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Guide to successfully select a LIMS

Proven steps to software selection for LIMS and lab informatics solutions

by

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10. May 2009

Summary

Laboratory Information Management Systems (LIMS) are the prime software applications in laboratories to support the daily operation and to manage analytical data. LIMS can be found in many different industries while the focal point is on chemicals, pharmaceuticals, utilities and service labs. Mainly in larger operations LIMS complement other IT-systems on the laboratory and the enterprise level leading to integrated application scenarios. This increases the relevance to select the right LIMS application in order to match the requirements of all participants. The process of selecting a software product needs to consider aspects like business objectives, the work process, IT-infrastructure and user requirements. The steps to take follow a proven concept from the scope definition to the analysis phase and up to the selection process itself. Due to flexibility in the single building blocks it can be applied to all size of laboratories.

I. Introduction

The need to streamline operations for economic and efficiency reasons as well as the technological advance has led most laboratories to employ IT-systems. They are mainly used to support the lab instruments, to perform documentation tasks or to handle data evaluation. Such applications range from spreadsheet programs to chromatographic data systems.

Laboratory Information Management Systems (LIMS) represent the next level in the IT hierarchy. They are mainly used to support the operational tasks in the laboratory with respect to planning, sample management, data acquisition as well as data analysis and reporting. Strong arguments for a LIMS are requirements to handle increasing number of data, to meet regulatory demands of authorities or to communicate data to other systems in the company.

Surveys done by market research companies[1] show that commercial LIMS are mainly employed in the chemical and pharmaceutical industry or at utility providers. Besides many other kinds of labs, service or governmental laboratories make use of such systems.

The scope of a LIMS may vary depending on the type of operation and the size of a laboratory. Nevertheless, many basic requirements concerning functionality and ease of use are the same. Differences can rather be found in the demand for data communications and interfacing or with regard to individual data processing and reporting. This implies that the selection of a LIMS for the own laboratory has to put its focus on the individual needs and objectives to end up with the best product.

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[1] Strategic Directions International, Inc., 2009 Worldwide survey of LIMS users (promo)

The typical selection process for software is comprised of a number of steps which follow a logical path – establish a project team, define requirements and RFP, evaluate vendor response and make a decision. Still, many project teams struggle due to inadequate planning, unexpected complexity and moving targets. This paper provides a guideline to successfully select LIMS software. It not only puts a focus on the selection process itself but includes a view on the business process for an increased overall benefit. By building a business case, the project goal to implement a new LIMS can be balanced with the objectives, with alternative solutions and also with the expectations for an improved IT-supported laboratory workflow. As a result, the selection process will be based on a widely accepted and approved project scope tying in project team, users and management.

Selecting the right LIMS for the laboratory is very often crucial due to the size of the investment. Besides this aspect, achieving the best match of a LIMS product with the requirements will ensure acceptance on a user level as well as in the IT-department which is important to operate the system successfully over its lifetime of 10 years or even more. The procedure described in this paper may help to ease the relevant project tasks for selecting a LIMS.

II. Project organization

The first step in the LIMS selection process is to establish a project organization. Projects rely on people and require clearly defined goals as well as rules on how to perform the tasks. It is up to the management to define the resources of the project and to establish the general conditions. A kick-off meeting may serve as a platform to initiate the project as soon as it is approved:

- Define the project goals and objectives
- Establish a steering committee and the project's core team
- Determine the project time frame, phases and the budget
- Agree on review and controlling mechanisms
- Empower the team members to perform the project tasks and assign specific responsibilities

Depending on the size of the project and of the company the staffing of the team may vary. Nevertheless, it is important to select participants who represent the relevant parts of the organization involved in the project. They must be knowledgable about their specific working areas and they need to have acceptance in the team and the user community. A LIMS project takes months to get finished, i.e. the project members need to be available for the whole period in time. Even if it is not a full time assignment, sufficient time resources are crucial to the success of the project.

The project team is supposed to perform the tasks in the given scope. The first step should be to structure the project and build a project plan using tools like Excel or specific project management software. Certain tasks do require specific know how. Therefore, plan for additional education e.g. with respect to requirements analysis or concerning the typical functionality of a LIMS system. This definitely adds to the quality of work and provides additional security in the project.

Project team		
Team member	**Function**	**Type**
system owner	responsible for the project and budget	Steering
management representatives	guidance, monitoring the overall project performance, rules and decisions	Steering
project manager	planning and coordinating the project tasks, guidance for the team, reporting	Core
lab specialist	member representing the laboratory in the selection and specification tasks	Core
IT representative	member representing the IT dept. to ensure consistency with the IT strategy	Core
key user	representative of involved departments to assist in the selection process by adding user specific views and requirements	temporarily
consultant	optional member to advise and support the team in all project phases	Core

III. Building a business case

The reasons for purchasing a LIMS vary depending on the organization. Arguments range from the inability to handle the increasing data volume, to problems in complying with regulations up to the need to replace an outdated system. In many instances the laboratory has managed to convince the executives of the need for a system and the project is started. The objective is to select a LIMS for the laboratory which fits into the existing IT infrastructure. The assignment is to prepare a request for proposal and to select the vendor in a given budget.

This approach is straight forward and fits many companies and LIMS projects. However, it misses out on the chance to optimize the IT-investment in concert with the performance of the laboratory and all the other stakeholders. The project's objective is too narrow and it does not consider alternative solutions or the impact of business processes and collaboration in the company.

Building a business case will prove the intitial project idea and provide guidance for the next steps in the selection process. Harmonized laboratory workflows or streamlined information flow to other departments not only improve the overall performance but also reduce the complexity of the LIMS and the project cost.

Building a business case should follow a specific procedure:

1. Scope definition

Projects require clear visions on what to accomplish and a firm definition of the scope in order to be successful. In a first step, a serious analysis should be done. It needs to identify the driving forces for implementing the system and the affected parties in the organization. This allows to define the scope for developing the business case and to reassess the initial project goals and objectives. Perspective for an improved working environment attracts supporter in all involved departments, while increased efficiency and lower costs are the arguments for the management to push the project.
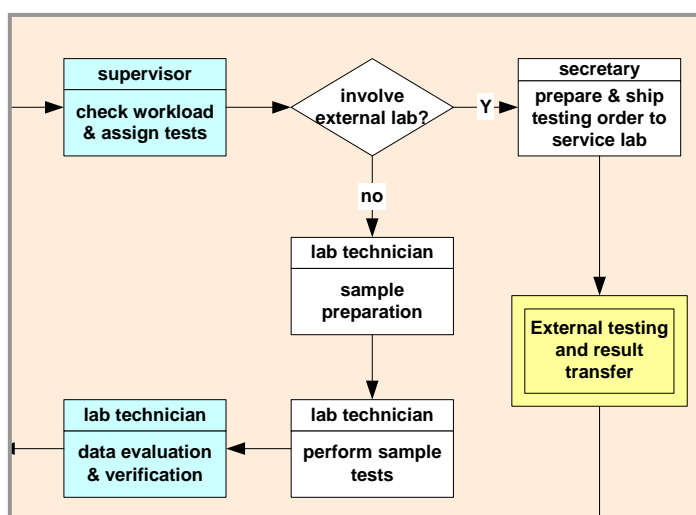
2. Analysis of business operations

A laboratory's business is pretty transparent especially if it is a single lab unit. Bigger operations split up in several laboratories or even different locations tend to perform their tasks in a distinct way even though they work on identical topics. This provides a big potential for optimization by harmonizing the business process and the IT-systems. Harmonization facilitates the implementation of a LIMS because the required functionality will also be streamlined reducing special features and additional costs.

To achieve this goal, the analysis of the business operations should be divided in three tasks:

a) Business process analysis

An analysis of the information and sample workflow in the laboratory will deliver a clear picture on the internal business process. It also shows interdependancies with other groups – located internally or externally – like production or suppliers.

The process analysis can be performed by interviewing key personell in the lab supported by checklists and question-naires. Ideally a process map is drawn showing the relevant workflows and the major tasks. It will serve as a basis for the business case evaluation.

b) Analysis of IT-infrastructure

The LIMS project typically builds on an existing IT fundament. Therefore it is important to collect the relevant information about software applications, servers, databases, data volumes and lab instruments employed. It is also of interest what IT-systems are used outside of the laboratory for future communications. This picture needs to be complemented by key figures of the lab showing the number of samples, tests and potential LIMS users.

c) Evaluation of the business case

The evaluation of the documented business operation of the laboratory aims at the question on how to achieve the prime project objectives in the best way. Ideally, a part of the team prepares the business case by analyzing deficiencies proposing improvements to the workflow and to alternative solutions concerning LIMS or other IT applications. Not only in this phase can it be helpful to make use of internal or external consultants for an unbiased view on the issues.

A thorough discussion of the pros and cons is required which might end up in a redefinition of the LIMS project, e.g. by adding an ELN and changing some workflows. The approval of the proposed strategy for the business and IT-scenario is to be made in the project team involving also management representatives to get the broadest support possible. The objectives and success metrics will be adjusted.

At the end of this phase even a first cost-benefit analysis can be performed to back up the decision with economic arguments. After this the selection process of the LIMS should start.

IV. LIMS selection process

The selection of a LIMS can be done in several ways. However, a decision based on a visit of the vendor's exhibition booth or the purchase of a product based on a colleague's recommendation is not considered a valid option. The reason to neglect these methods is the lack of substance with respect to the requirements definition and the impracticality to seriously verify the system's functionality.

So it is common sense that a secure selection process can only be achieved by using a solid requirements specification. This specification has to be matched to the vendor's system to evaluate its capabilities. For laboratories operating in regulated environments this approach is indispensible in order to establish a basis for the validation of the LIMS. The following steps briefly describe the required activities.

a) User requirements analysis (URS)

The purpose of this analysis phase is the definition of all relevant business requirements with respect to the new LIMS. A document called "user requirements specification" needs to be prepared to communicate the lab's expectations to the LIMS vendor.

The analysis task is to be performed by the project team and requires a good knowledge about the laboratory itself as well as know-how about LIMS and its typical functionality. It is beneficial to base the requirements analysis on the approved business case developed in the earlier project phase. It serves as a guideline for the scope to avoid moving project targets and it also defines the prospective, IT-supported lab processes.

The requirements analysis has to involve power users in the laboratory to define the needs and to ensure acceptance by involving the prospective users. The main tasks are:

- Preparation of the analysis (meetings, questionnaires, documentation tools)
- Performing workshops and interviews to collect the user requirements
- Gathering requirements related to IT, technology and implementation
- Compiling the functional and technical requirements for the system (URS)

The user requirements specification is the key document for the selection of the LIMS. Therefore it has to be complete and specific in its statements. The requirements need to be detailed enough to allow for a differentiation between several LIMS in the evaluation phase. Preferably, the structure of the URS reflects the lab's workflow while grouping the requirements according to the typical LIMS modules. A classification of requirements in mandatory and optional items provides a higher focus on the important topics.
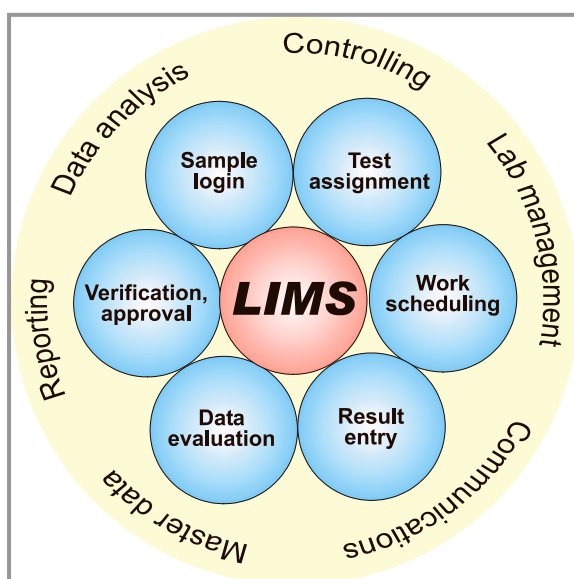
Requirements specifications prepared for regulated environments like the pharmaceutical industry have to make sure that each LIMS requirement can be referenced and tested as a single item in the software validation process. Verbose descriptions should be avoided in favour of short and clear statements.

The technical part of the URS is similar in importance. It has to clearly state the IT technology acceptable to the company. Typically, this includes issues like databases to use, operating system platform and aspects of the system design. In addition, communication requirements to lab applications like chromatographic data systems, electronic lab notebooks (ELN) or scientific data systems (SDMS, ECM) have to be specified in a firm and precise manner.

b) Identification of potential vendors

The identification of LIMS vendors having the potential to successfully supply the desired system is another crucial point in the project. The number of commercial LIMS listed on the website of LIMSource[2] is around 200 and there are still some missing. In fact many of them will not be the first choice or they do not offer their product in the region the laboratory is located. So the initial step is to prepare a shortlist of vendors which should be considered in the project. The criteria to apply are typically:

- experience in the field of activity the laboratory is working in
- vendor reputation and references
- state of the art LIMS product
- compatibility of the technical platform

The identification of potential candidates can be performed by …

- Screening LIMS market overviews and the Internet
- Attending conferences and exhibitions
- Involving consultants with specific market knowledge
- Asking business partners in other companies

In case the number of vendors is still to large, an RFI (request for information) can be sent out to narrow down a pre-selected group of candidates based on a few but meaningful questions.

Ideally, the number of LIMS vendors to include in a tender should be 5 to a maximum of 10. The reason is the considerable effort to evaluate the responses and the quotations.

c) RFP development and tender offer

The preparation of the request of proposal (RFP) is the last step before the tender is issued to the vendors. Normally the task is performed by the project manager and the purchasing department. The RFP has to be prepared in a way that it combines several parts:

- information about the organization and its laboratory
- the user requirements specification (URS)
- data about the expected type and extent of the response
- some legal conditions.

The RFP should include the following topics in order to communicate the expectations clearly and to minimize evaluation effort:

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[2] LIMSource, LIMS resource on the Internet (www.limsource.com)

- guidelines on how to structure the quotation
- rules on how to answer the requirements
- information about the scoring model to be applied in the evaluation (mandatory for some public tenders)

The request for proposal is to be sent out to the pre-selected vendors by the purchasing department. This may vary for public tenders since it is normally not possible to restrict it to certain vendors due to legal aspects.

The time frame to respond to the RFP should be about 4-6 weeks depending on the project. For this time period a contact in the project team and in the purchasing department needs to be established to answer questions of the LIMS vendors.

d) Vendor scoring and gap analysis

Proposals received from the different vendors need to be reviewed and matched to the specifications defined in the RFP. Very often this evaluation process is underestimated concerning time needed and the rating procedure itself. Nevertheless, the response evaluation is the most important step to isolate the two prime vendors out of the list. The focus on this top group reduces the effort to come to a final decision.

The evaluation of the vendor proposals should be done in a formalized process to apply a replicable standard. A proven procedure involves:

- preparation of a selection matrix which lists the requirements and applys a weighted grade point suitablity model
- parallel review of the proposals in a team scoring each requirement
- prepare a vendor ranking and match the score to the price to receive a price-performancce ratio
- identify the two final candidates

The procedure works very well if the RFP insisted on a clear structured vendor proposal. Despite this, the team will need to direct its attention to comparable scorings especially when vendor statements are ambigous or vague. At the end, the response evaluation does not only deliver the two principal vendors but it also shows some gaps and weaknesses of the LIMS compared to the requirements. This knowledge can be used in the further evaluation.

The next steps in the selection process serve the purpose to elect the champion. The approach to take may vary depending on the individual project situation. However, the actions listed below are best suited to secure the decision:

- check some of the vendor's reference customers e.g. by phone to learn about product and working relationship

- investigate on the status of the LIMS vendor; e.g stability, performance
- schedule a vendor presentation to demonstrate the features of the LIMS based on a few specific use cases provided by the team (proof of concept)
- optionally perform an on-site visit at a reference customer

All activities should be well balanced with respect to effort and the gain in knowledge. In any case, all actions should be evaluted and rated concerning the vendor performance to round off the picture.

e) System selection

The decision for the LIMS vendor to be used in the company and its laboratories is to be made on basis of the facts collected up till now. For this, the results of each step need to be compiled – RFP response evaluation, vendor presentations and other activities. The overview of the formal scoring should be complemented by the gap analysis to get a good benchmark for the vendor and system qualification.

The LIMS project team will have to assess the results by discussing and analyzing the remaining risks. These can be financial aspects or a partially unmet business objective due to a lack in LIMS functionality or in technology.

The results of the system selection process should be compiled in a management report highlighting the relevant data to justify the recommendation of the project team for a certain LIMS vendor. The presented data need to provide the management and the system sponsor a sound basis for a final decision.

V. Conclusion

The selection of a software product like a LIMS is a challenging task requiring a qualified project team to drive the process. The foundation for a successful implementation of a highly supportive laboratory information management system is laid in the planning phase. The process for selecting the right LIMS can be based on proven steps to define the scope, to specify the requirements, to solicit proposals and to do the vendor evaluation. Additional benefits can be realized if a business process analysis is included to harmonize the workflows and the flow of information before the LIMS is planned.

Employing the selection strategy outlined in this paper facilitates the whole process and provides additional security to find the ideal system. In addition, the knowledge and the documents developed in the selection phase will prove valuable when the implementation of the LIMS is performed. Time savings and a sound basis to verify the scope and quality of delivery are just two aspects where the initial effort will pay off.

Author

Rainer Jonak is a senior consultant and director of the lab informatics consultancy IMCOR GmbH. He holds a degree in chemical engineering and has worked several years in the chemical industry and in university research labs. From 1980 to 1993 he held positions in development, consulting and management at a German LIMS vendor and 3 years of that as the manager of the US subsidiary. After founding IMCOR he focused solely on vendor independent LIMS and lab informatics consulting.

About IMCOR

IMCOR is a privately-held laboratory informatics consultancy located in Germany. It is dedicated to Laboratory Information and Management Systems (LIMS) and related solutions. IMCOR's mission is to provide vendor independent consulting services with a strong focus on software selection projects and related analysis of business processes. Earlier occupational activities in the chemical industry and in a LIMS system house laid the foundation for the high expertise of IMCOR's consultants. The company's clients can be found primarily in the chemical and pharmaceutical industry but also several large governmental laboratories were served.

In the past years, IT-related services like custom software development and web based solutions were added to IMCOR's portfolio to stay on top of the rapidly evolving technology. The company primarily operates in Europe with a natural focus on German speaking countries.

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