# LABORATORY INFORMATION MANAGEMENT SYSTEMS: IMPLEMENTATION CONSIDERATIONS

*Arvinder Loomba, San Jose State University, Department of Organization & Management, BT 657, College of Business, San Jose, CA 95192-0070, 408-94-3578, loomba_a@cob.sjsu.edu*
*Michael Morad, Abbott Hematology, 5440 Patrick Henry Drive, Santa Clara, CA 95054, 408-567-3255, moradnm@yahoo.com*

## ABSTRACT

In recent times, hospital and private sector laboratories are investing in data management technologies and implementing Laboratory Information Management Systems (LIMS) into obsolete lab environments. We analyze LIMS implementation process using a real-life case at medical device division of a Fortune 500 biotechnology company, and how it improved efficiency, error proofing and data management to the lab operations. In our analysis, we address assessment of user need, identification of software specifications, software development, scope of validation activities, and finally Go-Live implementation into a laboratory environment. Throughout the paper lessons learned at the medical device company will be explained and then compared to what is happening within the industry in order to identify common practices within the medical and biotechnology sectors.

**Keywords:** LIMS; IT implementation; healthcare; laboratory management systems.

## INTRODUCTION

### Background

Today healthcare companies have a critical dependence on information. Consecutively, improving its management and reducing errors has a potential of netting operational benefits to all departments and importantly its overall efficiency, competitiveness and responsiveness [1][2][3]. Such improvements in laboratory setting generally include either expanding the amount of information managed or implementing an additional or new laboratory information management systems (LIMS). These LIMS are usually commercial off-the-shelf (COTS) software applications or suites that are based on standards, languages and processes and include a variety of tools and methods to support the specific activities of information management. In a modern company there will be a large number of different systems including finance, payroll, customer relationship management (CRM), product data management (PDM) and material management systems. This set of LIMS or software applications form a complex system, which in itself needs to be well aligned to the company, efficient and also responsive. Because of this, LIMS that are not well aligned to the company or the existing information infrastructure can have a significant detrimental effect on the company and its performance.

### Components of LIMS

A LIMS is made up hardware which often includes a server, numerous workstations, wiring, printers, and network hubs that bring all the wiring together. More importantly a LIMS is software that is more than often customized for a specific laboratory. A LIMS is unlike any other piece of laboratory

automation equipment available to the analytical bioscience practitioner. It can prove beneficial in environment within the laboratory and to external stakeholders. Consecutively, LIMS has two targets: (i) the laboratory: the information generator; (ii) the organization: the information user. The problem is how to site and implement a system so that it hits both targets effectively.

Fig. 1 shows an outline of the functions that a LIMS should follow ideally. The illustration shows a LIMS situated at the interface between a laboratory and an organization. Samples are generated in the organization and logged into the LIMS, the samples are analyzed within the laboratory and data are produced and reduced within the LIMS environment to information, which is transmitted back into the organization.

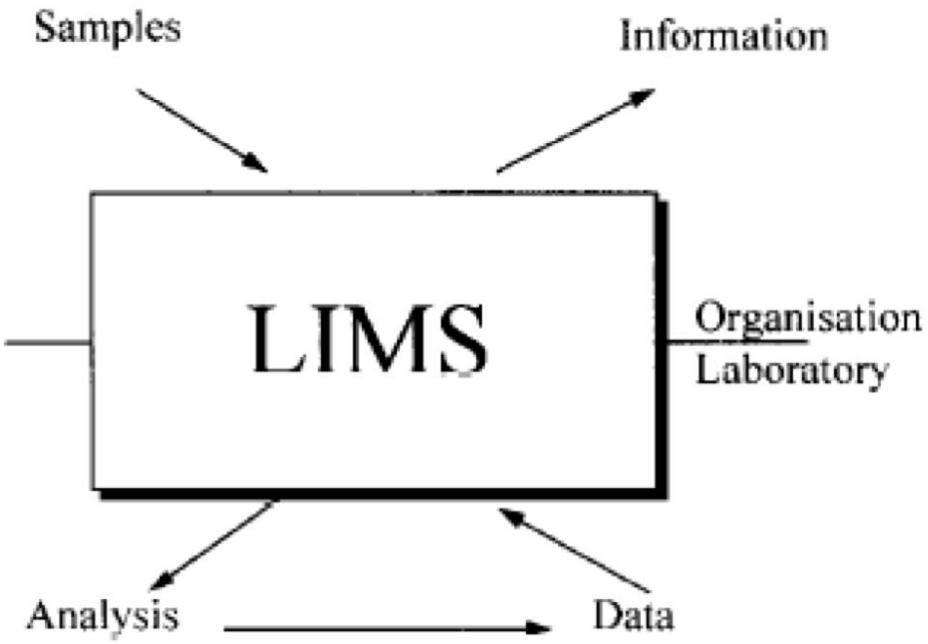


**Figure 1**: The ideal implementation of a LIMS. The interface between the laboratory and the organization shows that the LIMS benefits both.

Although many companies develop and sell off-the-shelf LIMS products theses companies also sell services for customization or else very few labs could ever use such software. At the Fortune 500 Company studied in this case investments were made in a specific IT department that develops and customizes LIMS software for all of its businesses worldwide. This multi-million dollar investment by the company clearly demonstrates their appreciation of the value of a LIMS in their laboratory operations.

When the medical device company decided it was time to implement a LIMS in the Quality Control (QC) laboratory it was largely due to costly lab errors, inefficiency and non-existent data management. The medical device company's QC laboratory tests and releases approximately one thousand lots of reagent product per year, performs stability studies on over fifty different products and maintains over thirty separate instruments in order to maintain its operational objectives. As more and more labs within biotechnology companies and hospitals perform high throughput and routine tests the reliance on a LIMS infrastructure is no longer an option [4]. For example, when looking at the science behind genomics and microarray technology customized data management systems have proven to be a robust solution in both private and academic environments. Without the use of data management systems

technologies such as microarray gene expression profiling would prove to be impossible to manage [4]. This same concept applies to genotyping laboratories that rely on such tools to process large amounts of data in an efficient and safe manner. These labs rely on data management systems and software to reliably and safely characterize patient genotypes in order to provide physicians with treatment options for their patients [5]. Like gene expression and genotyping laboratories, clinical and QC laboratories in both the private and clinical sectors have come to the point where data management is an absolute necessity due to the large volume of testing and data generation that occurs within them.

## CASE STUDY

When a LIMS project is initiated, it is critical to clearly identify the needs of the users of the software in order to identify the requirements for the software so that the software developers can deliver a product that is appropriate for the setting in which it will be used. When the medical device company's QC laboratory scientists were asked what they needed from a LIMS the following were their responses:

A system that can perform calculations and disposition product as pass or fail.

A system that can record what materials were used for a test so if there was a problem further down in the process materials used could be traceable and easily identified.

A system that can determine where samples are in the lab. Specifically, what phase of testing and product release are the samples at.

A system that can aid in workload management and test scheduling.

A system that can track and trend product and instrument performance as a tool for investigations as well as proactive instrument and product monitoring.

A system that can alert scientists when a stability test point is coming due so that is not inadvertently missed.

A system that can reduce human errors.

With these seven user requirements came over two years of software development activities that created software that satisfied each requirement. In addition to the requirements the software developers had to develop customized interfaces to each instrument platform in the laboratory so that the LIMS could communicate effectively with the instrument to send and receive data over the lab network. For the software developers this proved to be the most challenging phase of the project.

The project management of the medical device company's LIMS project was very challenging for the project team and even for senior management. The project plan included a Gantt chart with over two hundred tasks, one hundred of which were directly related to the implementation of the software into the lab environment. The project milestones included the development of the user requirements and software specifications, the development of the instrument platform interfaces, the conversion of the written lab processes into electronic test protocols, the validation of the software and all associated test protocols, the training of the lab and support staff and finally the go-live implementation of the LIMS. The project management of the LIMS implementation in the medical device company's QC laboratory proved to be difficult for the project team because the scope of work and the level of detail required was not fully realized until the project started to progress.

The first two years of the project was focused on the software development where the laboratory scientists provided their requirements and feedback on the design as it progressed. It was not until the project team faced the task of the conversion of the written lab processes into the electronic test protocols did the amount of work and detail required come to fruition. What the team estimated to take only two weeks to complete actually took two to three months. This lack of experience of a LIMS implementation is what made the project management so difficult for the project team.

For senior management the challenges were managing the budget of the project and preventing scope creep. As the project became popular in the business unit more and more laboratories wanted to become a part of the LIMS implementation. These laboratories included departments such as technical support, medical affairs, manufacturing and new product development. Each of these departments wanted to put in their own customized features to meet their own user requirements. Senior management had to make a decision to limit the implementation to only the QC lab so that the project could stay on course and within budget. This decision was met with a lot of resistance and disappointment, but senior management maintained their decision and the integrity of the project.

When a company or hospital makes the decision to implement a LIMS it comes with the very difficult task of convincing senior management to fund such an expensive project. For example, the medical device company's QC laboratory LIMS project cost the business unit approximately half of a million dollars over a three-year period. Since a LIMS can be very expensive and take a lot of time to implement senior management at any organization needs to be assured that such an investment will provide a reasonable return.

In general, most laboratory managers justify the implementation of a LIMS by claiming it will bring increased organization and it will improve the overall efficiency of the laboratory [6]. According to Steve Rushing in his article titled, "Consider how an LIS fits into your enterprise's strategy," he states, "it's time to move away from a microscopic obsession with incremental lab gains and take a macroscopic view of where your overall enterprise is heading" [7]. In addition, in his article Mr. Rushing emphasizes how a LIMS can support acquisitions and consolidation while enhancing an organizations overall business strategy [7].

Although a LIMS can be a very large investment of an organization's time and money it can also bring forth many advantages. The first of these advantages is the ability of electronic record keeping. Paper-based processes are not only obsolete and cumbersome, but they often lead to an increased rate of human error. By interfacing instrumentation to an electronic record keeping system you virtually eliminate all human interactions between a patient's test results and their medical record. This includes calculations that must be performed to determine drug therapy levels, flagging of abnormal test results, and alerting physicians of a life-threatening test result. This leads to another great advantage of a LIMS implementation in a laboratory. This advantage is the reduced need of technical staff to perform calculations, interpret the test results, and report results to physicians.

Another advantage of having a LIMS is that scientists and physicians have immediate access to an electronic library of data. Data can be plotted over time for a specific patient. Data can be plotted over time for a specific laboratory instrument. For example, in a hospital laboratory a LIMS can allow for laboratory staff to be able to efficiently handle large amounts of data that is generated from their numerous instruments and have the ability to organize and plot the data to be able to monitor the numerous instruments and maintain quality control throughout the laboratory [8].

One of the many advantages of a LIMS in a laboratory environment is the ability to encourage good laboratory practices by the implementation of standardized protocols, record keeping, and data analysis [8]. These areas are just a few of the many entry points of where human errors enter lab operations and cost laboratories a lot of time, money, and effort. More importantly, these areas are where human errors can lead to a delayed or improper medical treatment to a patient.

For the medical device company's QC laboratory the justifications used for the implementation of a LIMS were very much alike those discussed above. Senior management was assured that the system would bring greater efficiency, productivity, and compliance to the laboratory through several different methods. The first of these methods was the electronic data management of product release testing data, on-market product stability testing data and instrument quality control data. This feature gave the laboratory the ability to track and trend data within minutes through electronic data mining inquiries that

aided in product and instrument monitoring as well as investigations. Next, the LIMS offered an error proofing system that used a prevention approach. The automation portion of the system enforced compliance by forcing the laboratory staff to follow standardized procedures. The system then automatically performed calculations and assigned a disposition of pass or fail to each test completed. Given the number of human errors and corrective actions that had occurred in the QC lab over the years the investment in a LIMS was an easy decision.

The scope of validation activities that is necessary for the implementation of a LIMS depends on what the system will do. If the system is simply transmitting data from an instrument to a database the scope of validation is much less than if the system is performing calculations and then disposition test results. There are other things to consider such as trending reports and statistical reports that can be generated from the LIMS and will also have to be validated.

The medical device company's QC laboratory LIMS entailed all of these mentioned above and as a result the validation activities took several months to complete. The validation activities were done in phases and started with the base software within the server. The validation then expanded to the instrument platform interfaces and communication to the server. Next, the validation activities focused on the laboratory test protocols. This area of validation proved to be the most time-consuming and tedious of all the areas because it involved a lot of detail that was built into the paper-based procedures that were used for over twenty years. It was extremely important that the intent and science behind the test procedures was not altered in any way during the conversion and validation from a paper-based process to a completely electronic process. Finally, the validation activities concluded with the customized reports that were created for lab management and quality assurance to be able to monitor and run the lab efficiently.

Like validation, the actual Go-Live implementation for a LIMS can vary greatly upon the scope of what the LIMS is designed to do. One thing that must be considered for a LIMS implementation is how many workstations are needed throughout the laboratory to allow for efficient operations. It would not be appropriate to have a scientist waiting in line with patient samples in his or her hand in order to gain access to the next available LIMS workstation. More importantly, the training that must be conducted with the lab staff and support groups before going live with the system is something that must be well thought out. Most likely there will need to be numerous training sessions with the different types of personnel that will interact with the LIMS. The repetition of training is necessary for the staff to build a feeling of confidence and comfort with the LIMS. In addition to this, lab management may want to consider a phased rollout of the system in lieu of just flipping the switch completely all at once. This is sometimes preferred just in case something goes wrong so that the entire lab will not be shut down and crippled. These are just a few of the things that must be thought about while planning a LIMS implementation.

With the LIMS implementation the medical device company's QC laboratory management chose to do several training sessions along with a three-phase rollout. The first phase entailed instrument quality control testing and monitoring, the second phase focused on product release testing and the final phase focused on product stability testing and customized reports. The entire implementation period lasted for three months so that there was ample time for adjustment in-between each phase. The medical device company's QC laboratory implementation was not flawless, however at no time was the lab crippled or unable to test product. Some of the issues that came up during the implementation were networking issues where one instrument was not talking to the server. Another issue was where some lab scientists could not access certain areas of the LIMS because they did not have the appropriate access levels on their accounts. Overall, all of the issues that surfaced were minor in nature and they were resolved fairly quickly as not to cause any major interruptions. This fairly uneventful implementation was largely due in part to good planning with a phased implementation and the fact that support staff from IT and the

software development teams were on hand in the lab for the first week of each phase of the implementation. This allowed any issue to be triaged immediately and in most cases resolved before anyone could even learn of the event occurring.

## CONCLUSIONS

The implementation of a LIMS in a hospital or biotechnology laboratory is a complex and difficult process. The process begins with collecting the needs of the system users and then translating those needs into system requirements. Next, the software development cycle begins and can take years to complete, depending on the complexity of the system and the number of instrument interfaces that must be created. As the project is well under way the conversion of legacy paper-based processes must be converted into electronic test protocols that become embedded into the LIMS. The final phase of a LIMS project is the validation of the entire system and then implementing the system into the lab environment.

For the medical device company's QC laboratory the LIMS project took over three and a half years from beginning until end. When a hospital or other organization is considering implementing a LIMS in their lab environments senior management must fully appreciate the amount of time, money and dedication that must be given to allow for such a project to succeed. In the case of the medical device company there were several occasions where the project was questioned and almost canceled. It was the determination of the dedicated project team and the project manager that convinced senior management to allow the project to be completed and appreciated as it is used today.

## REFERENCES

A full set of references is available upon request from Arvinder Loomba, San Jose State University.