent system, whether an existing commercial application, an amalgam of systems, or an in-house solution. Once the decision has been made, the selection and deployment of a new LIMS should move quickly and decisively. This white paper serves as a guide to selecting a commercial (LIMS).

Key Stakeholders Benefitting from this Document

Safeguarding data, faster product release, and improved compliance benefit the entire company, but certain stakeholders can derive specific benefits from this document:

Quality Control

Quality Control (QC) personnel are invested in data accuracy and completeness of testing. Modern commercial LIMS provide field-level data authentication to trap entries inconsistent with pre-established rules. Reproducibility in calculations is a critical concern as well as ensuring that all required testing has been completed within prescribed limits.

Lab Supervisors

Supervisory personnel are responsible for first level review. Commercial LIMS can queue up work to be reviewed and notify supervisors of impending review tasks. Work assignments and laboratory workload balancing are also functions capable of being monitored and managed within a LIMS, and the automation of these tasks greatly improves supervisor productivity.

Information Technology

Ensuring that LIMS are utilizing current technology are chief objectives of IT, as are clear maintenance and support policies. IT is also going to be very interested in the underlying technology utilized in the design of the product.

Quality Assurance

Quality Assurance (QA) personnel are interested in the tools the LIMS supplies that facilitate the implementation of QA policies, ensure that regulatory requirements such as 21 CFR 11 are met, and allow for quick access to information to respond to audit requests.

Laboratory Personnel

The success of any LIMS is most reliant upon the user community being willing to use and trust the system. The fundamental axiom held by LIMS users is that the software must make life easier, not more difficult, and software that increases user workload invites shortcuts and workarounds—none of which benefit the enterprise.

Identification of Objectives

While many enterprises start with a call to arms of business analysts, lab managers, subject matter experts, and a plethora of related resources in an attempt to capture requirements, few companies take the time to examine the high level objectives for a new LIMS, or how they intend to measure the success of the deployment. Doing so requires that the scientific enterprise is required to step back to consider a new paradigm: an approach that demands a departure from the comfortable examination and documentation of existing system functionality in the belief that doing so establishes the underpinning of their next system. Using an incumbent system as a frame of reference, by definition, sidesteps potential process improvements made available within the workflow of the enterprise, the leveraging of new technology, and the functional innovations that accompany the natural evolution of software.

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Process Improvements

Scientific enterprises often neglect the opportunity to improve work processes whether precipitated by the advent of new software, or simply identified as an artifact of an in-depth examination of the current state. No matter how simple or complex an operation, some introspection of the current state environment can reveal benefits previously obscured by the routine of daily activities. While some companies may have experienced business analysts in-house, others may elect to engage a consulting firm to expeditiously identify and articulate process improvement opportunities. No matter which course is taken, the time investment in examining and possibly improving workflow may reap benefits for the lifetime of the LIMS. Something as simple as identifying redundant paperwork, delayed notification of impending work for analysts, or a backlog of completed work pending review by supervisory personnel are all impediments to productivity that can be eliminated with the deployment of a LIMS.

For example, if we hold a meeting of laboratory personnel and ask them how they are aware of work to do in the morning when they arrive, they might say they walk by a shelf and examine it to see if there are samples to be tested on that shelf. If there are none at the time, they may return later and check the shelf again. Perhaps the second time, they see samples sitting on the shelf and take them to their work areas. Now, ask the same set of lab personnel how that process might be improved with a LIMS, they might ask for automatic notification when samples are logged into the system. Perhaps these samples are sent to a dashboard on the user's computer so they can see them when they log on in the morning.

We have thus identified a means of improving a process, and we can now transform that need into a system requirement.

One of the most significant benefits to understanding current state operations is that a small amount of additional effort, assigning time values to existing tasks, can yield metrics for system success. The vast majority of scientific enterprises that have budgeted thousands or millions of dollars for a LIMS project do so without a plan for gauging the success of the implementation. These companies often don't consider the quantification of time and effort associated with specific current state tasks for the purpose of establishing a baseline by which to measure post-deployment success.

Once process improvements have been identified, a collateral benefit can be derived from the process improvements identified in a future state environment. Referring back to the tendency of companies to develop requirements by simply documenting the operation of their current system, examination of the current state environment may reveal tasks that provide no visible benefit to the laboratory, but may have remained in place as legacy processes whose origins have long been forgotten. Elimination of archaic work processes, and enhanced focus on those processes bringing real business benefit to the enterprise, should be added to the more mainstream user requirements documentation process.

System Requirements Analysis

System Functions

From the perspective of using requirements for system selection, the most common error in requirements gathering is to spend a great deal of time documenting tasks that are ubiquitous to all commercial LIMS on the market, and play no role in differentiation between systems. While many of these common functions should be included in a software demonstration so that observers can compare "apples-to-apples" between candidate applications, they do not by themselves serve to differentiate one product from another.

It is not right or wrong to include such basic functions in a requirements document or a demonstration script, but the true differentiation between products occurs at a more detailed level, such as the one mentioned in the previous section regarding a sample backlog list. While the ability to view a list of samples to be tested is common to all LIMS, being able to send samples to be tested to a user's dashboard may vary greatly between LIMS suppliers. What may be an out-of-the-box function for one system may be a customization for another.

Once the functional requirements have been identified, there are usually requirements originating from the IT and Quality organizations as well. Certain technological platforms may be required by IT or strongly suggested. A Microsoft platform might be a corporate standard from IT, or perhaps multi-device support. The Quality organization may require detailed information on what compliance tools may be available from the supplier, or may include requirements on specific certifications.

New Technology

The competitive nature of the informatics industry incentivizes the top-tier suppliers of LIMS to constantly innovate to be competitive. The most visible manifestations of these innovations are new and improved functions that are demonstrable to potential customers. More important to customers, and frequently overlooked, are underlying technological design aspects that may have long-range effects. While some suppliers team with major platform/database vendors to ensure that they can keep pace with the latest improvements to these critical foundational elements, other suppliers rely upon older technology that their engineering teams are familiar with, preferring to emphasize user-level functional changes with more curb appeal.

Major vendors have strong and differing opinions as to how to approach web support, cloud technology, and open device platforms. System requirements should not only spell out any corporate standards for IT-preferred platforms, but also ask questions for database support and web architectures.

Enterprises identifying technological requirements must realize that underlying platform, database and system interface technology lacks the aforementioned curb appeal of user-accessible functions, but carries long-term system sustainability and maintenance ramifications. A very serious mistake made by companies calling out technological requirements is to not properly weight them vis-à-vis the more superficial cosmetic functions.

Architecture

There is generally a significant difference of opinions on system architecture. Rich Internet Application, JavaFX, Zero plug-ins, multi-tiered, and HTML5 are all buzzwords associated with system architecture, and all have advantages or disadvantages in terms of device support, system interfaces, server and browser performance, etc.

Is support for non-Microsoft OS devices important? What are the local cyber security policies? Are there hardware or database standards in place? Oracle or Microsoft SQL Server for a database?

The support for web services and APIs interfaces to key applications such as SAP, Chromatography Data Systems (CDS), IsoTrain, Blue Mountain Calibration Manager, and a host of other systems is also an important consideration. Some of these third parties only partner with LIMS suppliers who pass integration qualification testing while others offer APIs through partnership agreements. Canvassing the instrumentation employed within an enterprise is thus a separate but important consideration.

All of these questions are fair game in the system requirements, but few draw the attention of the general user community. Regardless, they are critical considerations and warrant their own section in the requirements specification.

System and Services Pricing

The most difficult comparison criteria in comparing candidate systems are the pricing details. That is largely due to the details regarding services. Fundamental software pricing is comparatively easy to understand compared to services pricing. The key point in assessing services is understanding the level of detail provided in the services quote. While many customers ask for fixed-price contracts, obtaining these without meticulous details regarding the deliverables can be counterproductive. The misconception held by prospective customers is that LIMS companies seek to expand their services offerings after-the-fact. The truth of the matter is that experienced developers, from the vendor's perspective, are better optimized by jump-starting deployments, with top-level technical resources better-served in navigating the more challenging requirements than to be locked into an account with constantly changing scope. So, customers seeking fixed-price quotations, if the vendor provides one, will find an agreement with extremely tight constraints, as well as specific language for addressing change requests. Time and Materials contracts, preferred by vendors, allow more flexibility to accommodate changing requirements without a detailed contract review.

System Selection

Once system requirements have been documented, the next step is the production of a demonstration script and developing a long-list review of candidate vendors

Reviewing complex software systems such as LIMS can be quite taxing. To lessen the impact and time required in the demo evaluation process, initial screening of candidate vendors can be used a as a means for reducing the number of vendors invited to demo to only those meeting a reasonable cross-section of requirements.

Long-list candidates are typically identified from Internet research, word-of-mouth recommendations, and previous selection efforts. Typically, long-list candidates are eliminated due to fundamental system shortcomings, lack of an installed base/references, and indications of corporate instability. For example, an application that only runs on an individual PC would likely be unsuitable for anything more than a small laboratory operation. Similarly, large software companies can also be eliminated quickly if it is discovered that, although they have a significant presence in some other sector such as Discovery or Supply Chain management, they might not have a similar industry footprint in LIMS. Better stated: proficiency and dominance in one sector does not always translate into similar success in tangential areas.

References are normally supplied to prospective customers at this point, and while some companies may ask to speak with references, many companies considering such a significant investment often include requests for on-site visits. The resultant short list of vendors, preferably no more than two or three, are generally invited to demo on-site and are sent the demo script. While vendor demos can be scheduled on the same day, it is more efficient and productive to book separate days to allow the demo audience to recover from a fusillade of marketing and functional information.

For the actual demo, most companies fill the audience with an amalgam of personnel from the various user groups, but usually call in specific Subject Matter Experts (SME) for only those elements in the demo most relevant to their own work areas. The pace of the demo is dictated by the demo script, and the scoring of functional items presented in the demo is the standard approach to accurately evaluate the presentations. Such a process warrants the full attention of the audience, hence another reason to hold only one vendor demo per day to prevent mental fatigue.

Prior to the demos, a scoring sheet needs to be developed detailing all of the demo script items, and specific scoring criteria that should be discussed before the first vendor demo. Weighting is generally used to prioritize section criteria, and most companies organize reviewers by specific interest or subject matter. Laboratory personnel who are experienced LIMS users are not assigned to evaluate the sections of the demo associated with LIMS architecture.

Most companies benefit by having a debriefing meeting after each demo so that specific topics can be discussed while the demo is fresh in the attendee's minds. These meetings are best facilitated by someone not directly involved in the decision-making process to ensure an unbiased discourse.

At the conclusion of the vendor demos the score sheets are tabulated and the vendors rated in terms of functionality, usability, etc. The final steps usually involve pricing negotiations, but pricing should only be a component of the final decision, and not the deciding factor.

Conclusion

While there is no substitute for experience in selecting a new LIMS, companies can approach the task systematically and greatly increase their chances for a successful deployment by following these straightforward steps. Proper system selection ensures enhanced user productivity and increased data confidence.

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