# Building a Proficient Project Team for a Successful LIMS Deployment

Team Collaboration

Project Management

Communication

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Change Management & Risk Mitigation

Project Scope & Deliverables

confience

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# INTRODUCTION

Laboratory Managers seek out a Laboratory Information Management System (LIMS) for many reasons; these include enhancing data quality, meeting compliance requirements, resource maximization, and cost savings. In today's complex regulatory environment, a LIMS is no longer a luxury; rather, it is a necessity for all professionally staffed and quality certified laboratories.

A modern LIMS provides features beyond sample tracking and data entry, affording laboratories the ability to schedule sample collection, shelf-life and stability studies, ensure data meets appropriate quality control standards, and populate configurable reports with that data. Additionally, the LIMS should support the management of inventory items including chemical reagents and assets, log and monitor staff training and certification,inst rument maintenance and calibration and corrective and preventative actions.
A comprehensive LIMS also provides ancillary functionality such as a web portal for access to results and reports outside the LIMS and a mobile application for use in field sampling.

The process of selecting a LIMS, partnering with a LIMS vendor, and deploying a new LIMS is complex and requires the input of a full complement of players from both the laboratory and the chosen vendor. This paper is designed to provide guidance on the necessary steps for a successful deployment of your chosen LIMS, and to offer insight into some of the best practices in overall Project Management.

**Buy-in – 30%**
Commitment from leadership with dedicated human resources, time and capital.

**Right LIMS – 20%**
A solid LIMS partner that knows your business with the expertise to conduct a needs assessment if needed.
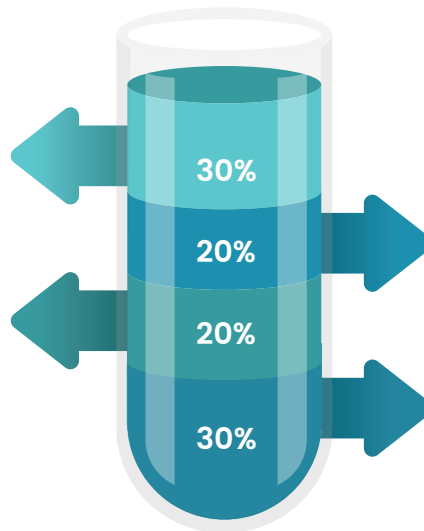
**Project Champion – 20%**
A project manager that is a cross between a cheerleader and a diplomat, to keep the project on track.

**Realistic Expectations – 30%**
An understanding that a significant amount of configuration must be completed before time and cost savings are realized.

*Figure 1 - Elements to a Successful LIMS Deployment*

## Preparing for a New LIMS

Building a culture of sustainability, efficiency, and compliance requires that Laboratory Managers take action to ensure that resources are maximized and waste reduced. Automation is an essential component. So where does a Laboratory Manager begin the task of selecting and implementing a new LIMS?

The LIMS selection and implementation process begins with assembling a multifunctional team of laboratory management, quality management, business, IT, and laboratory end-users for a solid understanding of the current state of the laboratory and what the vision is for the automated laboratory.

## Laboratory Needs Assessment

The process of understanding the laboratory's current state begins with a needs assessment that is conducted by the multifunctional team or an outside consultant. A needs assessment provides the laboratory with an outline of the current and to-be processes through an examination of what works, what could be improved upon, and what needs to change.

The outcome of the needs assessment is a final report that acts as a guide for the laboratory to use in identifying the best LIMS vendor to meet its needs and offers recommendations on best practices in implementing the new LIMS.

Topics that typically comprise a needs assessment final report include:

- Findings of surveys and comprehensive interviews with key lab management and staff
- Documentation of the roles and responsibilities of the LIMS team
- A basic understanding of the key LIMS requirements
- Documentation of current technology environment, including specifications of servers, software in use, and network infrastructure
- Opportunities for automation, such as barcoding, integration of instruments, automated tasks, limit checking, alerts, emails, and report generation
- Reporting requirements for each section
- Integration of systems (ERP, MRP, MES, etc.), including data to be shared and the frequency and direction of the exchange (to/from LIMS)
- Observations gathered by the team or consultant during the engagement
- Analysis conducted by cross-functional team
- Documented issues/risks/concerns and mitigation strategies
- Recommendations related to sample process flow that may include suggestions for streamlining/improving the current flow
- Recommended plan for automating laboratory processes based on the organization's business requirements
- Efficiency and data quality improvement metrics and KPIs
- Regulatory requirements that can be met/facilitated via automation

## Defining the Project Scope and Deliverables

Once the team has completed the review of the needs assessment report, they can begin to prioritize tasks and goals in terms of what should be included in the project scope. Often when the project scope is extensive, laboratories divide the project into phases, so that the work and impact on the organization is more manageable. This is critical because the team must be realistic about their expectations in terms of the desired level of automation and the budget, as well as the expertise of the team members. By breaking the project requirements into smaller groups such as: 1) Mandatory, 2) Beneficial, 3) Nice to Have, the laboratory team should realize the benefits and savings in the earliest phase, which will help to support the subsequent phases.

It is equally important to create a project plan that outlines each task, the necessary resources to execute each task, and a rough timeline. If the current team lacks the expertise in any area, hiring a consultant, filling a vacant position, or creating a new position may be warranted.

Planning for the implementation of a new LIMS involves careful consideration and definition of the project scope and defining the project team, resources, and budget required to see the project through to completion. These are principal elements of project planning that provide a vision of the full project lifecycle to ensure all goals are achievable.

There are many factors to consider in implementing a LIMS when defining the project scope, after the need and feasibility have been verified. A few of these considerations are included in the following table.

**Example Project Scope Consideration**

| |
|---|
| Volume of tests, methods, parameters, collection sites, products, customers, and contacts. These may affect the cost, number of licenses and static data set up, and will help you understand the size of your project scope. |
| The number of facilities and physical laboratory sites. |
| The number of unique departments in the laboratory. |
| Total number of users within each facility/lab. This can affect the rollout size and may reflect the need for a phased approach. |
| Understanding internal requirements, staff's expertise, infrastructure, timeline, capital, and contingency. |
| Number of instruments to be integrated and the potential ROI for each. |
| The need for system integrations including ERPs, MRPs MESs, Accounting, etc. |
| How many custom reports will be required, and will these be outsourced, or will internal IT staff create these reports? Can internal resources work on the lower priority reports to reduce overall project costs? |
| Is there a need for ancillary functionality, such as mobile technology (tablets/smartphones), customer portals, environmental monitoring, etc.? |
| Are there any unique requirements that may necessitate custom workflows, and how often are these executed? |

*Table 1 – Project Scope Consideration*

Clearly defining the project scope and objectives, and getting leadership buy-in cannot be underestimated. Including the end-users of the system in this process is also critical. In selecting the right LIMS for your organization, you should ask questions that can determine the key market the LIMS is designed to manage. Is it designed for use in a clinical or

pharmaceutical environment? If so, it may not work very well for a wastewater plant and vice versa. Choosing the wrong LIMS for your industry can result in costly customizations, delays, and an expanded project scope, to fit the solution to your laboratory.

Understanding and communicating stakeholder expectations and gaining their concurrence with the project plan are essential to a successful LIMS deployment. It is also important to have consensus on the delivered products and professional services, and to have them documented in enough detail that they can be delivered accurately and effectively.

## Project Management Requirements

It is important to assign a dedicated vendor and Laboratory Project Manager (PM) to oversee the project. These individuals should have project management experience, laboratory knowledge, and an understanding of how LIMS work. They will each serve as the single point of contact, and assist with managing the project deliverables, resources, and timeline.

The Laboratory's PM will serve as the LIMS Champion. They should have strong people and negotiation skills, with the ability to see the benefits of automation and help the rest of the team visualize these benefits as well. They will address any doubts and concerns from the team.



Manages the project plan

Defines the roles and functions of the project team

Understands and mitigates risks

Manages resources and project deliverables

Tracks and reports project progress and status

*Figure 2 – LIMS Project Manager Responsibilities*

## Laboratory Project Team Roles and Responsibilities

Part of the PM's responsibility is to define the roles and functions of the project team (Table 2), and identify the best resources for each role. The PM will help with allocation of resources and provide the team with a clearer understanding of their expected part(s) in the process. Typical project team roles include the Project Sponsor, who has decision-making capability. They are driving the project from an operational point of view to make sure that things continue to progress, and that the necessary resources are available. The PM is driving

the project from a timeline point of view, and/or getting the Project Sponsor involved if resources are unavailable.

An IT System Administrator and/or LIMS Administrator is vital. There may be an IT System Administrator performing server work, including database backups. They are moving database copies from development to testing to production, taking recurring snapshots, and doing restores, and may also act as the LIMS Administrator. Ideally, the LIMS Administrator should be someone from that laboratory, as that person will be responsible for ongoing maintenance of the LIMS, such as adding a new test, updating the version of parameter, changing limits, and/or providing frontline support to the team. Additionally, the team should include IT and laboratory subject matter experts.

| Role | Responsibility |
|---|---|
| **Project Manager** | Manages all project activity, directs implementation resources, reports progress and status, tracks events, functions as liaison to LIMS vendor, and signs-off on implementation deliverables, hardware delivery (if applicable), software installation, end-user and LIMS Administrator training.<br>**25-50% of time during project, assuming Project Manager is not playing LIMS Admin or DBA role. May increase for large/complex Project. 50-75% if acting as PM and LIMS Admin/LIMS DBA.** |
| **Project Sponsor** | Acts as a decision maker, especially for any issues between the laboratory and IT. Drives the project from an operational perspective, typically in conjunction with the Project Manager. Project Sponsor ensures adequate resources are allocated.<br>**10-15% of the time during project if Project Sponsor is not acting as Project Manager.** |
| **LIMS Database Administrator** | Assists with building and maintaining lab-side system integrations and instrumentation interfaces. Works with vendor to modify or design any additions to the current IT infrastructure. Participates in LIMS Administrator training.<br>**10-20% of time during Project, 5-10% of time after Project completion. Time estimates may increase with the need for System Integrations.** |
| **IT Subject Matter Experts** | Assists with building and maintaining lab-side system integrations and instrumentation interfaces. Works with LIMS vendor to modify or design any additions to the current IT infrastructure. Reviews system integration Requirements Documents (RDs). Assists with interfacing, installation, configuration of laboratory printers.<br>**10-20% of time during project, 5-10% of time after Project completion. Time estimates may increase with the need for System Integrations.** |
| **LIMS Administrator** | Responsible for LIMS Administration within the laboratory. Performs all laboratory SME responsibilities and acts as liaison between the Project Manager and other team members. Participates in LIMS Administrator and enhancement products training.<br>**25-50% of time during Project, 10-20% of time after Project completion. Note: Assumes one LIMS Administrator per Facility.** |
| **Lab Subject** | Responsible for gathering and populating the static data template to ensure it accounts for the current or future state workflow of the laboratory and samples. Participates in requirements gathering, reviews requirement documents for reports and parsers. Attends configuration working sessions. Lab SMEs also participate in end-user training.<br>**15-25% of time during Project, 5-10% of time after Project completion. May decrease for smaller Projects.** |

*Table 2 - Example Roles and Responsibilities*

The entire project team must have realistic expectations. Once the team is assembled, they should review the deliverables defined at the start of the project to ensure they are still relevant. If there have been changes, the PMs can choose to incorporate them into the scope either immediately, later, or not at all, keeping in mind that changes affect project scope, time, and cost.

The PMs should be managing the project plan, often executed as a timeline or project dashboard (Figure 3), while keeping the focus on the business value, and not the technical details.

A PM must have a good understanding of the activities, resources, and time required to produce the project deliverables and should be familiar with the resources available in terms of software tools, knowledge base, and mentors. The project plan should be regularly reviewed to ensure that the project is on budget and schedule and that there is a high-quality

work product. This review requires feedback from the team, so that if there are any issues, they can be addressed, and knowledge can be shared. Communication is critical to ensure that each team member is clear on their role and responsibility.

The workload will vary at distinct phases of the LIMS project, and the team must be prepared to execute on their tasks. The workload should be spread out so that each person can focus on their area of expertise, and tasks can be executed in parallel. Assigning all the work to one individual causes delays, as everything is dependent on the one resource creating a bottleneck. LIMS are best implemented with a team approach between the laboratory and the LIMS vendor, with frequent communication.

Tracking project progress is important, as the PMs can monitor and manage the actual progress with the planned progress and inform the team on the status. Any differences between the actual progress and planned progress/cost, schedule, and scope will need to be understood and managed to ensure the project stays on-track and on budget.
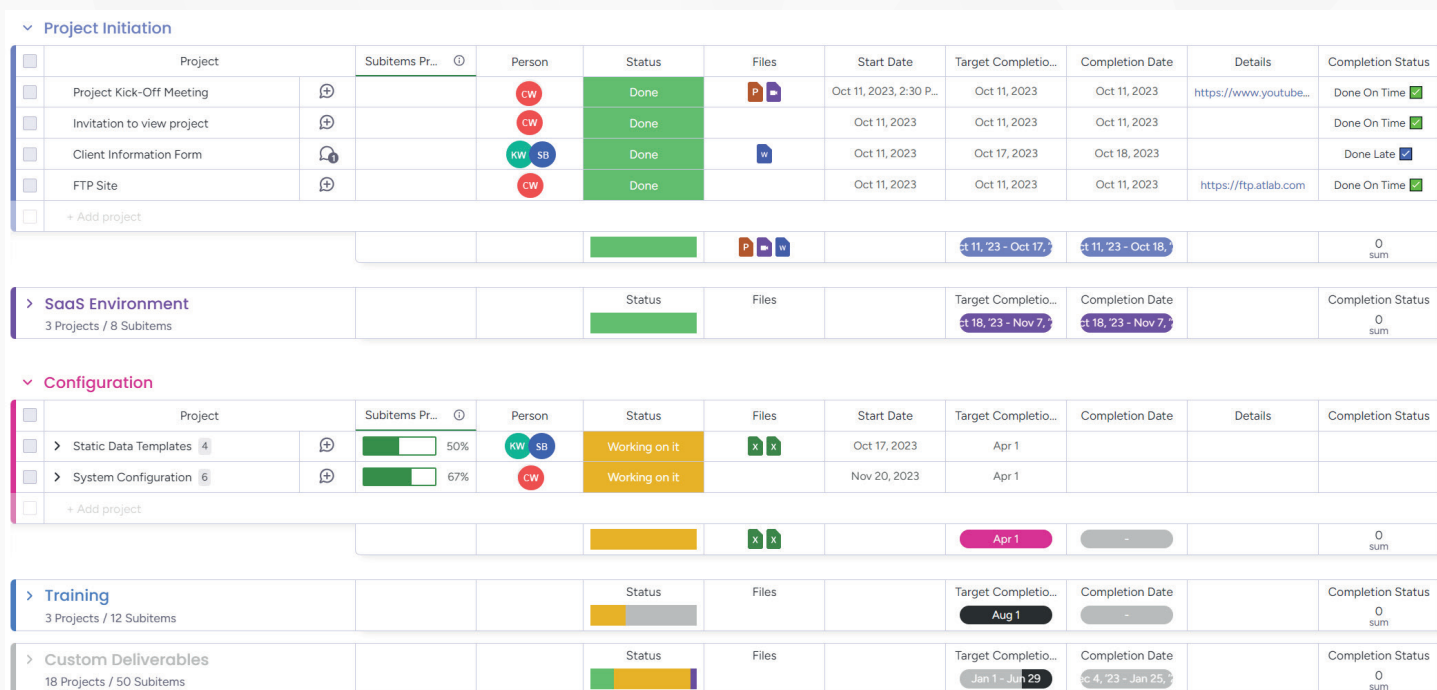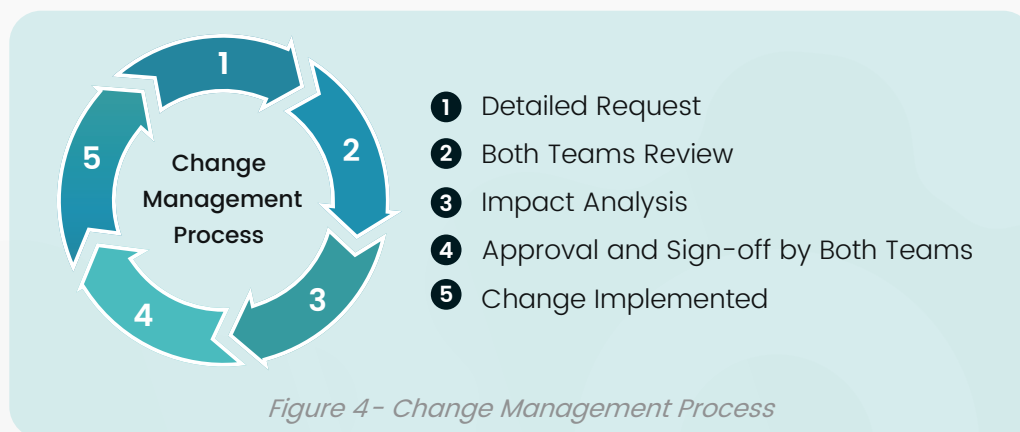


*Figure 3 – Example LIMS Project Dashboard (Monday.com)*

## Change Management and Risk Mitigation

Change management is as critical as planning is to the success of the project. It is important to have a change management process in place that requires both the vendor project team and the Laboratory project team to approve any change to scope of professional services, required deliverables, or any other aspect of the project. Changes should be timely requested and clearly documented so any impact on the project can be calculated. Teams should follow a process that requires a detailed write-up, review, and sign-off by both parties, prior to any change being instituted.

Another important skill that PMs must possess is understanding and mitigating risk. Risk management ensures that projects are executed according to plan, schedule, and cost. There may be too many risks to manage, so a project manager must triage the risks into several categories of the risk occurring-- highly likely, somewhat likely, and not likely, for example. The PM may manage the top 10 risks and be alert for new risks.



1. Detailed Request
2. Both Teams Review
3. Impact Analysis
4. Approval and Sign-off by Both Teams
5. Change Implemented

*Figure 4- Change Management Process*

Some examples of risks in LIMS projects include:

- Delay in hardware delivery
- Staff lacking the technical expertise to execute the tasks that were assigned to them
- Lack of management buy-in for the project
- High laboratory analyst turnover
- Old infrastructure that causes network outages

It is important that risks be identified as soon as possible and avoided. If a risk cannot be avoided, then it must be mitigated.

## SUMMARY

Many areas are important in project manament, but the areas of focus include:

1. Planning for the Project
2. Defining the Project Scope
3. Defining the Deliverables
4. Honest and Open Communication
5. Monitoring and Communicating Project Progress
6. Following Change Management Process
7. Understanding and Managing Project Risks