How Can a LIMS Needs Assessment Save the Laboratory Money?

Laboratories must have a clear plan when automating

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Figure 1: The major elements in the design of a Needs Assessment Plan

In today's fast-paced laboratory environment it is not only important that a laboratory have an integrated laboratory information management system (LIMS), it is essential for long-term viability. Data must be accurate, available quickly, converted into information and knowledge and in a format that is easily usable for managers, customers and employees. LIMS databases are designed to aid the laboratory in all aspects of sample analyses by facilitating rapid login, calculating turnaround times, maximizing productivity and profitability, QA/QC (quality assurance/quality control), regulatory compliance, as well as helping to meet accreditation requirements.

A LIMS also can automatically print or e-mail final analysis reports results, certificates of analysis and invoices and post them to an integrated, secure Web portal. Tasks associated with samples, such sample tracking, scheduling through reporting and disposal, benefit through the entire process when using a well implemented LIMS. Most managers know what is possible, but are not sure how to realize those productivity gains in their laboratory: what software tools to purchase, what hardware to purchase, what standard operating procedures to put into place, and what processes to execute.

In these cases, laboratory automation and a LIMS needs assessment can be extremely useful. We have all heard the horror stories in which the incorrect software tools, LIMS, and/or hardware were purchased and hundreds of thousands and, in some cases, millions of dollars were spent on toxic assets.

Starting any automation project without an assessment plan or a list of specifications is analogous to going on a road trip without a map or destination; you may have a great time and spend money, but you will never know where you are going or when you have arrived. A laboratory automation needs assessment provides a roadmap of exactly where the laboratory is currently (in terms of automation) and where it desires to be, with clear requirements, goals and milestones. A laboratory automation needs assessment looks at the current state of the laboratory (today) and compares that to where the laboratory would like to be or needs to be (in the future) to increase efficiency, productivity and profitability. A needs assessment is also often referred to as a "gap analysis."

For the needs assessment to be valuable, it must be conducted by someone who has laboratory and automation expertise. One without the other will yield a report that may be biased. It is important to carefully evaluate the individual who will be conducting the assessment. Learn how long have they been performing assessments, what are their credentials, and what is the feedback from their references. One of the advantages to having an external consultant who is familiar with the laboratory and IT environments is that this individual comes in "fresh" with no opinions. They can objectively observe operations and make recommendations based on what they have experienced to be successful in similar laboratory environments.

Needs assessment
What is a "need" in general and in terms of laboratory automation? A quick examination of an online dictionary reveals the word as either a verb (to require or be in want of, to be obliged) or a noun (the condition of lacking something, a requirement, necessity, poverty or destitution and distress). It is clear to see how these definitions also can relate to a laboratory environment. In essence, a laboratory needs assessment involves gathering requirements of what is necessary for the laboratory to become more automated, efficient, organized and productive.

A needs assessment is a useful tool to determine the current status of automation in a specific laboratory and provides information about the current operations, processes and procedures in place, such as the technology tools being utilized, resources, level of expertise with the current tools, and current challenges that the laboratory may face. For large organizations, it can be costly to perform a laboratory automation needs assessment because they typically have multiple departments, hundreds of employees and many processes and procedures that must be diagrammed, understood, evaluated and dissected to evaluate the efficiency of the laboratory workflow. Although this is such a critical step to the success of any project (especially laboratory automation), many companies don't really understand the benefits, or they feel that an assessment will require additional time and money for a project and slow down progress.
In reality, a thorough needs assessment will actually accelerate a project. Goals and objectives will be clearly defined,

adequate resources allocated, risks will be identified and discussed and plans will be put in place to mitigate those risks. Additionally, needs assessments often uncover unknown "gaps" or identify unknown risks which could cause project delay. This is also a resource inventory assessment; how are resources currently being utilized and what changes in resources are required to achieve the required level of automation?

Additionally, beginning any project without a plan or requirements means that a client really doesn't know what they are looking for, so they won't know when the "right" solution is presented to them and they can easily be mislead. This can cost clients hundreds of thousands to millions of dollars, not just in monetary loss, but also in wasted resources (employee time trying to implement an improper solution), which can in turn negatively impact morale and lead to further reductions in productivity and lack of buy-in in future projects.

I recently heard one example of a large public health laboratory that purchased thousands of dollars worth of label printers for bar-coding purposes. Once the printers arrived, it was realized that they were unable to print the bar-code size that was needed for the labels they required. To mitigate the inefficiencies in the bar-code printers, adapters were purchased to rectify the problem. These also did not work. Finally, requirements were documented, vendors were contacted, requirements reviewed and a new vendor was selected to provide the appropriate bar-code printers and labels that met the requirements of the laboratory. The fact that the requirements were not defined in the beginning of the project cost the laboratory valuable time and money that could have been spent on other programs.

Lack of a needs assessment plan cost the laboratory:

• time (almost a year was wasted which does not include employee time to try to make the label printers work)
• money (spent on all of the hardware, software, cables, and labels)
• the embarrassment of wasting money by selecting the incorrect vendor and hardware.

This is just one example of the importance of a needs assessment plan in a laboratory automation project.

Figure 1 depicts the major elements in the design of a needs assessment plan. The needs assessment plan can be broken down into six stages:

1. Objectives – What are you trying to understand or learn? It is important to determine as well as define why the assessment is being conducted. Determine purpose and objectives.
2. Target – You must identify the key team members/resources/stakeholders who will provide the information and data on the current state of the automation in the laboratory, as well as where the laboratory desires to be in terms of automation.
3. Sampling methods – It is important to define sampling in terms of how a subgroup of individuals will be selected and what tools will be used to extract information from this group. What will be their roles and responsibilities?
4. Data gathering – How do you plan to pull together and organize the data to prepare it for analysis in a meaningful manner?
5. Data analysis – How will the data be reviewed and analyzed? How will data be converted to information and finally into knowledge? Establish a realistic timeframe and work plan.
6. Decisions – What will be the criteria for making decisions? How will decisions be made and communicated?

Benefits of conducting an assessment
An automation needs assessment can be a powerful tool used to assign priority to technology tools, resources and service needs, as well as to develop strategies to address them. The next few sections will go into greater detail in describing the key elements of a needs assessment in order to provide the reader with a clear understanding of why it is important and to describe key elements. A comprehensive needs assessment:

• Describes the laboratory automation and LIMS needs of the laboratory and includes a sample workflow diagram.
• Furnishes an inventory of existing technologies in place, as well as resources available to the project as new technology tools or training are implemented.
• Provides a gap analysis of the met and unmet needs within the laboratory and ensures that everyone has a clear understanding of those needs.
• Presents results in formats useful for management in priority setting, in terms of resources required (human and budgetary), training, new technology tools or equipment needed.

Defining satisfied and unsatisfied needs
A significant part of the needs assessment is the examination of the needs and requirements of the laboratory. This list is generated based on data gathered and can be broken down in several ways.

• First, those automation and LIMS needs that are critical (definitely required, such as those due to regulatory compliance, i.e. CFR 21 Part 11);
• Then, those that the laboratory must have for meeting client's needs, such as secure, Web-based reporting;
• Finally, there are the nice to have needs, which can include daily automated reports on chemicals and reagents that are about to expire this month.

Although information on the chemicals and expiration dates can be queried, an automated feature is much nicer and will save the laboratory money in wasted chemicals, but probably not as much money as is saved with a Web portal. A Web portal allows clients to access their sample status, .pdf final analysis reports and invoices. So, the management team's

responsibility is to understand the cost benefit of each automation enhancement and to implement those that provide the laboratory with the largest cost savings, immediately followed by those that have a smaller return on investment. When a laboratory team defines every need as critical, projects can fail because there is no triage. Projects become overwhelming and, as a result, are poorly executed.

A satisfied need is a technology/resource/service within a laboratory that is currently being addressed through existing resources that are:

• Available to the laboratory when they are needed (full-time employees, contractors or consultants). An example is a laboratory that outsources their information technology needs, such as a contractor that maintains the laboratory network and computing infrastructure or provides programming support on an hourly basis.
• Appropriate in skill set and accessible to the laboratory when needed. An unsatisfied need is a technology/resource/service within the laboratory or organization that is not currently being addressed through existing technology/services and activities because:
• No services (resources: consultants, contractors or employees) are currently available to facilitate automation goals.
• Required technology tools/resources/services are either unavailable or inaccessible.

Key questions to be answered
A laboratory automation and data management needs assessment provides critical information about the current state of a laboratory. In collecting needs assessment data, it is important to ensure that you are interviewing key stakeholders. Stakeholders are those individuals that are intimately familiar with the internal operations of the laboratory and interact directly with:

• Customers, from securing the business to sample login
• the group responsible for the analysis (SOPs, QA/QC, validation, etc.) and reporting
• those responsible for billing.
Some examples of specific questions in a needs assessment may include:
• What are the risks, practices, attitudes or beliefs of the key stakeholders in the laboratory? Are they excited about new technology? Do they fear change? Will they "buy in" to new sample processes or procedures that are more efficient but very different from the way in which samples were processed in the past?
• To what extent is the laboratory currently relying on external contractors to provide critical services?
• What barriers (if any) do key laboratory automation stakeholders experience? Are there adequate computers and required software to complete work tasks on time, or is the lack of computers impeding productivity? What type of training will be required? Are there adequate software licenses for key productivity tools? • What programs or strategies work best with the stakeholders in rolling out new technology?
• What resources (laboratory, IT, management) and services are available, accessible and appropriate for this laboratory automation project? Has a project manager been identified? Are there adequate resources (people, time and money) to execute the requirements indentified by the needs assessment, or does the scope of the project need to be scaled back?

Types of data
During the course of the laboratory automation needs assessment, several types of data will be collected for analysis. These include:

• Primary data: original data that is collected and analyzed during the on-site meetings, interviews and focus groups.
• Secondary data: information that was collected by another person and can include internally conducted needs assessments, as well as assessments done by others.
• Qualitative and quantitative data: Qualitative data is defined as data that is presented in a narrative format that cannot be expressed numerically. This information is typically the result of observations, focus groups, or interviews. Numerical data is often much easier to present, as it can be displayed graphically in bar graphs, pie charts or histograms. This quantitative data is often the result of survey questions with close-ended questions or statistics from within the laboratory such as typical turnaround times for various types of samples, number of samples processed by each laboratory analyst or average time spent on each test method. A good needs assessment should contain a combination of both qualitative and quantitative data. The data should be formatted and presented in a clear and concise manner that will facilitate decision making.

Methodologies
There are many different methodologies that can be used, and all will yield data. Some methods are more suited toward certain environments, and the consultant will evaluate which tools are appropriate based on conversations and observations of the laboratory environment and culture. Secondary data refers to data that was pre-existing (collected either by the laboratory personnel, a consultant or someone else familiar with the laboratory). This is data that can be analyzed or re-analyzed as part of the needs assessment. However, it must be weighed in terms of the age of the data, as laboratories are constantly evolving.

Another very useful method of obtaining data is the use of focus groups. These are typically small groups whose discussion is planned and facilitated by an experienced moderator. Another useful technique is the use of in-depth interviews, as some people are shy and do not speak up in groups and have difficulty in conveying or articulating their needs in a group setting. Individuals selected for in-depth interviews must be carefully selected for their expertise and knowledge of the laboratory environment. Since one person at a time is interviewed, this method is time-consuming.

An additional method is holding laboratory meetings. Laboratory meetings involve a large group of laboratory stakeholders

fom which qualitative data is collected in a less formal setting. These meetings also are facilitated and documented; some consultants may choose to videotape or tape record the meetings for future review. Finally, there is the survey or questionnaire. This quantitative method involves collecting data from a sampling of individuals in the laboratory. Information can be used to create group level summary statistics and results may be generalized to the entire laboratory. All of the data gathered, distilled and summarized will be parlayed into information and then knowledge of what is required to make the laboratory automation and laboratory information management system a success.

Presenting results and making decisions

Laboratory needs assessment data can be presented in many ways, and there are some ways to present the data that can enhance the outputs of the assessment. The team must decide when, how and in what form results will be presented and to what audience/s. In addition, the team responsible for the needs assessment must discuss what efforts may be needed to promote the acceptance of the assessment results by the laboratory community. It is helpful to organize the needs assessment data by target laboratory population. If there were needs identified in the quality control area, present those needs to that particular group for discussion. Select clear, easy-to-understand language and include multi-media formats for the presentation of the results. The use of these formats will facilitate discussions and the decision making process. Then consider all of the potential uses of the results. For example, the need or requirement may be displayed in a table alongside a column that lists the cost to meet that need and another column that depicts the return on investment for that specific requirement.

Following the presentation of results, some decisions will be very easy to make in financial terms. If one additional resource is hired and provided the proper technology tools, it is anticipated that this individual could complete a specified amount of work that would generate some amount of revenue. If the calculations are weighted in the direction of significant financial increase, the decision is even easier. Some decisions may not provide exact data. In these cases, managers must rely on historical data and assumptions based on available information.

Conclusions

As a result of reviewing the needs assessment final report, the laboratory team will have a better high-level understanding of where the laboratory stands in terms of laboratory automation, what gaps currently exist and what steps are required to move the laboratory to a higher level of efficiency and automation.

Another benefit of the needs assessment is that, since the entire team provided feedback for the needs assessment, there is a good understanding of the processes, as well as why certain automation tools are a higher priority than others. This promotes team "buy in," as each member was involved in the process and completely understands their role in the deployment of the enterprise automation solution. The cost of the assessment is well worth the enhanced understanding of the automation needs, as it documents the savings of automation enhancements and defines total project costs.

The primary goal is to utilize proven tools, techniques and methods to better understand the laboratory's current automation position and what is needed to move the laboratory to the level of automation that is optimal for their business. Too many projects begin with the "ready, fire, aim" mentality in which things can be fixed later. This approach can be frustrating and has the potential to be a costly approach toward laboratory automation. A poorly planned project not only costs a company money, but negatively impacts employee morale.

On the other hand, a well-organized and planned project with a solid blueprint (based on an automation needs assessment) will provide positive return on investment, with a clear understanding of the total costs, requirements and resources clearly defined. A needs assessment will identify the knowledge, skills, capacity, expectations, tools and environment to execute a successful LIMS and laboratory automation project. A solid plan also will boost employee morale, as each team member will understand and appreciate their role in the project and share in the project success.

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