Thermo Scientific SampleManager LIMS Software

A complete laboratory solution

Thermo Fisher
SCIENTIFIC

Thermo Scientific™ SampleManager™ LIMS is more than just a laboratory management solution—it drives compliance, connectivity and efficiency to deliver increased productivity across your business. SampleManager includes:

- Comprehensive analytical data management (SDMS)

- Procedural execution (LES)

- Industry-leading instrument and system integration

- Unparalleled laboratory management capabilities

SampleManager LIMS Software

technical support

Various resources are provided to ensure dedicated and responsive support and training, enable collaboration with other users and drive continuous product improvement.

professional services

Our team has proven expertise in project management, implementation, validation and system optimization for laboratory software across all industries.

compliance, data integrity & security

Audit history
Ensure data integrity with audit history detailing the who, what, when and why for any events.

Access and security
Fully secured with passwords and eSignatures to meet FDA 21 CFR Part 11—customize user access to meet any regulatory requirements.

Training records
Ensure only qualified analysts run approved methods using in-service instruments, facilitating ISO 17025 compliance.

sample handling & procedural execution

Sample receipt
Streamlined reception of scheduled and ad-hoc samples using barcodes.

Test assignment
Fast automatic or ad-hoc test assignment.

Sample tracking
Simplified, highly granular location and chain of custody management using barcodes and RFID.

Procedural execution
Provides proof of SOP repeatability and drives quality by reducing analyst error.
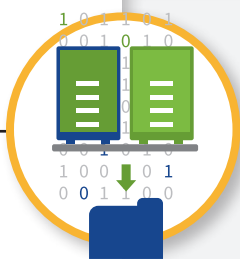
resource management

Instrument management
Minimize downtime by scheduling instrument calibration and servicing.

Stocks and suppliers
Keep track of your inventory and auto-decrement reagents when used in methods. Manage suppliers to drive quality and improve invoicing.

data handling

Result review
Automatically highlight out of spec results and automate any next steps or corrective action.

Data management
Securely archive all forms of raw analytical data according to regulatory requirements. Access without the original software, future-proofing your lab.

Result retrieval
Secure instrument integration eliminates manual transcription errors and reduces time spent on manual entry and review.

reporting & data visualization

Report delivery
Data is processed and results reported in the format required to enable rapid decision making.

Dashboard views
Dashboards provide an instant snapshot of lab/production/process health for any data stored in the LIMS.

SampleManager delivers

Thermo Scientific SampleManager LIMS delivers laboratory management, data management (SDMS) and procedural execution (LES) capabilities in a single solution, enabling organizations to realize increased productivity and streamlined operations. Laboratories across all industries including pharmaceutical, food and beverage, oil and gas, petrochemical, water and environmental, manufacturing and contract testing rely on SampleManager to unlock the power of their laboratory data.

The value of a Standard Enterprise LIMS

SampleManager is consistently deployed as a global solution, across multiple locations and into different laboratory types such as production, R&D and others. There are significant advantages of standardizing on a single LIMS:

- Lower support and maintenance, reduced system administration and simplified training

- Fewer systems and vendor relationships to maintain

- Multi-lingual systems, role/location dependent views and toolbars for frequently used functions

- Easier cross-company information sharing and collaboration

- Smoother integration with laboratory instruments and enterprise systems

- Upgrade paths which reflect previous investment and ongoing customer input

> "We needed a validated product that provides us with sufficient flexibility to deliver all the requirements that a pharmaceutical plant has such as data security and consistent quality data; fast and accurate data storage and recovery and all the industry functionality."
>
> — Ronaldo Galvao, Quality Operations Director – GPSG Brazil

compliance, data integrity & security

Audit history, access & security

Many LIMS users work in regulated environments and have to comply with standards such as 21 CFR Part 11, GAMP and ISO 17025. Data integrity is a key consideration regardless of lab function, so those in regulated and non-GMP environments will find value in SampleManager's fully configurable audit features:

• Full control of access to data review and approval

• System timeouts and password checks

• Extensive document versioning capabilities

• Sophisticated sample custody and incident management

• Configure secure electronic signatures for any system operation

• Log any events and who performed them, with time and date stamps and reasons for changes

Training records

Analysts' qualifications to operate instruments or run methods can be held in SampleManager, which ensures that only the instruments, methods and equipment they are trained on are available for their use. Notifications can be set to alert managers of retraining requirements ahead of time.

sample handling & procedural execution

Sample login and tracking

Integrity of samples, chain of custody and sample tracking are controlled using barcodes or RFID and highly specific location management functionality. SampleManager enables granular tracking of sample splitting and merging, providing enhanced traceability.

- Automate reception by pre-scheduling routine samples, supporting raw material and skip lot testing

- Automatically assign tests and specifications to samples and produce customized labels

- Track, display and report samples by any criteria recorded in the system

- Track every aspect of an analysis including instrument state and configuration, operator name and training level

Unique procedural execution

The integrated SampleManager Laboratory Execution System (LES) guides analysts through each step of a method to ensure compliance to the SOP and captures the complete process history. Drive quality and compliance through repeatable execution of methods and processes:

- Complete, detailed and step-by-step instructions for each method

- Illustrations demonstrate correct analytical techniques

- In-process checks confirm user qualifications and instrument availability

- Immediate check of step execution and process history

- Review by exception – Out of specification steps are flagged for fast procedure review

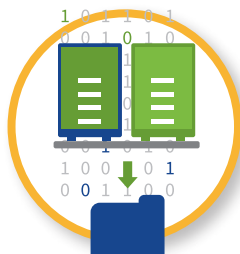# resource management

Stocks and suppliers

SampleManager reduces waste and ensures essential supply availability by managing stocks of consumables, reagents and other chemicals (including safety handling data) and carefully monitoring your lab inventory

- Automatically decrement stock usage and reorder supplies

- Management of approved suppliers enables effective control of budgets and quality

- Stock and inventory dashboards provide up-to-date overviews of resources

Instrument management

Instrument and equipment calibration and maintenance can be managed down to individual component parts, enabling forward planning to minimize downtime

data handling

Result entry and calculations

- Results are automatically transferred into SampleManager from integrated instruments and equipment

- Out-of-spec results can be highlighted on entry, enabling review by exception which minimizes review time

- OOS results can also automatically trigger follow up actions (such as direct re-test or confirmation) and initiate corrective action/incident log

- Advanced tools create complex calculation formulae to determine results from data

- An extensive library of mathematical functions can be extended with users' own calculations and formulae

- Calculations are automatically carried out as soon as the required data becomes available

- Incident Management functionality allows users to record, track and manage unforeseen events, enabling continuous improvement which is a critical factor of ISO 17025 compliance

Data management

SampleManager's SDMS (Scientific Data Management System) was designed with regulatory requirements in mind. Thermo Scientific™ Data Manager™ ensures that all raw data and associated metadata is accessible for the entire data lifecycle:

- Long term preservation and retrieval of raw instrument data

- Convert data to a vendor-neutral XML format

- View converted data from virtually any platform without the original instrument software

- Share, compare, search, query and reuse data across your organization

- Link raw data directly to the relevant sample records

reporting & data visualization

Reporting

Data and information are easily extracted from SampleManager and presented as actionable information in a clear, concise format—templates can be configured to specific user requirements. Report generation can be automated and sent to multiple destinations or individual stakeholders.

Data visualization

Any information stored within SampleManager can be displayed pictorially:

• Sample points on a map

• Locations in a laboratory, useful for Environmental Monitoring

• Critical points within a production process

The size and color of the points can be used to represent data, such as out-of-spec or out-of-trend results. This gives a rapid indication of process health, and pinpoints any issues or potential problems quickly so that action can be taken to investigate or remedy the situation.

Dashboards

Dashboards can also be generated using any data available within SampleManager:

• Personalize specific to role to provide the user with a quick snapshot of relevant information and Key Performance Indicators

• Display various formats including graphs, charts, tables and maps

• Users can drill down to investigate real-time data points in a dynamic environment
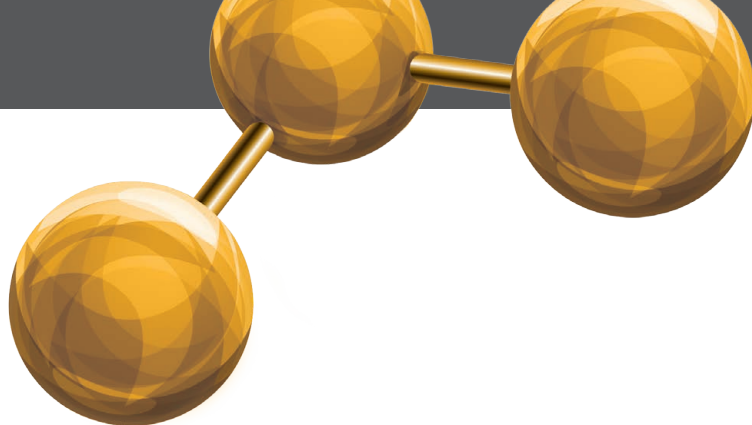
SampleManager Mobile

SampleManager's native mobile application enables access to LIMS via tablet, wherever there is an available internet/network connection.

• Secure user login using SampleManager credentials

• Receive and move samples; use the camera or Bluetooth® barcode scanner to scan samples and select records

• Browse and view samples

• Enter results manually or via remote instrument connectivity

• Familiar user-intuitive interface minimizes training requirements

• Access LES/Procedural ELN methods anywhere:
   —Start a new Lab Execution from an existing Lab Method
   —Locate running Lab Executions and resume work

Flexible, adaptable LIMS

SampleManager's unique workflow capabilities enable users to quickly build workflows which map to actual laboratory processes, automating decisions and actions and reducing the need for user intervention. Labs can easily adapt to new methods and process changes while simplifying initial system configuration, deployment and ongoing maintenance.

"We required a system that would integrate easily with other applications and instruments in and out of our laboratory, providing one standard user interface and helping enforce process standardization across multiple laboratories."

—Alberto Chiari, Technical and Geographical systems manager at AySA Water

Integration and connectivity

SampleManager is frequently connected with various solutions, enabling fast informed decisions. Flexible, user-friendly interfaces connect the LIMS with Manufacturing Execution Systems (MES), Process Information Management Systems (PIMS), Enterprise Resources Planning (ERP) systems, Chromatography Data Systems (CDS) and other analytical data management solutions, allowing you to gain a holistic view of your operations, achieve better control of plant operations and boost productivity.

Connection of all laboratory instrumentation, regardless of manufacturer or technique, improves quality and preserves data integrity. Instrument integration is enabled with bi-directional communication directly from SampleManager for run setup and result collection, eliminating data transcription errors.

Centralized chromatography and MS data management

For even smoother operations, SampleManager is tightly integrated with Thermo Scientific™ Chromeleon™ CDS (Chromatography Data System). The integration provides users with:

- Access to all LC, GC, IC and MS data within the same platform

- Full capability to monitor queue status and instrument health from the LIMS

- One streamlined, automated analysis process, including LES

- Multi-vendor, bi-directional chromatography and MS instrument control

- Calibration and maintenance of instruments—even down to the consumable parts

- Search batch or lot information across any instrument throughout the workflow

"SampleManager 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
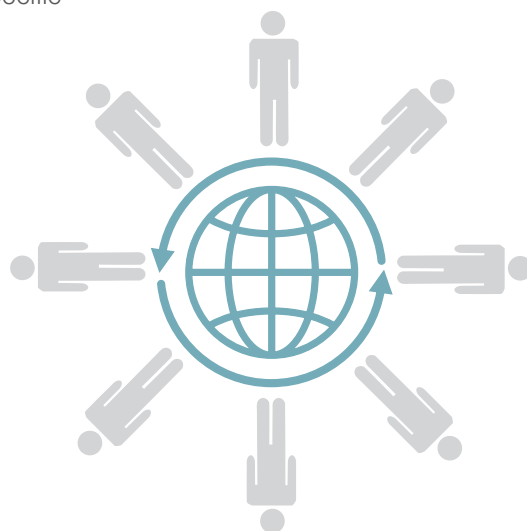
Specialized functionalities

In addition to features essential for all labs, SampleManager is also equipped with capabilities to help meet the business needs of specific environments and types of laboratory:

- **Stability studies** with powerful inventory functionality monitor and control stock levels of raw materials, in-process and finished products.

- **Comprehensive Environmental Monitoring** capabilities provide analysts with the tools required to plan and execute a solid EM program

- Advanced **SQC trend analysis** tracks product quality and production process performance over time

- Pre-configured **water management testing** enables sample planning, sampling and testing regimes and reports to support the latest regulatory requirements

- For **food and beverage testing**, SampleManager can build all the HACCP steps into the workflow structure, enabling complete traceability from individual batches of raw materials through to finished product

- Rapid data processing and information delivery enables process decisions to be made quickly and parameters adjusted to maximize output and margins. This is particularly valuable to customers in **production environments including mining, oil and gas, and petrochemical**.

- SampleManager enables full control of multi-level specifications, maximizing the margin achieved on each finished product—particularly useful for **manufacturing laboratories**

Professional services and technical support

Our team of services and support professionals are located across the globe, ready to implement, validate and optimize our solutions to enable customers to achieve maximum value from their laboratory software investment. Services projects are delivered either directly by Thermo Fisher Scientific consultants or by our approved partners, enabling us to provide a truly global service including local language and follow-the-sun support. Our project managers and consultants have a wealth of experience across various organization types, ensuring that industry and regulatory requirements as well as business-specific needs are taken into consideration. Support resources include:
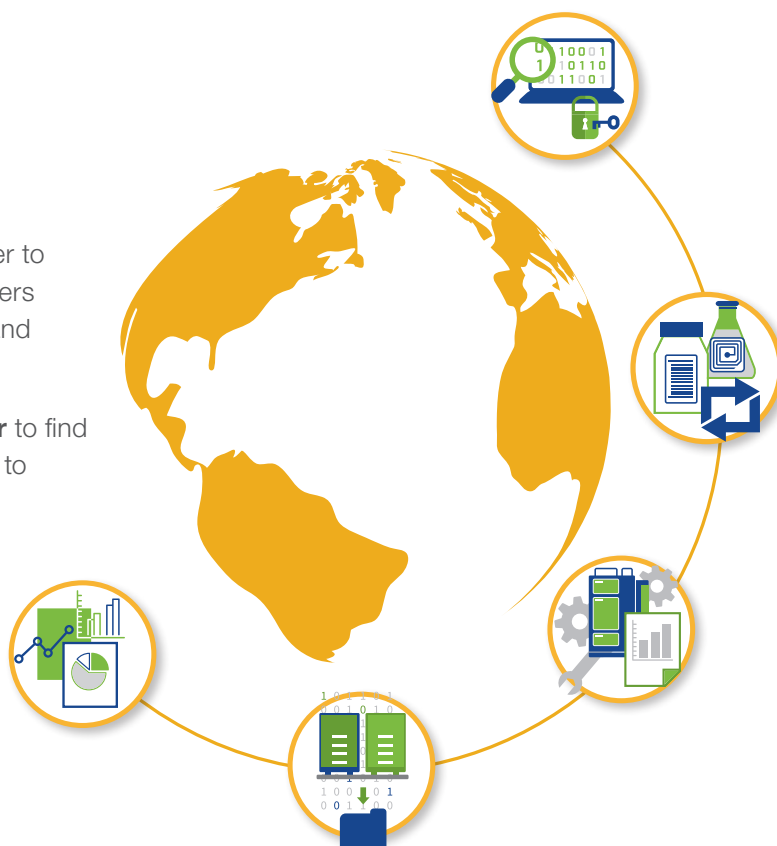
- Global support via phone, email and WebEx

- Diagnostic tools to expedite issue resolution

- Online product news and technical information

- Interactive product user forum

- Training solutions tailored to customer requirements

- Access to product updates and new versions

thermo scientific

In good company

Companies around the globe use SampleManager to help them deliver top-quality brands their customers trust, drug products that are relied on for health and well-being, fuels that power industry, and more.

Visit **www.thermofisher.com/samplemanager** to find out how organizations are using SampleManager to unlock the power of their laboratory data.

"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

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