

Choosing the right LIMS for your lab: Four key considerations

Dr Phil Williams, LIMS4U

In today's rapidly evolving laboratory landscape, selecting the right Laboratory Information Management System (LIMS) is crucial for managing complexity. The demand for laboratory services is surging, exacerbated by pandemic-related disruptions that exposed existing weaknesses. Technological advancements play a pivotal role in addressing these challenges. This paper outlines four critical elements for choosing the next generation of digital LIMS. These are:

- Lab performance
- Ensuring regulatory compliance
- Enhancing laboratory flexibility and agility
- Achieving cost efficiencies in lab operations

1. Lab performance



Upgrading or adopting a new LIMS involves assessing foundational aspects such as sample management, data entry, and reporting capabilities. The focus should be on specific functionalities tailored to the lab's unique needs. Key considerations include the system's ability to handle diverse samples, track touches during testing, offer e-signatures, date/time stamps, and manage data documentation comprehensively. Whether an instrument or human-driven process, factors like validation, calibration, and auditability must be taken into account.

Performance considerations: Evaluate solutions based on end-to-end functionality, pre-configured low-code workflows, a modular approach, and cloud-based delivery. The emphasis should be on seamless integration across data, people, processes, and instruments, fostering collaboration within and outside the organisation. Look for flexibility in on boarding, connectivity with legacy systems, and adaptability to various lab types.

End-to-end unity improves operations: Implement solutions that support business process management (BPM), enhancing productivity and innovation. Assess whether the chosen system unifies functions or perpetuates silos, aiming to replace inefficient software with BPM tools for seamless integration. Ensure multi-lab accessibility, simplicity for scientists, and compatibility with document/data sources, legacy systems, and Enterprise Resource Planning (ERP) systems.

Preconfigured, low-code workflows: Prioritise preconfigured workflows designed for specific lab types, facilitating rapid configuration without the need for coding programmers or extensive training. The advantage lies in the system's adaptability to changing regulatory or process requirements, ensuring updates and modifications without major operational disruptions. Expertise in low-code pre-configuration should be emphasised, allowing IT teams to focus on core objectives.

Tailor requirements by lab type: Different lab types, such as diagnostic, gene, CAR T-cell, immunotherapy, therapeutic R&D, and manufacturing/production QC, necessitate specific LIMS features. Tailoring the solution to meet the unique demands of each lab category, ensuring efficient management of samples, protocols, and analytical results.

Tailoring solutions for varied lab types:

In **Diagnostic labs**, comprehensive management of diverse sample types, from accessioning to reporting, is essential. A well-designed platform streamlines processes, allowing customers to monitor test progress. Choose a solution for diagnostic tests that easily updates workflows, integrates with contract systems, schedules instruments, and generates Certificates of Analysis.

For **CART, Genetic, Cell, and Immunotherapy labs**, specialised systems are vital. These labs demand solutions adept at managing biological samples and reagents, seamlessly

integrating with third parties, and ensuring accurate sample tracking. Look for systems supporting production processes, deviations, CAPAs, and adhering to quality, document, and governance standards.

Therapeutic R&D labs benefit from pre-configured modules facilitating protocol and sample searches, analysis tracking, and result investigation. Ensure the ability to monitor all aspects, from protocols and samples to instruments and data.

Quality Control or Stability Studies labs require organised QC processes harmonising multiple labs. Seek solutions handling sample requests from ERPs, structuring data entry/transfers with standard functionality, and facilitating digital management for stability studies. This reduces the risks associated with manual paper-based processes.

Selecting the next generation of digital LIMS involves careful consideration of Lab Performance, Regulatory Compliance, Flexibility, and Cost Efficiency. The chosen solution should provide end-to-end functionality, pre-configured low-code workflows, a modular approach, and cloud-based delivery. By tailoring requirements based on lab type, labs can streamline operations, adhere to regulatory standards, and future-proof their systems against evolving challenges.

2. Ensuring regulatory compliance in labs



In the ever-evolving landscape of laboratory operations, organisations are grappling with the increasing stringency of regulatory requirements imposed by government entities. This paper delves into the multifaceted realm of Regulatory Compliance, exploring how labs can navigate challenges, enhance data integrity, and meet Quality Assurance/Quality Control (QA/QC) needs.

As regulatory bodies intensify their oversight, labs are transitioning from manual to digital automation to enhance compliance. However, legacy systems and resource constraints pose significant barriers. Siloed systems impede integration, hindering data management and compliance efforts. This section addresses the complexities labs face in achieving regulatory compliance and emphasises the importance of a holistic approach.

2.1 Compliance considerations: To meet quality, regulatory, and compliance needs, labs must effectively manage samples, raw materials, data, documents, deviations, test instruments, training, Corrective and Preventive Actions (CAPAs), and non-conformance tracking. Consistent management of policies, procedures, validations, and workflows is essential for generating automatic audit trails and establishing a comprehensive Quality Management System.

2.2 Data integrity: Data integrity is foundational for compliance, with cloud-based technology playing a pivotal role in managing and distributing data efficiently. The use of a common platform enhances data integrity, facilitating one-to-many connections at

scale. Lab managers can leverage data lakes or cloud platforms to collaboratively store and use data, linking critical lab functions for improved supply chain management and scalability.

2.3 Compliance and quality control labs: Quality Control labs, responsible for detecting and correcting deficiencies in internal processes, face challenges in manual processes that jeopardise data integrity. Compliance involves adhering to Good Manufacturing Practices (GMP) or Good Laboratory Practices (GLP). Automation and preconfigured workflows enable secure tracking of files, databases, and equipment, ensuring adherence to regulatory requirements and generating audit trails.

2.4 Regulatory experience: Incorporating regulatory expertise into technology accelerates lab projects, ensuring compliance with global health authorities and the FDA. Compliance demands collaboration between human tasks and technology, covering areas such as document management and control, equipment tracking, and materials inventory management.

2.5 Document management and control: FDA-dependent labs benefit from a full-featured Document Management System (DMS) that monitors compliance with regulations like 21 CFR Part 11, ISO standards, GMP/GLP, and others. A DMS should be format-neutral, support real-time monitoring, and offer configurable flexibility for tailored repository needs. Integration with quality apps and desktop platforms enhances accessibility, and built-in control options ensure compliance with regulations.

2.6 Equipment and instrument tracking: Efficient tracking of testing equipment and analysis instruments is crucial for compliance. The module platform should include controls for calibration and preventative maintenance, with alerts and notifications enhancing resource management. Configuration should align with FDA and ISO guidelines, ensuring personnel are adequately trained and equipment stays compliant, reducing operational risks.

2.7 Materials inventory management and tracking: Documentation of material receipt, storage, and movement is vital. Labs need to track drug substances, develop hazard statements, and efficiently manage materials records. Automated systems facilitate tracking and archival of materials, ensuring compliance with regulatory requirements.

2.8 Credentialing and accreditation: Lab personnel credentialing and accreditation are paramount concerns for regulatory entities. A comprehensive DMS allows for the storage and retrieval of certification documents from accrediting groups, streamlining regulatory oversight while minimising the burden on labs.

Navigating the intricate landscape of regulatory compliance requires a comprehensive approach, addressing data integrity, quality control, and regulatory experience. Labs must leverage technology to streamline operations, enhance compliance, and stay audit-ready. By embracing digital solutions that encompass document management, equipment tracking, materials inventory, and regulatory expertise, labs can ensure regulatory compliance while fostering efficiency, accuracy, and innovation in their processes.

3. Enhancing laboratory flexibility and agility

Laboratories seeking to embrace new technologies and adapt to evolving needs must prioritise flexibility and agility. This paper explores the crucial aspects of choosing a compatible and secure foundation, addressing challenges related to government regulations, electronic security, and out-dated business models. The focus is on building a secure implementation roadmap for future advancements.

Flexibility and agility considerations

To facilitate timely improvements, labs should ensure compatibility and security across their entire structure. Overcoming challenges related to regulations and security requires a clear and secure implementation roadmap. Compatibility issues arise when existing systems come from various vendors, making it essential to assess integration possibilities and streamline processes.

A modular approach with a configurable Business Process Management (BPM) engine allows labs to manage diverse aspects of their operations, from customer orders to final reports. This modular strategy accommodates the varying retirement times of legacy systems, enabling seamless migration.

Cloud-based solutions prove ideal for multinational labs, offering flexibility for comprehensive reporting, supervisory reviews, and sponsor/vendor/business management. Implementing pre-configured dashboards and automated reporting streamlines compliance monitoring and ensures a consistent view of key performance indicators.

For supervisory tasks, workflow-driven modules manage detailed evaluations, facilitating the transition from paper-based to technology-driven processes. Modules for sponsor and vendor business management provide end-to-end solutions for contracts, protocols, employees, vendors, and products/services.

Flexibility and agility are paramount for labs navigating the complexities of technological advancements and regulatory compliance. A modular, cloud-based approach with a focus on comprehensive reporting and workflow automation ensures labs can adapt seamlessly to evolving requirements. By addressing compatibility challenges and embracing technology-driven processes, labs can create safer, more efficient, and productive workplaces. Engaging with experts and collaborating with vendors helps overcome obstacles, paving the way for successful integration and improved quality management.



4. Achieving cost efficiencies in lab operations

In the competitive landscape of laboratory operations, achieving more with limited resources becomes imperative. This section explores strategic considerations for optimising lab efficiencies, emphasising realistic goal-setting, Total Cost of Ownership (TCO) evaluation, and the reverse impact of cost on quality and regulatory compliance.

Laboratories face challenges such as non-standard manual operations, evolving demands, unclear data, and personnel issues. Setting realistic improvement goals while considering TCO is crucial. TCO encompasses lifetime maintenance costs, including facility and technology deployments, personnel costs, and more. Calculating TCO reveals the drawbacks of customising traditional technology solutions and the delays associated with waiting for custom manipulations.

4.1 Considering the reverse of cost

Retiring disparate systems for a collaborative workplace yields qualitative benefits. Quality and regulatory compliance enhance time-to-market, reduce the risk of product recall, and potentially increase market share. Upgrading systems like Laboratory Information Management Systems (LIMS) or Electronic Laboratory Notebooks (ELNs) requires strategic planning and consideration of outsourcing to expert vendors for custom development and maintenance.

4.2 Flexibility and cost optimisation

Purchasing a system, like LIMS, necessitates flexibility, reliability, reasonable pricing, and a swift implementation timeline. While no system is a perfect fit out-of-the-box, flexibility offers tailored configurations in a modular approach, allowing functions to 'Snap-On' as needed. Automation capabilities free resources, enabling rapid updates in response to regulatory or client demands.

4.3 Cloud cost TCO

Cloud-based platforms offer advantages in TCO by eliminating in-house servers, software, and infrastructure costs. With pay-as-you-go models, cloud solutions untie IT professionals from customisation efforts, saving on labour costs. Cloud adoption is expected to grow, with a projected 55 per cent lower ROI for cloud-based software compared to on-premises solutions. Prioritising low-hanging fruit for migration can fund more complex transitions.

4.4 Prioritise ROI and opportunities

Sequencing and prioritising low-hanging fruit aid in funding complex migrations. Upgrading from manual or outdated toolsets alone yields immediate savings. Prioritising faster turnaround times and reduced errors, especially through data entry elimination and audit upgrades, offers significant benefits.

5. The final word: Get started now

The key advice is to start the optimisation journey as soon as possible. Waiting for a perfect system or dealing with legacy systems may result in lost potential insights. Action is crucial, and practical, workable advice can pave the way for impactful changes. The investment payback period for a single, configurable platform is typically one year, making immediate action the best approach.

For more information, please email the author Dr Phil Williams at phil@lms4u.co.uk or visit 'LIMS4U' on LinkedIn. Phil has 38 years' experience in Lab automation. He founded LIMS4U in 2019 and offers LIMS marketing services primarily via LinkedIn (30,000+ followers).



LIMS4U

Acknowledgements & References:

Thanks to Xybion [1] who supplied some of the dialogue used.

1. <https://www.xybion.com>