eBook Quick Guide

A complete guide to LIMS selection

Contents

Focus on your science

As a scientist, it is important that you are working as efficiently and effectively as possible to ensure the success of your lab and your business.

You need to know that the generated data — regardless of whether the lab is testing food and beverages, chemicals, pharmaceuticals, metals or environmental samples — is accurate and secure. At the same time, you need to keep track of samples, resources, inventories, reports, methods, guidance and regulations.

The way you capture and store scientific data and how you manage all the elements of the lab, is crucial to advancing research and driving quality products.

A Laboratory Information Management System or LIMS is a safe, efficient and affordable digital solution to laboratory management. Using a LIMS, you can collect data and manage your lab processes easily, giving you more time to focus on making new discoveries or ensuring quality products.

What is a LIMS and how can it help?

The exponential growth of data, processes and technologies makes it difficult for labs to continue operating with analog-based models. Digital transformation is the solution to this new challenge as it allows labs to integrate digital technology to monitor processes, operations, and improve results, deliverables and customer experiences.[1]

A LIMS, or Laboratory Information Management System, is an essential component of a lab's digital transformation strategy, which improves lab productivity and efficiency by keeping track of the data associated with samples, experiments, workflows, and instruments.

The modern LIMS evolved from a sample-based tracking system to become the digital backbone of the lab. Acting as an additional member of your team, a LIMS automates workflows and tracks all the important information generated by the lab (e.g., samples, data, workflows, results, etc.). Yet, a LIMS does more than that; it allows you to actively manage entire lab processes from instrument maintenance, samples and associated data to people and consumables. A LIMS is a tool that helps to increase efficiency and reduce costs by standardizing workflows, improving data accessibility and reducing human errors.

What problems can a LIMS solve?

A LIMS enables labs to overcome challenges associated with manual operations, with real-time situational awareness. As a result, you can:

Do less manual work
Take your lab work to the next level by reducing manual operations and data manipulations. The software lets you generate more accurate data, by removing the possibility of human error, which in turn achieves more accurate results and improves time management. The data in the LIMS is easy to find, and metadata is both searchable and reportable.

Keep track of the situation
Monitoring your lab in real-time, gives you the power to see the status of everything in your system including samples, workflows and projects. You can track reagents and consumables; their expiration dates, inventory levels, and receive reminders when it's time to reorder. A LIMS allows you to record each step of the workflow and create schedules to optimize instrument usage and oversee required maintenance and instrument performance. Data is collected, and any changes are tracked throughout the sample lifecycle, producing a full audit trail of every action performed on each sample.

Demonstrate regulatory compliance
LIMS can be configured to support compliance with regulations (such as GMP, GXP, ISO 17025, 21CFR Part 11, and CAP/CLIA) and demonstrate complete sample traceability from data acquisition to results.

Why use a LIMS?

Using a LIMS is important for:

- Ensuring product quality and mitigating risk
- Supporting and demonstrating compliance and data integrity
- Ensuring that lab processes scale up in line with the growth rate of your business
- Tracking and managing environmental monitoring programs and stability studies
- Managing raw materials, and tracking operational efficiency through to finished products, with easy-to-interpret reports and Key Performance Indicators (KPIs)
- Reducing time spent tracking and recording on paper – helping you focus on delivering your best scientific results and innovations faster

77%
of CEOs stated that the COVID-19 pandemic has accelerated their digital transformation plans.[2]

$2 Trillion
was the total enterprise spending on digital transformations in 2019.[3]

Digital investment resulted in
10.4% growth
worldwide in 2020. It is predicted that by 2023, digitally transformed organizations will contribute to more than 50% of global GDP. [4]

How do you select the right LIMS?

It is important to procure a LIMS solution from a digital science partner with a reputation for compliance, proven deployment, and ease of use. The ideal solution should:

- Have little-to-no customization to support the existing lab workflow
- Be an easy-to-use system that can be implemented and qualified within a reasonable timeframe
- Address the key challenges of each industry, including internal and external regulatory requirements

When is the right time to use a LIMS?

While every organization is unique, the challenges they face are often similar. As your lab, or company's customer base grows, it will invariably need an IT infrastructure to support that growth. A LIMS solution can help streamline lab processes and provide quality control in a fully validated environment, to support the growth of your lab business.

The benefits of a pre-configured LIMS

Thermo Fisher Scientific offer LIMS solutions that are designed to grow and evolve as a lab's needs change. The benefits of pre-configured capabilities mean you can shorten time to deployment, reduce system complexity and ensure faster time to delivering value.

Various pre-configured solutions are offered as an implementation accelerator to Thermo Scientific™ SampleManager™ LIMS, built to deliver industry-standard functionality and enable faster ROI with reduced risk:

- Pharma QA/QC Solution
- Refinery Solution
- Food and Beverage Solution
- Biorepository Solution

These options are ideal for customers seeking a leading, comprehensive solution with a high return on investment. The pre-configured solutions can be expanded for additional efficiency gains in the future, such as digitizing standard operating procedures (SOPs), using tablets to manage SOP execution, exploring additional integration points, capturing data directly from instruments and eliminating paper.

SampleManager LIMS is a highly configurable solution which can be tailored to suit the needs of almost any environment. Other industries and applications can benefit from pre-configured capabilities, depending on the needs and workflows of the lab.

Learn more about out pre-configured LIMS Solutions

- Food and Beverage Solution
- Refinery Solution
- Pharma QA/QC Solution
- Biorepository Solution

What deployment options are available?

Cloud – managed by Thermo Fisher Scientific

Customers receive end-to-end support from Thermo Fisher Scientific, including provisions, installation, configuration and maintenance of the software.

Cloud – managed by you

Customers manage all aspects of the deployment, installation, and maintenance of the infrastructure and software products.

On-premises

Customers deploy and manage Thermo Scientific™ LIMS in their own internal infrastructure.

Learn more about Thermo Scientific™ LIMS software and what it can do for your lab.

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Next-generation solutions accelerate scientific research and streamline manufacturing operations. Make sure you determine the informatics capabilities required to deliver the right solution to fit your unique needs.

Key features of a LIMS

1. Sample management / accessioning / tracking

Managing shipment, accessioning, and inventory processes to ensure sample integrity, data quality, and a proper chain of custody.

2. Instrument management

Monitoring the status of the lab's instruments, schedule work and maintenance to optimize uptime and ensure appropriate resourcing for busy periods.

3. Inventory management

Tracking where items (e.g., stock supplies and reagents) are located, whether they are in date, and assigning automatic reorder alerts.

4. Laboratory management

Visibility and management of all laboratory resources, as well as having an overview of the labs' status to determine timelines, report on turnaround times, and resource projects.

5. SOP compliance

Guiding analysts through workflows and capturing all actions to ensure compliance to the SOP.

6. Workflow capabilities

Graphical workflows map to actual laboratory processes, automating decisions and actions, reducing the need for user intervention and enabling adaption to process changes.

7. Lab automation

Connectivity to control liquid handling instruments and synthesis workstations of different vendors.

8. Collaborative work environment

Collecting and sharing data securely in real-time with collaborators in your lab or across the globe.

9. Enterprise integration

Connecting to enterprise systems (e.g., Enterprise Resource Planning (ERP), Manufacturing Execution Systems (MES)) and other laboratory systems (e.g., Electronic Lab Notebooks (ELN), Chromatography Data Systems (CDS)).

10. Cloud or on-premises deployment

Modern LIMS offer the option to deploy either on premises, or via a managed cloud which reduces the initial hardware and IT investment.

11. Drive and demonstrate regulatory compliance

Secure system access and capabilities to comply with the latest industry regulations and data integrity guidance documents including GxP, ISO 17025 and FDA 21 CFR Part 11.

12. Data security

LIMS can use identity and access management systems including OAuth2.0, and can also be set up for multi-factor authentication.

13. Mobile LIMS

Mobile application to execute methods and collect and process samples via tablet, wherever there is an available internet/ network connection.

14. Dashboards and data visualization

Tracking the lab's overall performance and assigned work.

15. Reporting and data analytics

The system captures all relationships and metadata, and that information can be reported on, shared, analyzed, and audited, enabling users to work with data in context.

16. Data archival

Ensuring proper electronic records retention and data archival to comply with the latest regulatory requirements.

What extended capabilities are available with a LIMS?

Collaborate and share data across chemistry, biopharmaceutical or academic research with Core ELN software

Thermo Scientific™ Core ELN software is a flexible electronic laboratory notebook (ELN) for capturing, analyzing, managing, and sharing vital scientific data and information. This solution lets you quickly and easily build notebooks, entries, and sections to meet the needs of your lab. Data can be assembled into an experiment from external data systems, spreadsheets, presentations, and documents. Features include the ability to:

- Seamlessly integrate with existing workflows for end-to-end visibility across experiments
- Leverage the flexibility of the ELN by designing a notebook entry using your own format
- Ensure intellectual property is recorded and maintained
- Automate the data review process and notify reviews by emails
- Enforce e-signature approvals with a date and time stamp

ELN software offers a range of deployment options in the cloud, on-premises, or within your own infrastructure.

Drive process compliance with LES

For labs looking to drive process compliance and enable electronic management and execution of SOPs, the Laboratory Execution System (LES) in Thermo Scientific™ SampleManager LIMS™ software is an essential tool. The system allows you to reduce paper use, break down complex procedures so they are

easier to understand, record information far more accurately, and ensure compliance and data integrity. An LES replaces traditional physical lab notebooks and allows you to digitize lab procedures, guide staff through complex procedural tasks step-by-step, check resource availability and record data directly to SampleManager LIMS software.

Power efficiency with lab integration tools
For labs that require the translation and consolidation of vast, disparate data sources into actionable information, Thermo Fisher's complete suite of integration tools can help to take data integration one step further.

Thermo Fisher has partnered with leading instrument and system vendors as well as leading data standards organizations — such as the Allotrope Foundation and the Pistoia Alliance — to support a common language for scientific collaboration, FAIR data principles, and thus, facilitate data sharing and automation.

Secure raw data with Scientific Data Management Systems (SDMS)
With an SDMS, you can better store and search for lab data and knowledge, speed up workflows and approval processes, and optimize collaboration between staff. The system acts as a centralized document management system — rather like a single source of truth — collecting, cataloging, and storing data generated in your lab as well as managing any unstructured data.

The data management capabilities in SampleManager LIMS are designed with regulatory requirements in mind, ensuring that all raw data and associated metadata is secure and accessible for the entire data lifecycle with no requirement for the original instrument software.

What integration options are available with a LIMS?

A LIMS, combined with data visualization capabilities, such as dashboards to display information from your laboratory (e.g., key performance indicators (KPIS)), provides significant insight and benefits. Connecting LIMS to elements such as instruments and equipment, as well as other enterprise systems, offers a far more holistic view of operations and supports data integrity and compliance.

Instrument integration
From balances and pH meters to complex data systems, we offer a range of solutions to connect your lab instruments. Our connectivity solutions support bidirectional instrument communication, enabling you to transmit sample identification and sequence data to an instrument and receive results in return. These flexible solutions handle a variety of communication protocols.

System integration
With advanced integration capabilities connecting your LIMS to other analytical data and enterprise management solutions including, Manufacturing Execution Systems (MES), Process Information Management Systems (PIMS), Enterprise Resource Planning (ERP) systems and Chromatography Data Systems (CDS), Thermo Fisher provides the tools for a holistic view of your operations. By connecting your lab data to advanced visualization tools like Microsoft Power BI, Tableau, and R-Shiny, these solutions support faster decision making, provide better control of plant operations, and drive productivity.

Learn more about LIMS, LES, ELN and SDMS software

A LIMS to suit your needs

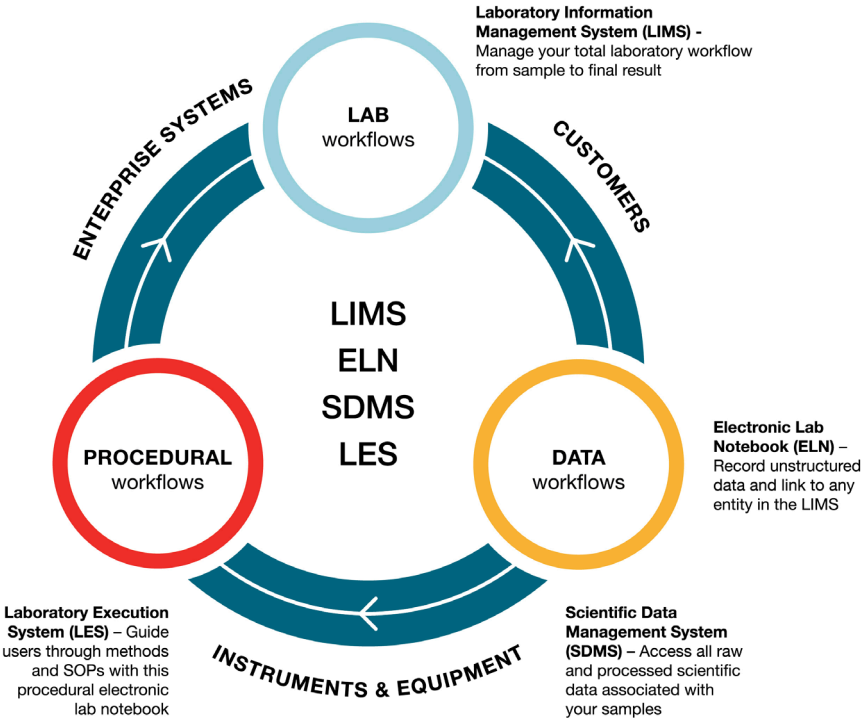
A LIMS can feature specialized capabilities for small labs or start-up research facilities through to enterprise-level development, process development, and manufacturing labs.

Define, capture and manage your R&D lab data across workflows

Designed for managing research and development, lab data and workflows, Thermo Scientific™ Core LIMS software has the flexibility to evolve with new advances in science and technology, including new instruments, techniques, data types, and tools. Core LIMS meets your needs for collecting, sharing, analyzing and archiving scientific data, but it's also designed to be flexible and easy to adapt.

Drive quality and compliance in Process Development and Manufacturing

Thermo Scientific™ SampleManager™ LIMS, LES, ELN and SDMS software is a complete, comprehensive solution for lab data and process management. It allows labs to quickly build workflows that map to actual laboratory processes, automate decisions and actions, and reduce the need for user intervention. The software facilitates compliance with standards such as 21 CFR Part 11, GMP and ISO 17025. Labs adhering to ALCOA+ guidelines can also rely on the LIMS security, electronic signature, and complete audit trail to enable compliance. SampleManager software works hand-in hand with enterprise systems including ERP, MES and other solutions, connecting your laboratory to your business.



ALCOA+	
Attributable	Who did what and when is recorded using secure access and e-signatures to log all actions
Legible	All data including associated metadata are retrievable and readable for full lifecycle following future-proofed XML conversion
Contemporaneous	Actions are recorded at the point of being made using the mobile SampleManager LIMS app and LED to step through processes
Original	Audit trail shows original data and any changes made with time and date stamps
Accurate	Any data changes including calculations are documented in audit trail. Instrument integration eliminates transcription errors
+Complete +Consistent +Enduring +Available	Data cannot be lost and/or deleted; metadata also available Data processes recorded chronologically with time/date stamps Future-proofed and compliant XML data archived Data easily accessible direct from the sample record

Addressing specific market needs

A LIMS can have specific capabilities to address market needs. By selecting a LIMS with pre-configured capabilities, customers can speed up deployment and realize faster time to value.

Bioanalysis

Challenge: Managing all elements of study data, from design through reporting.

A LIMS offers bioanalysis researchers:

- Tools to manage bioanalytical studies, from initiation through study close out
- Study coordinators, scientists and technicians can move logically through each step in the workflow, simplifying bioanalytical support for nonclinical and clinical studies

Find out more here

Chemical and Petrochemical

Challenge: Chemical manufacturers need to ensure quality, safety, and efficacy of their products.

A LIMS offers chemical manufacturers:

- Optimization of the efficiency and throughput of continuous processes
- Compliance with regulations and safety standards
- Solid QA testing and continuous real-time monitoring
- Scalability and flexibility with solutions that integrate easily with other applications and instruments in and out of the lab
- One standard user-interface enabling data sharing across the organization

Find out more here

Clinical Testing and Molecular Diagnostics

Challenge: Lack of integration with clinical systems means that samples have to be entered manually, and clinical workflows are disconnected.

A LIMS software can provide:

- Reliability and flexibility to perform complex analyses (next-generation sequencing, pathology, microarray, and qPCR analysis)
- Enhanced lab speed, quality, and productivity
- Dashboards to plan and schedule employee work and monitor sample queues and statuses
- Streamlined end-to-end information flow to strengthen data integrity
- Transmission of test requests and results in HL7 format, enabling physicians to provide treatments to patients more quickly

Find out more here

Environmental

Challenge: Environmental testing labs determine the quality of everything from the air we breathe to the water we drink. For these labs, it is critical to stay on top of the latest local and international regulations and testing requirements.

A LIMS helps water and environmental testing labs to:

- Manage entire processes from sample collection to the final report
- Comply with ISO 17025 and NELAC requirements
- Improve efficiencies, cost savings, and compliance

Find out more here

Food and Beverage

Challenge: To ensure food safety, food producers need to standardize and harmonize operations at all stages of food production, from the production of raw ingredients to the final packaged product.

A LIMS can help food labs to:

- Achieve full compliance with even the strictest regulatory requirements (e.g., ISO 17025, FSMA, HACCP, ISO 22000)
- Manage batch relationships between raw ingredients, processed materials, and packaged goods
- Manage SOPs electronically and drive analysts step-by-step through ASTM methods for various food and beverage testing processes

Find out more here

Forensic Testing

Challenge: Forensic testing labs need to employ rigorous sample collection and storage protocols and well as to comply with stringent regulations (e.g., American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) and ISO 17025) to ensure chain of custody and minimize the potential for sample degradation.

A LIMS can help forensic testing labs to:

- Manage the complete forensic testing process, including case management, to help ensure traceability and certainty of results
- Drive quality results and repeatability through controlled process execution
- Comply with data integrity lifecycles
- Confirm resource suitability through in-process checks to ensure compliance to ISO 17025
- Track chain of custody from receipt through archival
- Connect directly to instruments and equipment to eliminate transcription errors
- Manage a variety of complicated data types for DNA ballistics, and chemical testing

Find out more here

Manufacturing

Challenge: Manufacturers are constantly challenged with producing consistently high-quality products in less time and with fewer resources. To achieve this, processes must be streamlined, systems connected, and continual process improvement implemented. They also need to ensure their product consistently meets the stringent specifications of the customer. Rigorous testing produces large amounts of data which must be shared with stakeholders quickly, in order to make necessary adjustments to production controls.

A LIMS can help manufacturers to:

- Map lab processes, connect with production and other enterprise systems to share critical information
- Enable continual improvement by driving quality and repeatability
- Manage batch relationships between raw materials, processed materials, and final products
- Comply with industry and regulatory requirements (e.g., ISO 17025)
- Outline acceptable quality levels for different customers, enabling immediate checks and rapid product release

Find out more here

Metals and Mining

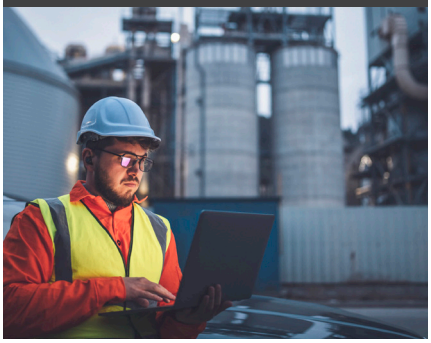
Challenge: Mining companies rely on lab testing to verify the quality of their end products and maintain adherence to local environmental, governmental and other regulatory requirements (e.g., ISO 17025, 14001).

A LIMS helps the mining industry to:

- Improve efficiency and quality from mineral exploration through to final processing
- Implement a complete lab automation solution by integrating instruments with lab and business systems
- Connect the lab to the production facility, delivering scalability, and reliability as well as automation
- Track, monitor, measure, analyze, and report critical events and actions in real-time
- Comply with industry regulations: enhanced compliance features as well as interactive graphs, charts, tables, maps, and other data mining tools, help to produce full audit trails and gather, review, and analyze real-time data in a dynamic environment

Find out more here

Oil and Gas



Challenge: The oil and gas industry needs to reduce production costs, streamline lab operations, and comply with quality standards and regulations.

A LIMS software helps oil and gas organizations to:

- Control their processes with rigorous testing and real-time monitoring
- Optimize performance by connecting critical instrumentation (in and out of the lab) and data
- Comply with regulations and monitor product quality, plant performance, and environmental conditions for maximum quality

Find out more here

Pharma and Biopharma

Challenge: Pharmaceutical labs have different requirements depending on their specifications. For example, R&D labs need to be agile in managing diverse types and volumes of data. On the other hand, pharma QA/QC labs need to strictly adhere to SOPs and achieve and demonstrate regulatory compliance.

A LIMS offers different options to the pharmaceutical industry:

- A LIMS for R&D labs can have capabilities for sample and inventory management, sample preparation and analysis, instrument and software integration, and workload management across many different types of R&D workflows (e.g., molecular biology, genomics, biobanking, purification, and formulation)
- A LIMS for a bioanalysis lab can ensure that studies are conducted and the associated data managed according to industry regulations
- A LIMS for process development and manufacturing can maintain data integrity, drive compliance to regulations and manage processes such as environmental monitoring, stability testing or retaining sample management

Find out more here

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The features and benefits of a LIMS

LIMS are constantly evolving to serve the needs of different lab environments and workflows. Some of the most critical benefits of a current LIMS include:

Sample location and tracking

A LIMS allows you to log samples and record their exact location (site, lab, freezer, shelf, box, cell), while also tracking and recording each step throughout the sample lifecycle to produce a full audit trail of every action.

Reagents and consumables inventory

A LIMS allows you to record all reagents and consumables, track standards and component reagents and record who prepared them, deprecate volumes as reagents are used, and prompt users when it is time to reorder. Notably, by recording their expiration dates it can also restrict the use of expired goods.

Instrument integration

A LIMS allows you to integrate data produced by various instruments from different vendors. By analyzing QC results to determine which samples meet expected criteria, it can then route approved samples to their next step in the workflow and failed samples back to the previous workflow step.

Instrument maintenance

A LIMS allows you to record instrument calibration results and receive prompts for scheduled preventative maintenance. While these instruments are undergoing calibration or maintenance, they can be removed as selectable options within the LIMS, so technicians are not using instruments which are out of service.

Development, optimization, and expansion of workflows

A LIMS can support multiple samples, protocols and workflows from multiple instruments from different manufacturers. This flexibility allows you to add new workflows quickly and easily through configuration.

Configurability

A LIMS allows you to configure unique workflows and processes quickly and easily without the need for custom coding or support from the provider.

Modularity

A modular LIMS allows you to construct new workflows using other components from existing workflows or add new modules to reflect your lab's expanding expertise.

Report and dashboard generation

A LIMS allows you to visualize data and generate reports in real time to see the status of all samples and projects, and to generate valuable quality control information to improve processes.

Compliance

A LIMS can be configured to support compliance to industry and regulatory standards (e.g., ISO 17025 and GxP), proper data handling (e.g., 21 CFR Part 11) and data integrity guidance.

How can your organization benefit from a LIMS?

A LIMS from Thermo Fisher Scientific can be configured to support diverse workflows, lab types, and user communities across the enterprise by connecting lab personnel, IT and systems administrators, and management.

- Lab managers can manage specifications, test methods and procedures, sampling frequencies, operator training, and more
- Lab scientists and technicians can execute laboratory testing quickly and easily or with step-by-step guidance through LES for more complex methods
- IT and systems administrators can deploy your laboratory infrastructure in the cloud or on premises and integrate with other laboratory or enterprise systems
- Management can track lab performance against key metrics through enterprise dashboards and data visualization tools

"The LIMS is extremely easy to use. Laboratory productivity has been considerably enhanced and sample turnaround has been accelerated while ensuring optimum product quality."

– Henrik Behrndt, Lead Systems Consultant, Global Production Quality, Chr. Hansen

Efficiencies gained by implementing a LIMS

Implementing a LIMS can bring value to your business and your lab operation. Determining the efficiencies gained as an outcome of the implementation requires consideration of both the tangible and intangible aspects.

Tangible aspects include, for example, saving time and sample turnaround in each of your lab's processes as well as achieving and maintaining compliance. Intangible aspects, on the other hand, include the cost of poor data quality, returned products, alienated customers, halting production to measure quality problems, the potential loss of brand value, or the cost of compliance violations in the lab and manufacturing processes.

How can a LIMS reduce manual processes?

Partnering with Thermo Fisher Scientific will help you identify the right solution for your organization and seize opportunities that make lab operations more efficient. For example, the right LIMS can provide complete oversight into asset management for your lab and staff, by giving you a 360° view into the life cycle of a sample and laboratory workflows.

Automated data capture and processing reduces the time required to review and release data, improves data quality assurance, gives you visibility into who has completed a task and when, eliminates manual transcription errors, and gives you control over where raw data is stored.

The implementation of a LIMS also results in cost savings outside the lab. For example, it reduces the labor related to the data transfer to another system and the time required to organize lab data with non-lab data (e.g., certificate of analysis generation, or matching batch/lot quality to customer specs). Furthermore, it reduces the cost in inventories (including eliminating time out of manufacturing or research and development) and the risks of having product recalls (due to increased accuracy and precision during manufacturing). Overall, a LIMS improves turnaround times, laboratory process evaluation and capacity without increasing capital and labor.

How can a LIMS reduce paper processes?

By using an LES, it is possible to replace traditional physical lab books with digital ones, thus allowing you to reduce the use of paper in the lab. An LES enables the digitization of complex procedures so that you can walk your team through procedural tasks, step-by-step, checking resource availability, and recording data directly into SampleManager LIMS as you go.

An LES eliminates the need to manually record and enter data. Users record information directly into SampleManager software during the procedure, thereby ensuring that data is always accurately recorded and safely stored. Instrument and equipment systems connect directly to the LES – making this a completely digital process. This means recorded data is far more accurate, because it is only entered once, ensuing compliance and data integrity.

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A LIMS for regulatory compliance and data integrity

What regulatory and compliance requirements do I need to consider?

Wherever you are in the world, regulatory compliance is unavoidable. As a legal mandate, it is also the moral compass to ensure that your lab is both legally and ethically sound and adhering to industry and international standards. Regulatory compliance ensures standardization, protection and quality of the data and helps build trust in the communities you serve as well as the marketability of your business. However, compliance can be challenging, thus; it is important to consider the time and cost required to set up specific infrastructure and hire dedicated, competent personnel. Regulations also change; therefore, you must stay up-to-date with evolving industry requirements and actively implement these changes.[1] Below are listed some common regulatory agencies and a selection of their requirements (Table 1).

Table 1. An overview of the different regulatory agencies and their requirements.

Requirements	How can a LIMS help?
FDA 21 code of federal regulations (CFR), part 11	
• Integrity of electronic records • Electronic signature controls • Audit trail • System access control	• Easily manage all records in a digital format • Users can be provided with role-based permission to access electronic records • Audit trails and compliant electronic signatures can be used to demonstrate compliance
ISO/IEC 17025:2017	
• Effective operational quality management systems in place covering: control of records, organizational structure, purchasing services and supplies, internal audits and document control • Personnel must be trained to execute processes and use instruments • The ability to ensure the quality of tests and results, the traceability of methods, the reporting of results as well as the review of requests, tenders and contracts • Ensure system and its configurations are properly validated, with security to prevent unauthorized access and preserve data integrity • Ensure vendor uses a certified quality management system to develop, maintain and support your solution	• Manage all requirements in one place. Documents can be reviewed and updated in a central resource. Permission based access can also be set based on individual user requirements • Keep track of all staff members in the lab (e.g., their training history and level of competence per employee) and all instruments in the lab (e.g., their calibration and maintenance cycle history) • Quickly access and review all the process requirement requests and select the right data to meet compliance requirements • Integrate LIMS with analytical instruments to automatically transfer the test results from the instrument into the LIMS, with minimal human interaction • Keep track of quality control results, managing a complete audit trail of each activity along with a date and time stamp, to present back to regulators and customers • Ensure vendor uses a certified quality management system to develop, maintain and support your solution
Good laboratory practice (GLP) for quality, measurability, traceability and integrity	
• Following SOPs • Proper labelling of reagents • Assigning instruments to only trained analysts • Calibrating and maintaining instruments • Reporting and secure archival of experimental data and results	• Easily track documentation for individual reagents and generate barcodes to properly label inventory and enable traceability • Track personnel permission controls and training, and their competency level and assign instrumentation accordingly • Enable full traceability of samples and test data to drive data integrity
EU general data protection regulations (GDPR)	
• Maintaining records of all processing activities related to protected data • Protecting sensitive information of EU subjects • Authenticating key lab activities	• Features and functionality to support GDPR, such as access controls, audit logs, search and reporting functionality, and importing and exporting capabilities • For hosted systems features like encryption, firewall technology, and intrusion monitoring and detection
Health insurance portability and accountability act (HIPAA)	
• Role-based access permission to staff for safeguarding Protected Health Information (PHI) • Audit trail • Encrypted data transmission and data security	• Assign user role-based access permissions so only authorized users can access PHI data • Generate an audit trail to ensure the data is properly secured

Clinical laboratory improvement amendments (CLIA)

- Document management
- Lab inventory management (reagent and lot tracking)
- Quality control and quality assurance
- Instrument calibration and maintenance
- Ensure accurate and reliable test results
- Keep track of quality control data and easily detect trend in samples and identify outliers and take responsible action
- Support data integrity around testing through controlled workflows, permission controls, audit logs, etc

ISO 15189:2012

- Maintaining confidentiality of PHI
- Defining user role-based authorities and responsibilities
- Validating the system used by a lab to store, collect, process, report and retrieve test and patient data
- Documenting operation details and ensure accessibility to authorized users
- Protecting data and information from unauthorized users
- Validating the test results and associated comments
- Restrict access to patient information via role-based access permission
- Upload all data and test results using an established workflow to ensure that data is validated
- Audit trails to demonstrate compliance
- Maintain data integrity throughout the workflow

ISO 20387

- Maintaining electronic records of samples to secure PHI
- Assignment of tasks to competent technicians
- Instrument calibration and maintenance
- Audit trail – recording the dates and times of all biobanking activities
- Features to support traceability and documentation around the of factors including, sample life-cycle, storage conditions, preservation, inventory
- Training records ensure tasks are assigned only to trained personnel
- Instrument management capabilities support proactive service and maintenance to improve uptime

International society for biological and environmental repositories (ISBER) best practices

- Manage and track samples and locate stored samples
- Audit trail – recording the dates of all biobanking activities
- User role-based access permission to PHI
- Track a sample from acquisition to disposal through its life cycle
- Track sample storage in real-time
- Easily pull up sample storage information

FDA food safety modernization act (FSMA)

- Traceability of food samples through the supply chain to ensure data quality and food safety
- Addressing and tracking food contamination issues
- Implementing corrective and preventative measures to eliminate the risk of contamination
- Achieve complete traceability of samples through the supply chain
- Access samples via a one-dimensional or two-dimensional barcode
- Trace packaged product back to raw materials more easily
- Track chain of custody and sample handling during the stages in production

Hazard analysis and critical control point (HACCP)

- Capture sample and test information to formulate a preventative control plan
- Document and review all procedures and predefined SOPs
- Risk assessment through identification of physical, chemical and biological hazards
- Staff training and competency assessments
- Periodic tracking of information related to incidents
- Trace sample information form accessioning to disposal.
- Track all information related to a test, including data of when it was ordered and processes, who processed it, and validated it
- Keep all lab documentation in one place
- Maintain staff training requirements and limit staff who are competent to handle an instrument

Best practices for regulatory compliance

- Proactively establish policies and procedures to meet compliance and quality requirements
- Have a code of conduct for your teams to established common and expected behaviors, accountability and corrective and preventative actions. This can be supported by setting up a compliance team to improve staff communications
- Conduct regular internal audits
- Ensure your staff are compliance trained
- Adopt a risk-based approach for analysis and manage of risk

Role of a LIMS in driving regulatory compliance

A LIMS can help laboratories across different industries to comply with relevant regulatory requirements and follow best practices. A LIMS helps laboratories to:

- Follow standards and best practices prescribed for an industry
- Securely manage all internal and external documents and track their revision history
- Automate and streamline QA/QC processes and ensure traceability throughout the sample life cycle
- Drive laboratory staff to follow SOPs and minimize errors through controlled workflows
- Support validation and approval of multiple test results before releasing the test reports
- Maintain staff training records so that analytical tasks are only assigned to trained staff
- Schedule equipment calibration, record calibration and maintenance data, and prevent the use of out of service instruments
- Generate Certificates of Analysis (CoAs) and export data and reports as per reporting standards
- Maintain a Chain of Custody (CoC) and a verifiable audit trail
- Ensure only authorized staff are able to create, modify or approve records
- Export data and reports

Compliance with FAIR data principles

Implementing a LIMS can not only make a significant contribution to the digital transformation of your lab, but it can also help you to comply with the FAIR data principles.[1] A LIMS can be used to capture FAIR data and metadata at the moment of observation or directly from each particular instrument. This makes it easier to navigate, manage, analyze and apply internal and external data. The LIMS can record and manage data associated with a myriad of laboratory activities over and above those just associated with sample testing, and make the data accessible within a standard database. As a result, the ability to easily search a single source of data allows researchers to make better, more informed decisions. It also helps to reduce paper use and manual processes and allows integration with wider business functions.

References

1. Acharya A. Regulatory compliance & best practices: How a LIMS helps laboratories stay ahead of the curve". *Labroots.com.* https://events.labroots.com/event/LaboratoryAutomationAndInformatics2021/login?return=Auditorium/n1157013.

Planning a LIMS implementation

Key planning considerations

With proper planning and communication, as well as the right LIMS partner, you can avoid common implementation pitfalls – such as extended timelines, scope creep, unanticipated costs, and slow/low user adoption. Thermo Fisher Scientific Business Analysts (BAs) are available to help throughout the LIMS implementation process to define the right lab informatics solution and ensure you are never alone in the process.

Engage stakeholders early

Everybody in the lab is busy. It can be a challenge to orchestrate a planning meeting to discuss a future LIMS solution, or to imagine an ideal "future state" for your lab. Having a BA visit your benches and discuss processes as they happen (*in situ*) is often more productive.

When a BA observes a process first-hand, they can begin to capture unvoiced requirements. For example, it is important to know the size of the physical items (e.g., tubes, plates) that need LIMS identifiers to determine how much information can fit onto the label. Do users expect to pre-generate labels from a printer in another room and bring them into the lab or generate them on-demand in the lab? Will personal protective equipment (PPE) prevent users from interacting with the LIMS via mouse and keyboard at a specific lab step?

This observation process is not passive. It requires BAs to ask probing questions about your lab activities as they happen. An entirely different set of questions looks at the lab process holistically. However, by questioning, the BA is laying the foundation for continuous process improvement. Just as important, you're signaling that you value – and plan to incorporate – their input.

While the focus of a LIMS is the lab bench, it's essential to gather requirements from all stakeholders. End users are the tip of the iceberg. Other teams will need access to LIMS data or be involved with the care and feeding of the LIMS. By involving database administrators (DBAs) and IT colleagues early in the process, you can reduce the risk of unplanned surprises later.

Put your lab on the map: define your workflows using process maps

Before you select a vendor, map your lab's end-to-end workflows. To do this:

- Draw your process maps and SIPOCs (suppliers, inputs, process, outputs, and customers), including decision points and parallel operations. You can go low-tech using whiteboards, but an investment in software (e.g., Lucidchart, Visio) can accelerate the process by eliminating the translation step from a whiteboard photo to a shareable diagram

- Validate the process maps against the actual in-lab procedures

- Ask the end-users to help, championing this effort for each workflow and each lab within the organization to best understand the flow of data and interactions between the scientists and the systems they interact with

Now that your process map contains all the steps, inputs and outputs, and documentation, you're all set to look for a solution that can adapt to your requirements.

Use your tools to leverage your process maps to help select a vendor

A LIMS is the digital representation of your real-life lab processes. Having undertaken process mapping, you have a clearer picture of what you need your LIMS to do. Using your process maps, begin talking to vendors. Working from the process maps can save you substantial time and cost by reducing the requirements for discovery work.

For example, if you'd like your LIMS built against your current lab state, the vendor should be able to use your existing process maps to design and develop it (or a slightly modified version). Or, if you want to implement a LIMS while also optimizing your lab process, you should work with your vendor to develop "future state" process maps.

LIMS vendors can have very different approaches to projects and implementations. It would be best to find a vendor that not only meets your business needs but is one that you can trust.

Gather around: designing your LIMS

To begin designing your solution, a quality vendor will hold frequent meetings. Early in the process, these sessions will be able to translate the process diagrams to LIMS functional requirements. BAs and super-users who have intimate knowledge of the lab processes will be instrumental.

As the implementation proceeds, some sessions will be "show and tell" to preview specific functionality. To encourage end-user buy-in, you may involve as many 'relevant' people as possible in these meetings; fostering an open dialog during these sessions is essential. Getting feedback early can help to avoid costly re-work further down the line, ultimately increasing the likelihood of delivering the project on time and within budget, and of gaining user adoption.

What are the challenges of implementing a LIMS?

Adopting a LIMS system brings many benefits to your lab, but there can be potential challenges to look out for when implementing LIMS software.

Data migration
When you're ready to make a LIMS part of your lab's digital transformation, moving over data through the migration process can take time, and can involve some manual data entry. For the most part the software will take care of the migration, but you may want to enlist the help of an expert to help oversee the migration process to ensure that there is no data lost or corrupted during the transfer.

Staff training in the new system
Switching to a new LIMS application has the clear benefit of removing many manual tasks and procedures. You will need to invest time to train your colleagues to orientate and understand the capabilities of the new system. You should be prepared for a potential dip in performance during this transition period to the new LIMS solution.

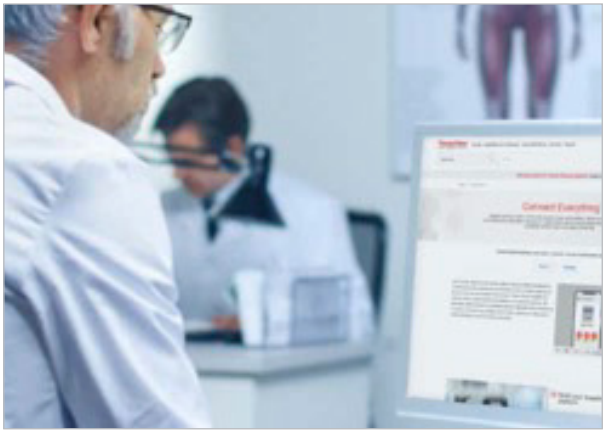
Latent interoperability
Some older lab management systems can contain data in several incompatible formats. In the past you may have had to enter test results manually, and this data format might be incompatible with your new solution.

As part of the migration, you may have to reformat your data or even update the legacy software that you plan to integrate. This is something that you should review in advance of any implementation project.

"SampleManager (LIMS software) gathers all our results, and makes them accessible for the whole organization. Configuration is easy and user friendly, and the on-site support from Thermo Fisher during our implementation was excellent."

– Karen Halling, Laboratory Manager, Shell

On-demand resources and support



Brochures, case studies and videos

Our website is the first port of call as you research the right LIMS solution for your lab. The site features a wealth of case studies, brochures, and video content.

Find out more about our LIMS solutions

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Subscribe to our Connected Lab blog to help you to make the digital transformation of your lab meaningful, relatable and accessible. The blog features posts relevant for scientists and researchers across all industries and applications.

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Speak to a member of our team

Our LIMS solutions are designed to enable scientific discovery, engineered to support industry and designed for the human experience. Thermo Fisher Scientific staff are here to support you, throughout your scientific journey.

Contact us to see how we can help

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