



# SCICORD

## LIMS Buyer's Journey

Selection, Implementation,  
and Maintenance of an  
Informatics Platform for Your Lab

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# OVERVIEW

## 1.1 PURPOSE OF THIS GUIDE

Selecting the right LIMS or Informatics Platform for regulated environments is a complex and critical process. Implementing and maintaining a compliant digital solution requires significant effort, making it essential to make informed, strategic decisions from the start. This guide is designed to streamline the purchasing process, reducing the risk of buyer's remorse by equipping tech buying teams with the insights needed to make confident, well-informed choices.

LIMS projects demand substantial investments in money, resources, and time. A single implementation can cost hundreds of thousands to millions of dollars and require extensive labor hours. Given these stakes, failure is not an option.

Getting the implementation right the first time is just as crucial. To ensure your LIMS optimizes laboratory productivity and efficiency while maximizing business value, following a comprehensive and proven methodology is key.

According to the 2022 Gartner Functional Business Buyers Survey:

The experience of purchasing and adopting enterprise technology is quite poor. Despite tech providers using sophisticated tools and tactics to advertise and sell their technology, tech buying cycles are long and often not successful.

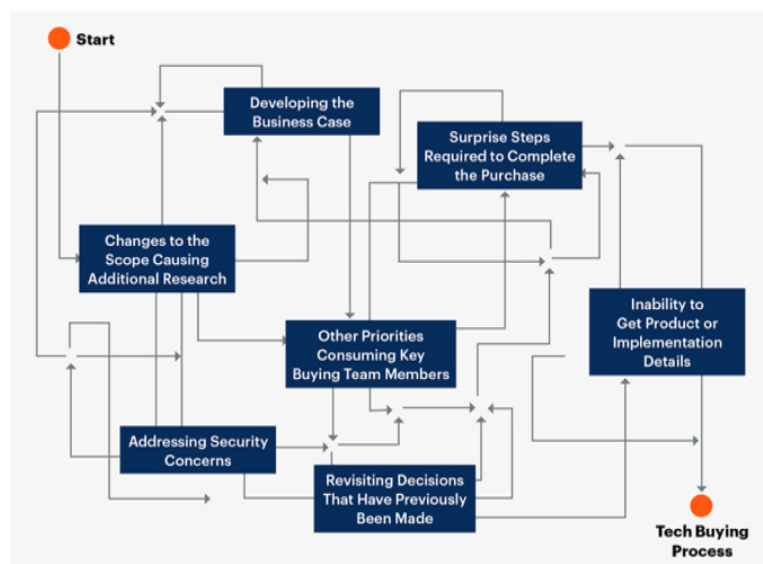
### Gartner Research provides the following points:

- Over 70% of buying teams experience significant delays
- Average tech buying cycle spans over 17 months
- 81% of buyers express some kind of purchase regret.

### Contributors to purchase dysfunction:

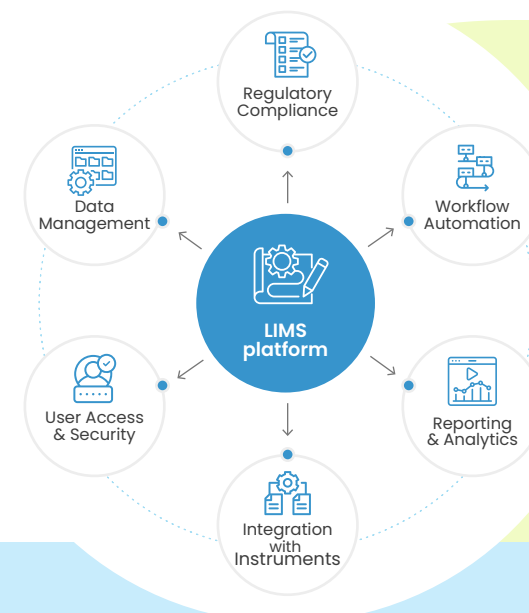
- Changes in scope causing additional research
- Discovering "surprise steps" needed to complete the purchase
- Composition of buying team

### Common Contributors of Delays in the Tech Buying Process



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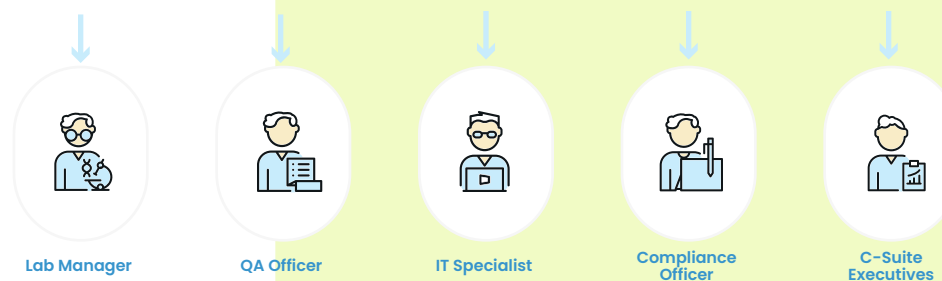
Gartner



## 1.2 WHO IS THIS GUIDE FOR?

This guide is intended for decision-makers and tech buying teams evaluating LIMS or Informatics Platforms, particularly in regulated industries. It is tailored for professionals responsible for selecting and implementing compliant digital solutions, including lab managers, IT specialists, quality assurance personnel, and regulatory compliance officers.

By providing key insights and strategic guidance, this guide helps ensure your organization selects a solution that meets both current operational needs and long-term growth objectives.



# DRIVERS FOR CHANGE

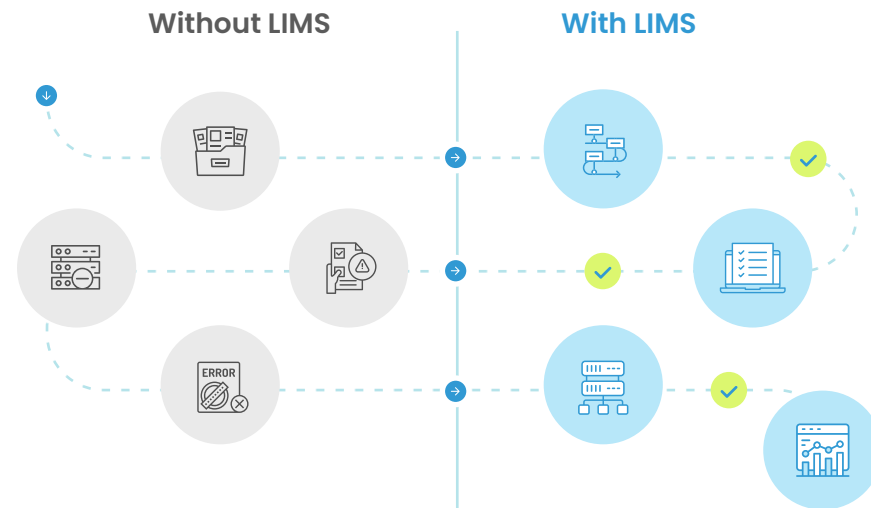
## Buying Journey Roadmap



Successful scientific organizations inevitably encounter challenges that necessitate moving beyond traditional paper-based methods, file shares, and spreadsheets—or even upgrading from an existing LIMS to a more advanced LIMS or Informatics Platform.

In today's fast-paced and evolving scientific landscape, laboratories must overcome numerous obstacles that make adopting a Laboratory Information Management System (LIMS) essential. Key factors driving this transition include the need for more efficient data management, enhanced regulatory compliance, and improved operational efficiency.

Laboratories handle vast amounts of complex data, requiring secure, accurate management solutions. Additionally, strict regulatory standards demand meticulous record-keeping and traceability, both of which a LIMS can efficiently facilitate. The growing emphasis on productivity and cost-effectiveness further pushes laboratories toward solutions that streamline workflows, minimize manual errors, and seamlessly integrate with laboratory instruments and systems.



## 2.1 SMALL TO MEDIUM ORGANIZATIONS

Use Case	Situation	Challenge	Expected Outcome
<b>Business growth</b>	Your organization is either growing, expects growth in the near-term, OR project portfolio is expanding. Data and samples are managed in spreadsheets or paper systems.	You realize that growth (number of samples, tests, staff, processes) will strain your current data management processes and stunt the expected growth.	Easy to use digital solution to manage samples and data. The solution enhances data integrity, supports sharing across your organization, automates repetitive processes, provides data security, allows visualization to drive insights, and enables organizational growth.
<b>Products are newly subject to regulatory oversight</b>	Your organization has developed product(s) which are ready to progress to a stage with some level of regulatory oversight. Data is recorded using spreadsheets, paper, and non-compliant products such as Microsoft Office or Google Docs.	You realize that your current processes are not suitable to manage data for a regulated product.	Informatics Platform which enforces compliance with regulatory expectations, and which encompasses your testing, formulations, manufacture, instruments / equipment). The digital solution can be implemented quickly, is easy to use, provides data security and comprehensive compliance
<b>Recent audit finding</b>	Organization has received a negative comment from internal (quality assurance) or external (FDA, Customer) auditor.	You must respond to the audit finding with enhanced compliant data management processes.	Implement an Informatics Platform to conform with regulatory expectations for testing, formulations, manufacture, instruments /equipment). The digital solution must be implemented quickly, be easy to use, provide data security and comprehensive compliance.



<b>Turnover in personnel</b>	Your organization has experienced a loss of experienced scientists. Company knowledge is locked in paper notebooks and spreadsheets which cannot be easily searched. Finding information has become difficult.	You recognize that turnover in personnel is hindering your operational effectiveness. Your research and development efforts are hampered by difficulties in accessing necessary information when required	Implement an Informatics Platform to digitize your company information in an easily searchable format. The digital solution must be implemented quickly, be easy to use, provide data security and comprehensive compliance.
<b>Resource constrained</b>	Your organization must accomplish more with limited resources. Handling new projects, compliance demands, and expanded scopes without increasing staff is essential. Your current documentation and review processes, reliant on spreadsheets and paper, are acting as bottlenecks.	You recognize that you must implement digital processes to enable staff to accomplish the new objectives without burning out	Implement an Informatics Platform to manage your samples and data more effectively. The solution must be easy to use, automate repetitive processes, be quickly implemented, and require minimal administrative overhead.
<b>New physical lab</b>	Your organization has acquired one or more labs with different ways of working and duplicated, often outdated legacy systems	To efficiently manage people and processes requires harmonized sample management, documentation, review, and reporting processes across labs.	Deploy an Informatics Platform to standardize workflows throughout your organization, modernizing and replacing outdated systems. This digital solution should achieve standardization while accommodating minor variations in scale and processes typical across laboratories. It must prioritize ease of use, rapid implementation, robust data security, and full compliance capabilities.
<b>Older digital system is no longer supported or requires extensive update</b>	Your organization implemented LIMS years ago.	The legacy LIMS may be: <ul style="list-style-type: none"> <li>- no longer supported.</li> <li>- requires an extensive update.</li> <li>- not well regarded by the user community.</li> <li>- requires extensive administration.</li> <li>- only partially implemented.</li> <li>- difficult to update to support process change</li> </ul>	Implement a comprehensive informatics platform which is <ul style="list-style-type: none"> <li>- accepted by the user community</li> <li>- simple to use and requires only minimal training</li> <li>- requires minimal administrative overhead</li> <li>- can be easily updated to accommodate change</li> </ul>
<b>Harmonization across the organization</b>	Several labs in your organization have merged under a single reporting structure.	The merged labs have different ways of working and legacy systems (often outdated).	Deploy an Informatics Platform to harmonize workflows across your merged labs, modernizing and replacing outdated systems. This digital solution should achieve standardization while accommodating minor variations in scale and processes typical across laboratories. It must prioritize ease of use, rapid implementation, robust data security, and full compliance capabilities. Change management is a key concern as the individual labs may be wedded to legacy systems.

## 2.2 MEDIUM TO LARGE ORGANIZATIONS

Use Case	Situation	Challenge	Expected Outcome
<b>Product line is changing requiring different solution</b>	New source of revenue kick starts review of current situation and alternative consideration:	The legacy LIMS may be: <ul style="list-style-type: none"> <li>- no longer supported.</li> <li>- requires an extensive update.</li> <li>- not well regarded by the user community.</li> <li>- requires extensive administration.</li> <li>- only partially implemented.</li> <li>- difficult to update to support process change</li> </ul>	Implement a comprehensive informatics platform which is <ul style="list-style-type: none"> <li>- accepted by the user community</li> <li>- simple to use and requires only minimal training</li> <li>- requires minimal administrative overhead</li> <li>- can be easily updated to accommodate change</li> </ul>
<b>Recent audit finding</b>	Organization has received a negative comment from internal (quality assurance) or external (FDA, Customer) auditor.	You must respond to the audit finding with enhanced compliant data management processes.	Implement an Informatics Platform to conform with regulatory expectations for testing, formulations, manufacture, instruments /equipment). The digital solution must be implemented quickly, be easy to use, provide data security and comprehensive compliance.
<b>Older digital system is no longer supported or requires extensive update</b>	Your organization implemented LIMS years ago.	The legacy LIMS may be: <ul style="list-style-type: none"> <li>- no longer supported.</li> <li>- requires an extensive update.</li> <li>- not well regarded by the user community.</li> <li>- requires extensive administration.</li> <li>- only partially implemented.</li> <li>- difficult to update to support process change</li> </ul>	Implement a comprehensive informatics platform which is <ul style="list-style-type: none"> <li>- accepted by the user community</li> <li>- simple to use and requires only minimal training</li> <li>- requires minimal administrative overhead</li> <li>- can be easily updated to accommodate change</li> </ul>
<b>Recent or proposed acquisition</b>	Your organization has acquired one or more labs.	The merged labs have different ways of working and legacy systems (often outdated).	Deploy an Informatics Platform to harmonize workflows across your merged labs, modernizing and replacing outdated systems.  This digital solution should achieve standardization while accommodating minor variations in scale and processes typical across laboratories. It must prioritize ease of use, rapid implementation, robust data security, and full compliance capabilities.  Change management is a key concern as the individual labs may be wedded to legacy systems.

## 2.3 CHANGE ROLES

Implementing a LIMS or Informatics Platform more in general brings significant organizational change, impacting various roles differently. Understanding how each stakeholder perceives and responds to this transformation is crucial for successful adoption. The following table outlines key roles affected by the change, highlighting their perspectives, concerns, and motivations.

Whether in a small-to-medium or large organization, individuals across lab operations, quality assurance, IT, and executive leadership play distinct roles in shaping the transition.

Recognizing their priorities and addressing their needs proactively can drive smoother implementation and long-term success



Lab Manager



QA Officer



IT Specialist



Compliance Officer



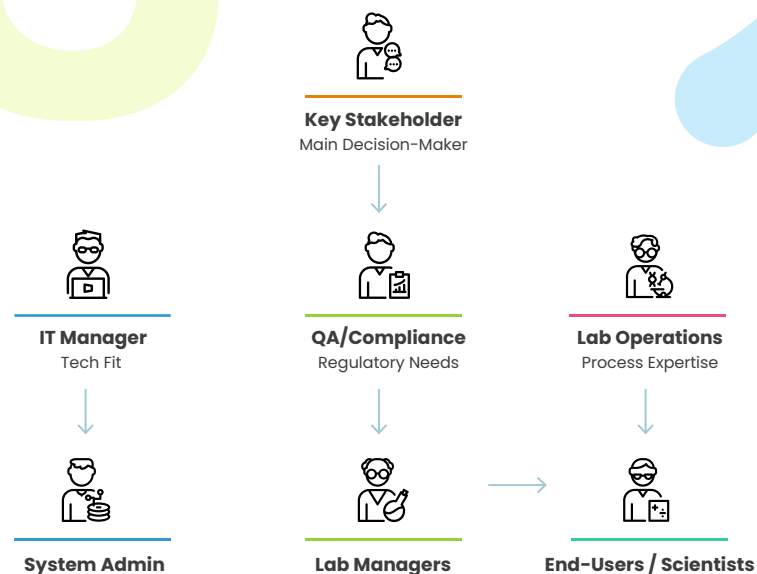
C-Suite Executives

Use Role	Small to Medium Organization	Large Organization
<b>Lab Staff (Analyst, Reviewer, Scientist)</b>	<ul style="list-style-type: none"> <li>• Realizes that the current situation (spreadsheets &amp; paper) is outdated.</li> <li>• Has digital experience in a prior organization and/or is technically proficient.</li> <li>• Motivated to effect a change and seeking personal or professional advancement</li> </ul>	<ul style="list-style-type: none"> <li>• Realizes that the current company technology is outdated.</li> <li>• Has experience in a prior organization and/or is technically proficient.</li> <li>• Motivated to effect a change and seeking personal or professional advancement.</li> <li>• Probably does not have the support of lab management.</li> </ul>
<b>Lab Manager</b>	<ul style="list-style-type: none"> <li>• Is reacting to change. These folks tend to be older and often not digitally proficient BUT realize that they cannot continue spreadsheet &amp; paper processes in the new changed environment.</li> <li>• Resources are a big issue. Worries about the effort required to implement a digital solution and whether the solution will improve the situation.</li> <li>• Wants control. Dashboards and reports to ensure the lab is compliant and efficient.</li> <li>• Worries that the solution will be too complex for all personnel – wants simple to avoid extensive training.</li> <li>• Does not want massive change to lab processes. Knows that change is disruptive and requires effort.</li> </ul>	<ul style="list-style-type: none"> <li>• Tasked with turning around an existing operation with perceived faults.</li> <li>• Tasked with starting up a new department to support a new business opportunity.</li> <li>• Has LIMS experience.</li> <li>• Wants compliance baked into the organization through digital guard rails</li> <li>• Wants automation and instrument interface</li> <li>• Wants simplicity</li> <li>• Wants enforcement of compliance and operational rules.</li> </ul>
<b>Quality Assurance (Officer, Directory, IT)</b>	<ul style="list-style-type: none"> <li>• Is aware of compliance deficiencies</li> <li>• Knows LIMS will enforce compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Has received internal or external compliance deficiency notification</li> <li>• Is aware of current technology deficiencies</li> </ul>
<b>IT Staff (Director, Business Analyst)</b>	<ul style="list-style-type: none"> <li>• Is the gatekeeper to assure the proposed digital solution can work in the company infrastructure</li> <li>• Is overworked</li> <li>• Can be motivated by elimination of multiple legacy systems</li> </ul>	<ul style="list-style-type: none"> <li>• Involved in the buying team</li> <li>• Understands the complexities of current infrastructure</li> <li>• Is the gatekeeper to assure the proposed digital solution can work in the company infrastructure</li> </ul>
<b>C-Suite</b>	<ul style="list-style-type: none"> <li>• May be involved in search in small organizations</li> <li>• Wants to know the benefits and cost</li> <li>• Wants to show benefits quickly – phased implementations are preferred</li> </ul>	<ul style="list-style-type: none"> <li>• Wants to know the benefits and cost</li> <li>• Prefers to retain and leverage investment in current technology stack</li> </ul>

# BUYING TEAM ROLES

Identifying and enabling a buying team is essential to a successful buying journey. According to Gartner Research, the buying teams are often:

- Led by business leaders with limited technical buying experience
- Given limited authority
- Unfamiliar with internal purchasing requirements



## A good buying team will:

- Include representatives from each impacted department or interest area
- Organize with defined roles and leadership
- Understand the organization processes for tech buying
- Have clearly defined goals and schedule
- Be aware of other planned or active initiatives in the organization which may impact requirements or resources
- Understand budget constraints
- Be provided with sufficient time
- Understand Current State and define KPIs (Key Performance Indicators) for the desired

When an organization decides to invest in a Laboratory Information Management System (LIMS), several roles are key to the buying team to obtain the expertise necessary to ensure the selected LIMS meets the organization's operational, regulatory, and strategic needs.

**Laboratory Manager** – provides Operational Oversight

- Defines laboratory-specific needs, including workflows, sample tracking, and data management requirements.
- Evaluates how the system will improve lab efficiency and productivity.
- Assesses ease of use and adaptability for the lab staff.

**IT Manager** – is responsible for technical Infrastructure and Integration

- Evaluates the LIMS for compatibility with existing IT infrastructure, including hardware, software, and databases.
- Assesses integration capabilities with ERP systems, instruments, and other enterprise tools.
- Ensures the LIMS meets data security, backup, and disaster recovery standards.

**Quality Assurance (QA) Manager** – verifies compliance and data integrity of the selected solution

- Ensures the LIMS complies with regulatory requirements such as FDA 21 CFR Part 11, GMP, and ISO standards.
- Assesses how the system supports audit trails, document management, and deviation tracking.
- Validates the LIMS's ability to enforce Standard Operating Procedures (SOPs) and quality control measures.

**Procurement Manager** – assesses budgeting and oversees vendor selection.

- Manages the overall procurement process, from vendor shortlisting to contract negotiation.
- Evaluates cost-effectiveness, ROI, and total cost of ownership (TCO).
- Negotiates pricing, licensing, and support agreements with vendors.

**Materials Management** – provides expertise for inventory, supply chain management, raw material life cycle, intermediate sampling, and finished goods release.

- Assesses the LIMS for features related to inventory tracking, such as reagent usage, expiry monitoring, and automated reordering.
- Ensures integration with supply chain and procurement systems.
- Responsible for raw material life cycle, intermediate sampling, and finished goods release.

**Lab Staff** – provides input regarding user experience and functionality

- Provides input on specific features required for R&D workflows, such as experiment tracking, data analysis, and collaboration tools.
- Evaluates usability and the LIMS's ability to support innovation and scientific research.
- Tests prototypes or demos for practical functionality.

**Rule of Thumb:** a well-structured buying team is crucial for selecting the right LIMS, ensuring alignment across technical, operational, and regulatory needs. Engaging key stakeholders early, defining clear goals, and understanding internal processes will streamline decision-making and improve adoption.



# LIMS REQUIREMENTS FOR YOUR LAB

## 4.1 CRITICAL FIRST STEP

Requirements play a pivotal role in the LIMS buying journey for several compelling reasons:

### Alignment:

Defining requirements ensures that the selected LIMS aligns with the specific needs, workflows, and objectives of the laboratory.

Alignment across stakeholders is an important outcome of the requirements definition process.

### Avoid Overlooked Needs:

By engaging key stakeholders and subject matter experts in requirement gathering, laboratories can ensure that all essential functionalities are accounted for in the selection criteria.

When meeting with vendors, requirements can be used as a checklist to ensure vendor demonstrations cover all aspects of the proposed solution.

### Minimizing Implementation Risks:

Well-defined requirements mitigate the risks associated with LIMS implementation, customization, and integration.

By clearly articulating expectations regarding data management, regulatory compliance, user experience, and scalability, laboratories can avoid misalignments between the chosen solution and their operational realities.

### Facilitating Vendor Evaluation:

Requirements serve as the basis for evaluating and comparing different LIMS vendors and solutions.

By providing a standardized set of criteria against which vendors can demonstrate their capabilities, laboratories can make informed decisions based on how well each solution meets their specific requirements.

## 4.2 DEFINITION PROCESS

Requirements are a key first step in the buying journey and will define your reasons for making the change and the benefits to be derived.

Because the buying team is likely to uncover new ways of working or alternative processes as the buying journey progresses, we recommend two distinct requirement document releases.

### High Level:

Draft at least a high-level set of requirements prior to initiating research or contacting vendors.

This can be as straightforward as a checklist that outlines the specific aspects of your lab's needs and requirements.

The advantages of this initial requirements document release are:

- **Focused Research**
  - o Efficiency: With a clear understanding of your needs, you can quickly filter out functionality that is not required, saving time and effort.
  - o Relevance: Your research will be more relevant, as you will be looking at features and capabilities that align with your lab's needs.
- **Buying-Team Alignment**
  - o Unified Vision: High-level requirements ensure all stakeholders are aligned on what the lab needs from the LIMS."
- **Vendor Communication**
  - o Effective Communication: Clear requirements enable more effective communication with vendors, as you can articulate exactly what you need.
  - o Tailored Demos: Vendors can tailor their demonstrations to your specific needs, providing a clearer picture of how their system can help your lab.
- **Pricing**
  - o Vendors are more likely to provide accurate price estimates given a defined scope.

### Optimized:

Update your requirements prior to vendor selection and after initial research or vendor interactions.

Include new ways of working identified during research, vendor talks, and team discussions. Incorporate any discovered benefits to maximize ROI.

### Comprehensive:

Add detail to each high-level requirement to avoid misalignment within the team and with potential vendors. Include example workflows for clarification.

## 4.3 TOPICS TO COVER

Considering a wide range of factors by key stakeholders is crucial for successfully implementing LIMS and Informatics Platform.

The topics included in this section facilitate a thorough review of an organization's situation and priorities, encouraging stakeholders to evaluate each topic's relevance.

Implementing a digital platform using a phased approach may be preferred by the organization.

To ensure a selected vendor solution can meet all implementation phases, requirements for the fully implemented solution should be included.

We suggest retaining a comprehensive list of topics throughout the definition process, allowing for a collective assessment from diverse perspectives.

A simplified version of the document may be provided for signatures and vendors by removing not applicable sections.

## 4.4 REQUIREMENT TOPICS

### 4.4.1 Sample Management

- **Sample login**, consider user interface and automation for high sample volumes.
- **Sample types**, what types of samples are managed and what are the defining attributes.
- **Sample lifecycle**, decide if review/approval lifecycles are required for specific sample types.
- **Chain of custody**, do you need a formal log of each change in sample ownership?
- **Barcode tracking**, do you need efficiency and/or compliance using barcodes?
- **Sample storage and retrieval**, consider location management.
- **Sample disposal**,
- **Reports**, inventory, status, safety ...

### 4.4.2 Data Management

- **Data capture process**, consider any specialized execution processes required to record data.
- **Data structure**, how complex are your results and is specialized storage required?
- **Data integrity**
  - **Data Entry Controls**, as validation checks and data entry templates to ensure that only accurate and complete data is entered into the system.
  - **Audit Trail**: track all actions performed on data within the system. This includes information such as who accessed the data, when they accessed it, and what changes were made.
  - **Data Backup and Recovery**, assure data backup and recovery capabilities will protect against data loss due to system failures, disasters, or other unforeseen events.
  - **Data Validation**, consider if your system requires built-in algorithms or rules to validate and verify data entered into the system for accuracy, completeness, and consistency.
- **Data Security**
  - **User Authentication**, your solution should require users to authenticate themselves before accessing the system. Does your organization have an SOP or organization wide authentication solution?
  - **Role-Based Access Control (RBAC)**, Will your solution require different levels of access to ensure that users only have access to the data and features necessary to perform their job duties.
  - **Encryption**, your solution should require encryption techniques to protect data both in transit and at rest to prevent unauthorized access to sensitive information, even if it is intercepted or compromised.
  - **Secure Communication Protocols**, your solution should use secure communication protocols such as HTTPS to encrypt data transmitted between clients and servers to prevent eavesdropping and data interception during communication.
  - **Physical Security**, your solution should be provisioned in secure data centers or facilities with restricted access to authorized personnel only.
  - **Regular Security Audits**, assure that the deployed solution is regularly audited for security and vulnerabilities in the system to ensure the system remains secure against evolving threats and compliance requirements.
- **Data migration**, do you have legacy data? If so, is there a benefit to having legacy data available in the new solution? Define any data sources to be migrated.
- **Instrument integration**, which instruments will benefit from automated setup or recording information and results? Is attaching instrument reports good enough?
  - List your instruments to be interfaced and specify the type of information to be transferred between the instrument and the digital platform.
- **Instrument calibration and maintenance tracking**, do you need the new platform to manage your instrument metrology? Do any of your instruments require specialized routine checks (example: daily balance check weights)

### 4.4.3 Workflow Management

- **Standard operating procedure**, what SOPs must be enforced by the proposed solution such as peer review and approval of your lab records.

- **Workflow automation**, consider how you expect the digital platform to automate your processes.
- **Task assignment and tracking**, does your organization require a digital solution for tasks (what needs to be done, when is the work required and by whom?)

### 4.4.4 Quality Control

- **QC sample management**: should the system assist in the preparation and analysis of QC samples?
- **Control charting and trending**: do you need visualizations/reports for your QC sample results?
- **Alerting for out-of-specification results**: do you work with specifications and if so, do you

### 4.4.5 Reporting and Analytics:

- **Report generation**
  - Consider the types of reports needed for compliance and operational efficiency (e.g., COA, trend reports).
  - Evaluate the ability to automate report generation.
  - Assess the flexibility in formatting and exporting reports.
- **Customizable reports**
  - Look for options to tailor reports to specific user needs.
  - Check the ease of use for non-technical users to create custom reports.
  - Ensure the system allows for templates and saving of report configurations.
- **Data visualization tools (e.g., charts, graphs)**
  - Determine the variety of visualization options available (e.g., bar charts, pie charts, scatter plots).
  - Evaluate the interactivity of the visualizations (e.g., drill-down capabilities, filter options).
  - Consider the integration of these tools with other software systems.
- **Statistical analysis capabilities**:
  - Verify the types of statistical analyses supported (e.g., regression analysis, hypothesis testing).
  - Assess the software's ability to handle large datasets.

### 4.4.6 User Management:

- **Roles and Permissions**: should users be provided with different levels of access to system functionality?
- **Training**: what are your expectations for user training?
- **Support**: do you have preferences for addressing user questions, resolving technical issues, and helping users encountering difficulties?
- **Feedback**: do you have organization specific requirements for gathering input and suggestions from users regarding system usability, functionality enhancements, and feature requests?

### 4.4.7 Audit Trail:

- **Logging of All User Actions** typically includes details such as the type of action performed, the timestamp of the action, the user responsible for the action, and any relevant contextual information (e.g., the specific data record affected). What logging is required for compliance in your organization
- **Audit Trail Review**, consider the various stakeholders who may need to review audit trail information for different reasons:
  - System administrators: Administrators use the audit trail to monitor user activities, identify potential security breaches or policy violations, and track system performance.

- o **Quality assurance personnel:** Quality assurance teams utilize the audit trail to verify data integrity, investigate discrepancies, and ensure compliance with regulatory standards and internal quality control procedures.
- o **Regulatory inspectors:** Regulatory agencies may require access to the audit trail as part of audits or inspections to assess data traceability, integrity, and compliance with regulatory requirements.
- o **Legal and forensic experts:** In the event of disputes, investigations, or legal proceedings, audit trail data may be analyzed by legal and forensic experts to reconstruct events, establish timelines, and provide evidence of actions.
- **Timestamps** are essential for detecting unauthorized or suspicious activities, identifying responsible parties, and ensuring the integrity and reliability of audit trail data. Does your organization require harmonization across time-zones?
- **User Identifiers:** associate each logged action with the user account responsible for initiating the action, facilitating accountability and attribution of activities to specific individuals.
- **Data Traceability** is a must for Regulatory Compliance. Which guidelines apply to your organization (Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and ISO 17025)?

#### 4.4.8 Compliance:

- **Compliance**, what regulatory standards (e.g., FDA, ISO) apply to your organization? Will you need different compliance across your organization?
- **Electronic signatures and records (21 CFR Part 11 compliance)**, what electronic signatures will be required (on lab records, custody, reports)
- **Audit readiness features**, consider how your digital records should be presented to internal or external regulators.

#### 4.4.9 Security:

- **Data Encryption** should cover data both in transit (moving between systems or over networks) and at rest (stored on disks or other storage media).
- **Network security** should include firewalls and intrusion detection.
- **Disaster Recovery** to ensure data integrity and continuity of operations in the event of unexpected incidents such as hardware failures, natural disasters, or cyberattacks.
- **Backup Procedures** must be provided to restore functionality after a disaster to minimize
- **User Authentication** to verify the identity of users before granting access to the system. Common authentication methods include passwords, biometrics (fingerprint or retina scans), smart cards, or two-factor authentication (combining two different authentication factors like a password and a security token).
- **Authorization** to determine the actions and resources an authenticated user is allowed to grant within the digital platform. This is typically based on the user's role, permissions, and privileges assigned by a system administrator.

#### 4.4.10 Integration:

- **Integration with other systems**, consider all systems which may require interactions with the proposed digital platform (e.g., ERP, QMS, Inventory). What if any transfer of information is required?
- **Integration Mechanics**, do other systems require specific communication protocols which will need to be supported by the proposed digital platform.
- **Compatibility with existing IT infrastructure**, consider operating systems (such as Windows, Linux, or macOS), database management systems (like MySQL, Oracle, or SQL Server), and communication protocols (such as HTTP, RESTful APIs, or SOAP) commonly used in the organization's IT environment.

#### 4.4.11 Performance:

- **System Response Times**, are there activities where response times are critical to success? Consider tasks such as retrieving data, executing queries, generating reports, and performing calculations.

- **Scalability**, do you foresee significant laboratory growth or expect higher throughput which will increase data volumes, user loads, and computational demands.
- **Geographical**, will the solution support multiple sites and if so, are they geographically distributed?

#### 4.4.12 Implementation:

- **Phasing**, many organizations elect to implement a digital platform using a phased approach. Can you break this requirement set into logical and implementable phases. Can a timeline be assigned to the phases?
- **Assessment and Planning**, do you want to include assessment of your operational workflows, data management, and compliance requirements in the implementation phase? Will you wish to reimagine your environment to enhance efficiency and compliance?
- **Data Migration**, will you need to extract existing data from legacy systems, spreadsheets, paper records, or other sources to be migrated into the digital Platform? Typically, legacy data is not very "clean". Will the legacy data require cleanup or transformation?
- **Change Management**, consider the activities required to assist your workforce as they transform to a digital platform.
- **Testing and Validation**, what deliverables are required to produce a "validated" system and which of these should be provided by the platform vendor. Go-Live and Support, are there any special considerations for your organization which could factor into vendor selection?

#### 4.4.13 Maintenance and Support:

- **Upgrades and Patches**, consider how your organization will manage new software versions which introduce new features, enhancements, and improvements in functionality, security, and performance. For organizations with validated systems, the versions must be tested and documented prior to installation. Your organization will need control of the release schedule. Additionally, consider how new releases are provided (maintenance fees?)
- **Technical Support Services**, consider acceptable venues and support hours for vendor assistance.
- **Vendor Support Agreements**, your purchasing department should be ready to review prospective vendor service level agreements (SLAs to specify response times, resolution times, availability, and escalation procedures for addressing support requests and service interruptions.

#### 4.4.14 Regulatory Requirements:

- **Adherence to Specific Industry Regulations**, define the regulatory requirements pertaining to your organization such as: FDA 21 CFR Part 11 (Electronic Records and Electronic Signatures), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Clinical Laboratory Improvement Amendments (CLIA), ISO 17025 (General requirements for the competence of testing and calibration laboratories).
- **Documentation of Compliance Features**, vendors should provide documentation of the compliance features and functionalities of their software solutions to demonstrate how they meet regulatory requirements. The documentation typically includes detailed descriptions of features related to data security, audit trails, user access controls, electronic signatures, data integrity, validation, and other relevant aspects.
- **Validation protocols**, vendors may assist with Performance Qualification test scripts, validation reports, and other evidence demonstrating the digital platform validation.

**Rule of Thumb:** a successful LIMS implementation requires clear requirements, stakeholder alignment, and a solution that balances functionality, usability, and long-term support. Prioritizing flexibility, integration, and total cost of ownership ensures a scalable and future-proof system.

# RESEARCH

Prior to researching a solution, define at least a high-level set of requirements as noted above. Once that is done, then reach out to consultants or conduct online research, and then compare vendor functionality to your requirements or submit an RFP (Request for Proposal) directly to the vendors. If there are vendors that fit your needs, then request an initial call to further ensure there is alignment with your requirements prior to requesting a demonstration; this may save a lot of time for both parties. Once the demonstrations have been conducted then ask for references so you can learn how the vendor's current customers interact with and feel about the vendor's product and service. This will lead to further evaluating the vendor's solution and its match with your lab and ultimately selecting a vendor.

## 5.1 CONSULTANTS

- **Does your team lack expertise and knowledge?** Consultants can add specialized knowledge and experience in the LIMS domain, to help your team make informed decisions. Consultants stay updated with the latest trends, technologies, and best practices, ensuring that the purchase is future proof.
- **Does your team require an objective perspective?** Consultants can provide an unbiased view, focusing on what is best for the company without internal politics influencing the decision.
- **Do you need to make a quick and efficient decision?** Consultants can help your team avoid mistakes, negotiate better deals with vendors, quickly narrow options based on their expertise, handle the legwork, and mitigate the risk of project failures.
- **Is your budget tight?** Consultants can be expensive, adding a significant cost to the procurement process.
- **Do you have the skill to hire a quality consultant?** Hiring a consultant can be as difficult as selecting a LIMS vendor. The selected consultant may not fully understand the unique needs and culture of the company, leading to recommendations that are not entirely suitable. A consultant may push for solutions that benefit their relationships with certain vendors rather than what is best for the company. The quality of consultants can vary significantly. Poorly chosen consultants might lack the necessary expertise or may not deliver value, resulting in wasted resources.
- **Does your team want a consultant?** Your team may resist the recommendations of external consultants, leading to friction and implementation challenges

## 5.2 ON-LINE SEARCH

Start with a web search to identify potential LIMS providers.


- Websites like Capterra, G2, and Software Advice offer reviews and comparisons.
- Industry Publications: Look for articles and case studies in industry journals and publications.
- Forums and Communities: Engage with user communities, forums, and LinkedIn groups for recommendations and experiences.

## 5.3 EVALUATION CRITERIA

Hopefully, you have already drafted a high-level requirements document which can be used as the basis for evaluation criteria. The primary sections of the criteria are listed below:

- **Functional Requirements:** List the key functionalities your lab needs, such as sample tracking, data management, and reporting.
- **Technical Requirements:** Consider technical aspects like system architecture, integration capabilities, scalability, and security.
- **Compliance and Regulatory Requirements:** Ensure the LIMS meets industry-specific regulations and standards (e.g., FDA 21 CFR 312.63).
- **Usability:** Assess the user interface, ease of use, and the learning curve for staff.
- **Support and Training:** Evaluate the quality of vendor support, training programs, and user resources.
- **Cost:** Consider both initial expenses and total cost of ownership, including licensing, implementation, maintenance, and support.

- ✓ Ease of Use
- ✓ Regulatory Compliance
- ✓ Integration Capabilities
- ✓ Cost of Ownership
- ✓ Customization vs. Configuration

 **70%** of tech buying teams face delays

 **17 MONTHS** Average tech buying cycle

 **80%** regret their decision

**Warning:** the administration cost of most LIMS is very high and often hidden. Adjustments to the system as you learn from implementation and future modifications required as your organization changes can be prohibitively expensive. In many cases, LIMS are simply shelved when organizations realize the cost of ongoing administration.

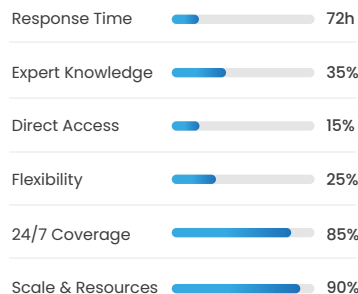
### 5.3.1 Large or Small Vendor

The size of a vendor can impact the outcome of your digital implementation and ongoing support. Some considerations:

- **Functionality:** larger vendors can often provide functionality across many departments in your organization. Be sure to determine if additional functionality is important to your deployment.
- **Usability:** large vendors often have amalgamated functionality from several smaller vendors. Usability can suffer and training can be difficult as each component has a different look & feel.
- **Support:** expect rapid response and individualized attention from smaller vendors. Your requirements are more likely to be incorporated into a smaller vendor's roadmap and delivered more quickly. Smaller vendors can provide personalized support, rapid customization, and are more innovative.



#### Large Vendors



#### Small Vendors



- **Expense:** pricing is often correlated to vendor size. Larger vendors are pricier, both in terms of upfront costs but even more so for ongoing maintenance and fees.
- **Risk:** large vendors often tout reliability, support resources, compatibility, updates, and support advantages. Smaller vendors with a 5 year or more track record can provide the same risk profile as a larger vendor.
- **Flexibility:** large vendors may offer less customization and may not be as responsive to specific needs or feedback.
- **Scalability:** what are your future state requirements? Do you need functionality only provided by a larger vendor?



### 5.3.2 Configuration versus Customization

Almost any vendor system must be configured or customized to meet your requirements.

Configuration involves setting up the LIMS software to fit your laboratory's specific processes and workflows using the built-in options and settings provided by the software. It does not involve altering code.

Customization involves altering the LIMS implementation by adding or modifying code to create new or change functionality. This approach is used when specific requirements cannot be met through configuration alone.

**Rule of thumb:** configuration is acceptable, customization should be avoided. If customization is required, the vendor should own and agree to support the customization through future releases. Customization will always cost more, complicate maintenance, limit support options, and result in longer implementation times.

### 5.3.3 Cloud or On-Prem

In the past, vendor solutions were primarily deployed within the customers' own IT infrastructure.

However, the advent of Software as a Service (SaaS) through Cloud deployments has significantly transformed these offerings. SaaS is a model in which applications are hosted by a service provider and delivered to customers over the internet. Typically, these applications are subscription-based, requiring users to pay a recurring fee to access the service.

SaaS is revolutionizing the future of Laboratory Information Management Systems (LIMS) by offering lower costs, reduced IT expenses, enhanced scalability, minimized downtime, rapid deployment, and superior security.

### 5.3.4 Niche or Platform

Vendor solutions contain differing functionality sets, from niche to digital platform. Selecting a focused niche solution to fix a specific issue or to just get started can be appealing but can have a negative long-term impact on your organization. A platform is the correct decision in all but rare circumstances.

Historically, vendors offered niche solutions:

- LIMS (Laboratory Information Management)
- ELN (Electronic Notebooks)
- LES/ MES (Laboratory/Manufacture Execution Systems)
- eBR (Electronic Batch Records)
- Metrology for Instruments/Equipment
- Inventory Solutions for Chemicals, Supplies ...
- EDMS (Electronic Data Management)
- QMS (Quality Management)

To obtain a digital solution, organizations were faced with the unenviable task of interfacing and maintaining these niche solutions. The landscape has changed dramatically, and vendors now offer Digital Platforms, which combine most if not all the functionality in a single product. Since many platform vendors charge only for functionality you use, the cost can be comparable to a niche solution.

Your organization may not currently require all the capabilities listed above but it is likely over time that some aspect of each niche functionality will be desired.

Purchasing a comprehensive platform solution initially avoids costly integration and maintenance issues over time.



- ✓ Ease of Use
- ✓ Regulatory Compliance
- ✓ Integration Capabilities
- ✓ Cost of Ownership
- ✓ Customization vs. Configuration

## 5.4 REQUEST FOR PROPOSAL

The request for proposal (RFP) is a document outlining your requirements and expectations. The document will typically include an introduction to your organization, an overview of what you're seeking from the vendor, a scope of work, requirements, evaluation criteria and other proposal requirements. The RFP can be sent to a group of vendors requesting responses based on how well they meet your requirements. An evaluation of the responses can define the vendor of choice or perhaps an ordered ranking.

**Insight:** RFPs can be played by LIMS vendors. Responses will need to be verified and scoring re-evaluated after determining actual fit to each requirement. Consider evaluation demonstrations rather than using RFPs which can be time consuming and not determinative.

## 5.5 DEMONSTRATIONS

Demonstrations are arguably the most effective tool for your buying team to picture how a vendor product will implement your requirements. More than 1 demonstration can be requested with additional detail investigated in each subsequent demo.

- 1) **Exploratory Demo:** introduction to a vendors functionality set and architecture. This demo can help winnow the field of vendors to a manageable subset.
- 2) **Use Case Demo:** provide vendors with specific use-case scenarios relevant to your lab. The subsequent demonstration can explore how the vendor solution can execute your processes out-of-the-box. The goal should be to select 2-3 vendors for focused consideration.
- 3) **Tailored Demo:** provide the vendor with specific work process flow charts, examples of your work processes and reports. Request a detailed demonstration of 1-2 key processes. The tailored demonstration will reveal the flexibility of the vendor product and implementation effort needed to meet your organization requirements.
- 4) **Free Trial:** if available, take advantage of free trials to test the system with your actual data and workflows.
- 5) **Paid Trial:** LIMS is typically too complex to allow free trials of configured systems and a non-configured system is unlikely to reveal the suitability of the LIMS for your organization. A paid trial for encompassing a small group within your organization can demonstrate the overall suitability of the vendor product. If successful, the money spent on the trial can be deducted from the overall implementation cost. If unsuccessful, avoiding the substantial costs associated with an unsuitable vendor product is well worth the cost of the paid trial.

## 5.6 REFERENCE CHECKS

Before choosing a vendor, it's wise to ask for customer references. Reputable vendors typically accommodate such requests if you show a certain level of commitment, at which point you can speak with previous customers to confirm your decision. Vendors usually avoid wasting their time or their customers' time unnecessarily, so don't forget to show genuine interest and provide at least your requirements to gain access to this information. Once you have access to customer references, here's an effective approach:

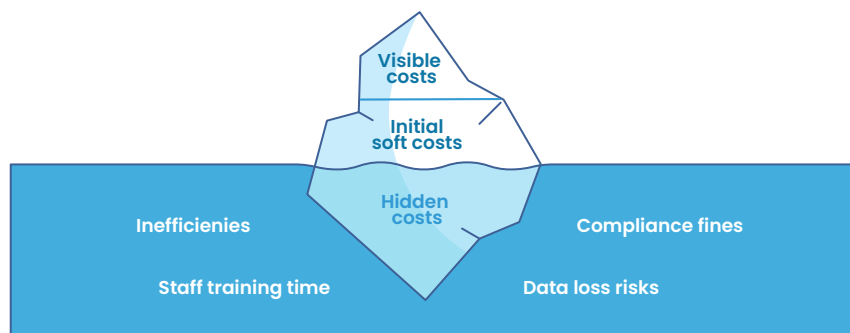
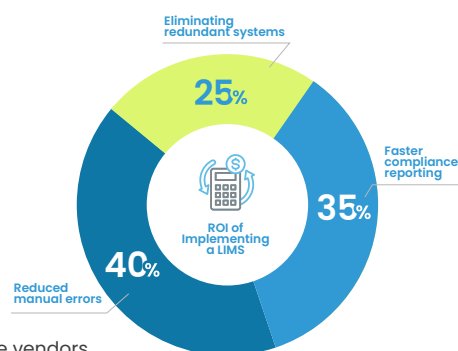
Ask references about the support they've received. Questions could include:

- Who answers the phone or responds to emails?
- How quick are their responses?
- Is the technical support team generally helpful?
- Have you faced any significant issues with the product? If so, how was it handled?
- Are you satisfied with the company overall?

## 5.7 EVALUATE VENDORS

Consolidate information gathered by the buying team

- **Technical Assessment:** have your IT team evaluated the technical aspects of the LIMS, including integration capabilities and data security.
- **User Feedback:** gather feedback from potential users within your lab who participate in demos and trials.
- **Score Vendors:** rate each vendor on each criterion (assign weighting criteria based on its importance to your lab) and calculate a total score for each vendor.
- **Assess Total Cost of Ownership:**
  - o Comparison: use the scoring matrix to compare the vendors objectively.
  - o Initial Costs: evaluate the initial purchase price, implementation fees, and any customization costs.
  - o Recurring Costs: consider ongoing costs such as subscription fees, maintenance, support, and training.
  - o Hidden Costs: look out for any potential hidden costs like additional modules, upgrades, or user licenses.



- **Implementation Plan:** work with the vendor to develop a high-level implementation plan, including timelines, resources, and training.
- **Terms and Conditions** review the contract terms, including service level agreements (SLAs), support, and maintenance agreements.
- **Price Negotiation:** negotiate pricing, payment terms, and any additional costs or discounts.

Platform evaluations should focus on key criteria to gain and maintain benefit for your organization.

- **Functionality:** fulfills your requirements across sample tracking, workflow management, inventory management, and data collection.
- **Usability:** intuitive and easy to navigate for various user expertise levels. Benefits are difficult to capture if users avoid the application.
- **Implementation:** rapid deployment of out-of-the-box functionality will capture benefit quickly and reduce risk to the project. Prioritize a cloud-based, SaaS (Software as a Service) provider to avoid internal IT spend.
- **No Custom Code:** any proposed customization of a vendor solution will increase project risk, limit future enhancements, and increase the cost of deploying future releases.
- **Platform:** avoid point solutions which require expensive and hard to maintain integrations.
- **Data Integrity:** assure Right-first-Time data entry. Electronic records and signatures are provided to meet regulatory requirements, including GxP and FDA 21 CFR Part 11 guidelines.

**Rule of thumb:** when evaluating LIMS vendors, prioritize functionality, usability, rapid deployment, data integrity, and total cost of ownership while avoiding custom code and point solutions.

## 5.8 SELECT THE VENDOR

Obtain an agreement within the buying team. A member of the team who does not agree to support the decision can have an adverse impact when attempting to get purchase approvals and later during LIMS implementation.

Obtain approval from key stakeholders and decision-makers within your organization. Other than requirements, items to consider may include when you need the LIMS to be up and running, whether it will be hosted on-premises or in the cloud, and the budget.

### Key Selection Factors

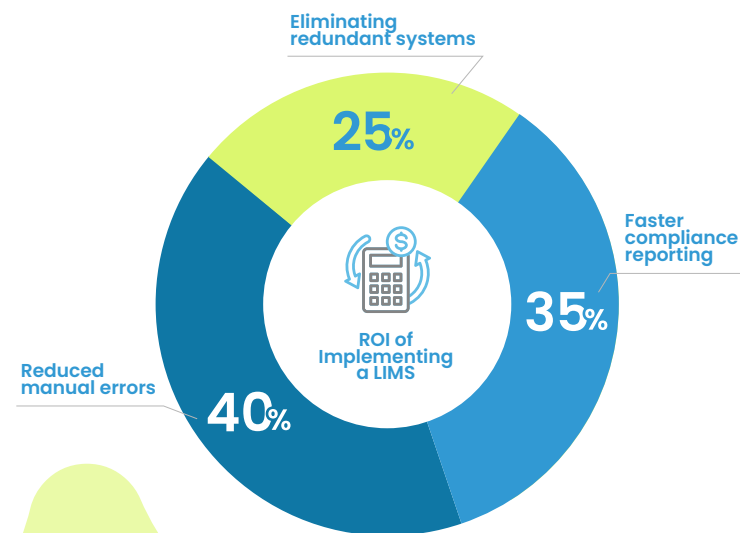


# PURCHASE

In most organizations, the purchasing process for a software application like LIMS requires completion of several steps.

Typical purchasing steps are listed below:

- **Budget:** the purchase must be included in the organization annual budget and the budgeted amount is sufficient to cover the cost of the LIMS.
- **Justification:** return on investment (ROI) calculations justify the expenditure to finance and management groups.
- **Compliance:** ensure the LIMS complies with industry-specific regulations and standards. Compliance may be documented in the form of Data Integrity or Data Quality questionnaires.
- **Legal Issues:** negotiate contract terms, including data privacy, intellectual property rights, and indemnity clauses. Contracts should be reviewed by the legal department to ensure all legal aspects are covered.
- **Technical Issues:** IT department signoff that the proposed Solution meets organizational standards for:
- **Security:** evaluating the software's security features to protect against cyber threats and data breaches.
- **Scalability:** ensuring the software can scale with the organization's growth.
- **Performance:** ensuring the software can handle the organization's workload without performance issues.
- **Compatibility:** ensuring the software is compatible with existing systems and infrastructure.
- **Approved Vendor List:** Purchasing department may have a process for admitting vendors to the approved list.



# IMPLEMENTATION

When implementing a new LIMS, it's important to keep in mind that there is still a lot of work to be done and that it will require both internal and external teamwork. Below are key parts to act on:

## **Define the Project Scope, Deliverables, and Responsibilities of Each Team Member:**

- Clearly outline the scope of the project, including goals, objectives, and expected outcomes.
- Define specific deliverables for each phase of the project.
- Assign responsibilities to team members and stakeholders, specifying their roles and contributions.

## **Install the Core System:**

- Procure and install the LIMS software – this may simply be to verify the initial system setup and basic functionality

## **Prepare Functional Specifications, Request Customization and Configure:**

- Develop detailed functional requirements based on business needs and user requirements.
- Document workflows, processes, and specific functionalities required from the LIMS.
- Outline any customization or integration needs with other systems.
- Plan and execute configuration tasks in stages, aligning with project milestones.
- Customize the LIMS settings to match functional specifications and user requirements.
- Conduct iterative testing and validation after each configuration stage.

## **Conduct Staff Training:**

- Develop a comprehensive training plan tailored to different user roles and responsibilities.
- Conduct initial training sessions to familiarize users with LIMS functionalities and workflows.
- Provide ongoing support and supplementary training as needed during the implementation phase.

## **Configure Instrument Interfaces:**

- Identify instruments requiring integration with the LIMS for data capture and analysis and deploy instrument interfaces if needed

## **Conduct Project Review and Necessary Testing**

- Gather key stakeholders to review project progress, outcomes, and any outstanding issues.
- Execute comprehensive tests to validate all functional requirements and system performance.
- Verify compliance with technical specifications, user acceptance criteria, and regulatory standards.
- Document test results and resolve any identified issues or discrepancies, if required

## **“Go to Production”:**

- Begin assigning and deploying project-specific tasks on the ‘live’ system. Hopefully, all the checks have been completed and everyone knows their roles and responsibilities in operating the system as well as the proper communication channels in case of any concerns.

# MAINTENANCE

Before purchasing, it is important to understand the support and maintenance expected from the vendor.

- **Support Team Expertise:** who specifically handles support inquiries? Ensure they are knowledgeable and capable of providing substantive assistance beyond basic message-taking.
- **Customer Support Approach:** how friendly and accommodating is the support team? This is crucial as support interactions often occur during frustrating moments.
- **Staff Turnover Impact:** does the support team experience high turnover? High turnover can delay issue resolution and affect service quality due to inexperienced staff.
- **Software Expertise Focus:** how focused is the support team on your specific software? Ensure they have specialized knowledge to effectively resolve issues.
- **Accessibility of Programmers:** are programmers easily accessible and proficient in your language? Direct access to programmers can expedite technical support.
- **Response Time Evaluation:** how quickly does the support team respond to inquiries? Test response times for both routine and urgent issues.
- **Escalation Process Transparency:** what is the process for escalating issues to senior management? Ensure clear guidelines for accessing higher levels of support when needed.
- **Software Upgrades Policy:** how are software upgrades handled? Ensure upgrades improve functionality without unnecessary costs or requiring full system purchases.
- **Cost Considerations:** what are the costs associated with support and maintenance? Clarify annual fees, upgrade charges, and any additional costs for enhancements.

These questions are designed to thoroughly assess a vendor's support and maintenance capabilities, aiding in making an informed decision aligned with your organization's needs and expectations.



## WANT TO LEARN MORE?

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