



Review

LIMS use in laboratory data management

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Abstract

Laboratory data management is a complex process involving both people and information in order to acquire, organize, store and distribute information. Information conversion to knowledge requires the application of many human qualities such as experience, intelligence, intuition and talent; it is not enough to simply acquire and own data, being necessary to have a proper understanding of the data structure and the required qualities to apply a suitable management system. Modern laboratories produce large amounts of data; with the continuous development of new technologies, both the quality and quantity of information is increasing, causing often significant problems and new methods are needed to manage this situation. Laboratory Information Management Systems (LIMS) provides a way of automating part of the laboratory system. As the primary function of most laboratories is to provide validated information under some time constraints and based on that information, allowing customers to make decisions, LIMS can save considerable amounts of time and dramatically improve the level of data access for all individuals involved in a given project; the sooner the user is notified of a problem, the sooner that problem can be fixed and the less the solution will cost. Several of the main benefits identified from current users of LIMS are: analytical data can be obtained instantly being also easily accessible online; large amounts of data can be stored without the need for traditional archiving; improvement of data quality as all the analytical instruments are integrated; automated tracking and management; automated customer reports; automated quality control. All these benefits can lead finally to a general improvement of laboratory efficiency. Despite LIMS have been used for more than twenty years, they still remain difficult to implement successfully. This paper provides a brief description of some of the existing technologies available to date, detailing the benefits that a LIMS can offer, giving finally an approach for the development of a successful LIMS implementation.

Keywords: LIMS, laboratory data management, IT

1. Introduction

Laboratory data management is an important topic for universities as well as for companies

and might create a huge increase in productivity of institutions. Laboratory data management strategies become more and more important as researchers and managers detect the importance of information as driving factors of the current economical system; development is driven by new research, new information that needs to be processed and finally new knowledge to be created, in a working environment in which more

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and more teams are often dislocated (a consequence of recent development of science, that tends to become a global scale one [1]). Some areas of modern science like the human genome project become a heavily dislocated effort on a worldwide scale; this is an essential point, considering the necessity to support such projects with appropriate IT systems [3].

Modern laboratories produce large amounts of data; with the continuous development of new technologies, both the quality and quantity of information is increasing, causing often significant problems and new methods are needed to manage this situation. The tracking of samples submitted to an analytical laboratory is a complex matter involving the recording of many details from receipt to completion of the required analyses and the generation and use of a great deal of information:

- **before and during the analysis:** origin of samples, date of receipt, allocation of sample numbers, listing of analyses required, identity of analysts, status of each analysis, events encountered during the analyses;
- **following the analysis:** time taken for each analysis, computation of results, statistical and other applications of chemometrics to the data, library and data bank searches, report generation in required format, transmission of report to required locations, archiving of results, collation with other results and data, receipts for work.

An analytical laboratory can utilize a software package called LIMS to carry out or control all of these requirements provided that computerized analytical instrumentation, computer terminals, printers and plotters, etc. are linked together in a local area network to facilitate the transfer of information between them. LIMS can provide on-line information about the samples analyzed in a laboratory: the current location of each sample in the laboratory, the method and status of each analysis, experimental data, calculated results, etc. However, LIMS is not only a tool to provide data to clients, but more importantly a management tool to improve the proficiency of the laboratory. There are lots of advantages in running a laboratory through a LIMS, such as: the ability to capture, transfer and process data for a variety of instruments and to report the results in any specified format; the ability to use or construct databases from any of the information generated, stored or accessible outside the laboratory; the ability to track the progress and status of each sample that passes through the laboratory [2, 4].

Requirements for a successful LIMS implementation

A successful LIMS installation and implementation requires a wide input from the laboratory and the LIMS vendor [2, 4, 5], the key factors being: 1) a thorough needs assessment; 2.) a realistic budget correlated with a proper LIMS vendor selection; 3.) organized implementation; 4.) a well documented validation plan; 5.) methods of performance measurement.

2. Needs Assessment

For the very beginning, it is necessary to invest time to clearly define the data management needs, the goals and the role that the LIMS will play in the laboratory. For this, it is important to build a team and a plan that includes the process maps and the main functions that the laboratory is trying to automate. This requires the creation of a multidisciplinary laboratory management team that consists of laboratory management, IT experts and key end-users; this personnel will work together to create a flow-diagram that capture the entire analytical processes, as well as define the requirements of the organization that host the laboratory. The scope must be a complete definition of all the requirements: the external environment ones besides system design may involve requirements that are not specified and finally - components which are not clearly defined, such as instrument interfaces, operations and implementations.

The following steps are important:

- creating a flow diagram that represents the samples' flow in the laboratory;
- reviewing the laboratory processes (how orders are received into the laboratory, how samples are received, prepared, tested, quality controlled, validated, approved and finally reported and invoiced to clients);
- examining each step in the flow diagram and trying to determine the average amount of time the sample spends at each processing stage;
- adding more detail to the flowchart in the form of specifications.

Performing a needs assessment within the laboratory is an excellent way to determine exactly what the laboratory needs in terms of data management, tracking and reporting. A needs assessment provides a very effective way to communicate to potential LIMS vendors what the LIMS is expected to do for the laboratory, in terms of well defined goals and objectives.

3. LIMS Vendor Selection

A performing LIMS will have many features that the laboratory may not use immediately, but may require as the laboratory grows and utilizes additional automation features. Core requirements for LIMS in analytical testing laboratories include sample tracking functionality, data entry, sample scheduling, integrated quality analysis/ quality control functions, time tracking, chemical reagent inventory, personnel and equipment management, query searching, maintenance, customer relationship management. To enhance productivity and data accuracy, laboratories often require instrument integration from their LIMS, enterprise system integration and data management tools that will meet specific regulatory requirements. LIMS can be purchased as customized commercial software packages or developed by a company's programmers. Purchasing a LIMS may be the most crucial decision a laboratory will ever make. Evaluating and selecting a LIMS is a difficult task as they appear mostly similar, however some LIMS have been developed to address the needs of a specific market, and thus lack the flexibility to meet the needs of many laboratories. In fact, LIMS have fit into two categories: *turnkey systems*, in which functions are predefined by the LIMS program, and *programmable systems*, in which most of the features are tailored to the individual laboratory. The turnkey LIMS is ready to use as installed, but its functions cannot be modified to suit the ever-changing and unique needs of the modern laboratory. The programmable LIMS can be altered to meet those requirements, but the system is not usable until the time-consuming and expensive customization process has been completed, and the laboratory must pay more each time it needs additional configurations to the system. Without a proper knowledge of the main features of LIMS, the end result in many cases is that a lot of laboratories end up purchasing a LIMS and then spending excessive time and money trying to make it work; lots of purchased LIMS are never fully implemented and this is often because the task was bigger than first anticipated and not enough time and/or proper resources were dedicated. Any laboratory that is interested in purchasing a LIMS can minimize this kind of risk by spending some time learning about LIMS and the features and benefits they offer. When a laboratory is planning the purchase of its first LIMS, the most important issue to consider is its requirements and expectations from the system. The following factors must be considered:

software, hardware, implementation costs - including software configuration and customization, software installation, training, support and updates.

Software. The acquisition of a LIMS involves high costs, but the software's cost is only a fraction of the expenses associated with installation of a new LIMS. When evaluating LIMS packages, laboratories should look for systems that closely follow their needs as there are many LIMS designed for a specific type of laboratory and may not provide the data flow, features and flexibility required. If the system appears to address a high percentage of the laboratory's data handling requirements (log-in options, status tracking, data marking, audit trails and other features that are vital to laboratory operation), then it is potentially a good fit.

Hardware. Unexpected expenses often arise when the software does not work with the laboratory's existing equipment; for this reason, budget estimates for the LIMS project should include new hardware, networking, cabling and even possible computer upgrades.

Implementation. About 30% of the overall LIMS implementation costs are associated with the configuration of the LIMS software required to meet the laboratory's needs: populating reference tables and libraries for sample or product types, tests to be performed, analytical methods, detection limits, quality control libraries, developing instrument interface routines, modification of existing forms, creation of user-defined forms and custom data entry forms. When evaluating the amount of work involved in the implementation of a LIMS for the laboratory, the LIMS administrator must: 1) make a list of what needs to be present in the LIMS for initial implementation; 2) compare this list to each LIMS; 3) determine if the LIMS administrator can make changes to the program if necessary; 4) if so, determine the level of expertise required to make the changes; 5) if the changes will require direct interaction from the vendor as customizations to the system, the laboratory will need an accurate estimate of the costs for such changes. Unfortunately, many manufacturers claim their LIMS can be customized or modified to integrate user-specific features, but often omit to mention that such work will cost the customer thousands of dollars. The laboratory must also determine whether the LIMS administrator can perform the software installation or if the vendor must install the software. If onsite installation is required, the laboratory needs to get a quotation for the cost of

Table 1. Some representative LIMS vendors

Company	Web-site	Country
AgileBio	www.agilebio.com	France
Agilent Technologies	www.chem.agilent.com	USA
Analytical Information Systems Ltd.	www.ais-lims.com	UK
Autoscribe Ltd.	www.autoscribe.co.uk	UK
Baytek International Inc.	www.baytekinternational.com	USA
Cardiac AS	www.cardiac.no	Norway
Cambridge Soft	www.cambridgesoft.com	USA
ChemWare Inc.	www.chemware.com	USA
Dynamic Databases	www.dynamicdatabases.com	USA
Ethosoft Inc.	www.ethosoft.com	USA
Finna Technologies Inc.	www.finnatech.com	USA
Genesis Microsystems Inc.	www.genesislims.com	USA
H&A Scientific, Inc.	www.hascientific.com	USA
L.I.M.S. Inc .	www.starlims.com	USA
Labit Solutions AB	www.labit.se	Sweden
LabLite LLC	www.lablite.com	USA
LabPlus Technologies Inc.	www.labplustech.com	USA
LabVantage Solutions	www.labvantage.com	USA
LabWare Inc.	www.labware.com	USA
LIMS+Ware	www.limsware.com	USA
Promium	www.promium.com	USA
Telecation	www.telecation.com	USA
Tribal Software Inc.	www.tribalsoftware.com	USA
Waters Corporation	www.creonlabcontrol.de	Germany
Wavefront Software Inc.	www.wavefrontsoftware.com	USA

this service, which will depend on the number of workstations using the LIMS as well as the network topology.

Support. LIMS vendors offer a wide variety of support options via the Internet, telephone or fax. During the first year, the laboratory has a greater need for technical support than in later years, due to the number and level of questions that routinely arise during initial LIMS implementation. The laboratory should ask whether the cost for programming assistance is the same as that for answering routine questions; some vendors may include the on-site training and some level of implementation assistance in the LIMS cost. If unsure as to what is included, the customer should request the answer in writing. Demo systems are sometimes modified by the vendor to include features or special reports that the vendor feels will be of interest to prospective customers. It is important to ask if each item is included in the cost; if a feature is desired, the buyer should ask what the vendor calls it and then be sure to include it in the system specifications in the quotation.

Software updates. A laboratory needs to ask detailed questions about the LIMS provider's bug-fix policy before making the purchase. Some vendors may require a facility to maintain a current software update contract in order to

obtain technical support, others try to pack updates and support in the same contract. Buyers need to understand both short- and long-term costs and obligations associated with any contracts they enter into.

The procedure of vendor selection needs to take into account current and future requirements and all the above-mentioned aspects. The most important information to gather from potential vendors is:

- a synopsis of the vendor's project development approach;
- the vendor's corporate information (size, financial stability, experience);
- a list of previous clients for similar type of work;
- the vendor's proposed personnel to be assigned to the project, including resumes;
- all required specifications involving hardware and software for the installation, operation and support of the LIMS;
- written answers of the vendor to each of the required features from information taken from the needs assessment;
- deadlines for initial and final project testing;
- details of the support plans that the vendor offers;

- cost proposal that includes pricing for each item (support, instrument integration, any customization, etc.);
- a defined protocol for handling delays and a procedure for resolving problems that may arise;
- a scripted demonstration of the LIMS against the requirements list created by the LIMS team.

4. Implementation

The LIMS vendor should provide a detailed written description of the implementation process for the LIMS project. A Certified LIMS Vendor will have a Quality Management System in place that ensures that there are QC checks throughout the entire installation process with extensive use of checklists and QC documents that follow the project plan; these vendors will also have to pass regular audits by a certifying agency. A project manager from the LIMS vendor and the laboratory must be assigned and responsibilities for each LIMS team members must be well defined. The vendor should provide pre-installation checklists in which the laboratory should answer in detail so that there are no surprises and the LIMS vendor is fully prepared. Pre-installation checklists are ideal ways to gather information on the laboratory requirements as they allow the laboratory to consider all the elements of the implementation in advance so that the team can better understand the reasons for configuring the system in certain ways. A detailed training plan that lists the table of contents and the approximate times of the training for various groups in the laboratory, including the use of training certificates after laboratory personnel have completed training.

5. Validation

LIMS validation is an important issue for many laboratories, particularly those that operate in regulatory environments. Vendor should offer a LIMS system validation package, including the purpose of the validation plan, how it will be conducted, how the validation will be documented and how the records will be retained. This package should include a formal test plan for validating the system, including the test data and acceptance criteria, that is reviewed with the client. The LIMS functionality must be extensively tested to ensure that it processes and stores the data properly and that functions and features work as defined.

6. Measuring Performance

It is essential to ensure that laboratory staff is well trained on the new LIMS and that they are aware of all of the advantages to be gained - especially for key team members.

The functional requirements should be revisited and compared to the final installed system to determine how well the requirements were actually met; the implemented LIMS should address all the issues which were identified in the needs assessment. It is important for the laboratory to attend vendor user group to ensure that the LIMS continues to meet changing regulatory requirements.

7. Conclusions

LIMS implementation is an extremely complex, time-consuming and expensive process. There are major risks involved in the implementation of a LIMS and there are various ways to reduce the risk of failure but none of them provide an ideal solution.

The guidelines presented here for successfully implementing a LIMS are useful but are in no way complete; what may work for one laboratory may be totally unsuitable for another. However, LIMS have been shown to work and they have been shown to be very profitable when employed correctly.

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