ThermoFisher SCIENTIFIC

Laboratory software

Rest assured

Driving compliance in critical production environments

Are you ready?

Visits from the U.S. Food and Drug Administration (FDA) and other regulatory bodies to check and verify processes, review training and work practices and ensure data integrity are inevitable for organizations that manufacture and supply infant formula.

Many labs are unable to easily locate and provide evidence to demonstrate adherence to validated processes, show that appropriate checks are in place, and ensure all analytical data is accurate, complete and consistent.

Laboratory data integrity in a Good Manufacturing Practices (GMP) environment can be defined as ensuring the accuracy, completeness and consistency of data over its entire life cycle, in compliance with applicable regulations.

In recent years, the FDA has increased its enforcement efforts, inspecting some laboratories at least twice a year. Not all inspections are announced in advance.

As outlined on U.S. FDA Form 482, inspectors can ask to examine any records of analyses, environmental monitoring, handling, storage and shipping, staff training and calibrations – anything pertinent to safe manufacturing of your products. You need confidence in your ability to retrieve this data at any time.

Did you know that the full raw analytical data collected must be kept electronically in case of inspection? A printout of a trace is not satisfactory.[1]

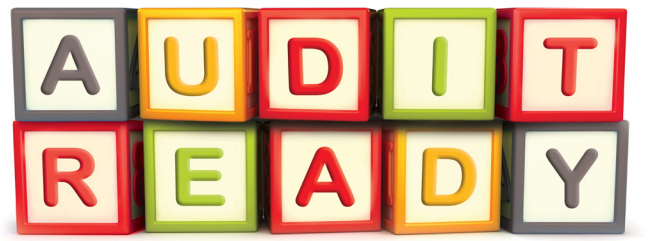
Focus on the importance of your lab data

Rest assured

Diminish the risk of an FDA Form 483 with a complete lab management and data traceability solution

No more searching for documentation to show that a procedure was followed correctly. No more time spent hunting for staff training records, environmental testing schedules, instrument calibration records and records to support evidence of U.S. FDA 21 CFR Part 11, ISO 9001, EU GMP Annex 11, ISO 17025 and cGXP compliance.

Thermo Scientific™ SampleManager™ LIMS software can help your business adhere to processes and reduce the risk of being issued a Form 483.

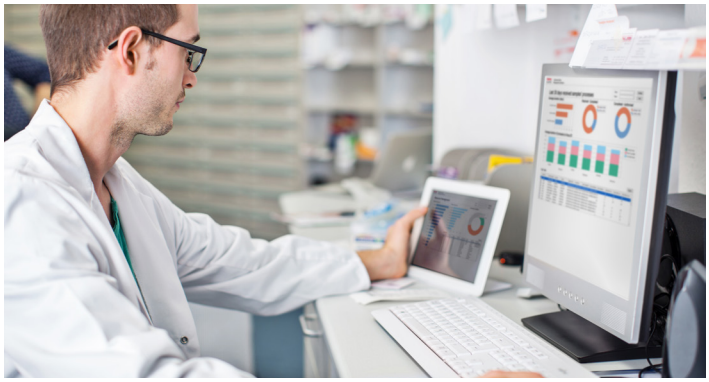


SampleManager software continues to be one of the most widely deployed LIMS in the world. The solution manages your lab, data and procedural workflows, connecting with other enterprise systems, instruments, equipment, and your customers, to deliver increased compliance and productivity across your business.

SampleManager LIMS is a fully compliant Laboratory Information Management System, Scientific Data Management System (SDMS) and Lab Execution System (LES), with seamless integration to Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS). For over 30 years, it has supported customers using the latest technologies and is developed, designed and supported in an ISO 9001 environment. Through configuration, not customization, SampleManager LIMS can be tailored to your specific business processes and laboratory workflows.

The software can help drive process compliance and enable electronic management and execution of Standard Operating Procedures (SOPs) – helping you to avoid potential Form 483 Inspectional Observations.

- Laboratory Execution guides users step-by-step through laboratory methods, driving adherence to processes
- Automatic result transfer and full audit trail preserves data integrity
- Electronic signatures provide unquestionable proof of all actions completed in the lab – secure and dependable evidence for auditors
- Integrated training records ensure operators are only able to use methods, instruments and equipment on which they are trained – alerts remind users to keep qualifications in date
- Comprehensive instrument and equipment management:
  - Enables breakdown into component parts for specific calibration and maintenance requirements
  - Ensures only ‘in service’ equipment can be selected
  - Each device used can be traced back from a sample/test
- Secure, future-proofed data archival ensures complete analytical data can be easily located, retrieved and viewed without the expense of additional software
- Thermo Fisher Scientific has helped hundreds of customers in highly regulated environments over the past thirty years, so you can rest assured you’ll be Audit Ready



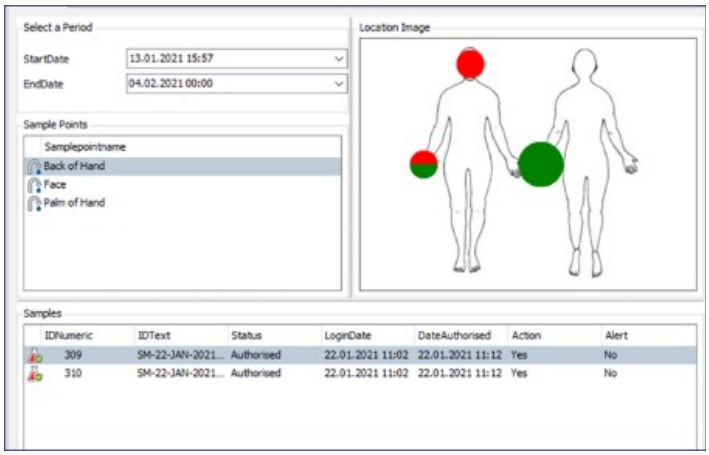
Dashboards improve quality by providing real-time information to quickly highlight exceptions and enable immediate corrective action

Managing environmental monitoring programs

SampleManager LIMS provides support for the creation and management of ingredients, prepared media, and media containers, as well as supplier management, stock batches and validation analysis.

The system supports EM program management from sampling plans through result monitoring and corrective action:

- Manage both regular and unscheduled sampling of lab or field-based locations and personnel points
- Configure sampling plans according to location, frequency, type of sample and method to be used
- Record and track all data including sample time and date, sampler ID, equipment used, shipment, condition on receipt, and any preparation for testing
- Manage cleanroom environments according to ISO standards
- Manage microbial samples using a pre-configured microbiology library and incubation support
- Dashboards and room/map/personnel views provide visual displays of contamination levels against set limits
- Corrective actions are managed to ensure appropriate action in the event of contamination



Personnel monitoring locations clearly indicate contaminant levels for immediate action

A solution you can rely on

A proven solution relied upon in highly regulated environments globally, SampleManager LIMS has been fully validated and successfully audited at hundreds of our client sites. Here's what you can expect:

Drives user through methods and SOPs in a stepwise fashion

Improves quality and consistency in processes

Automatically verifies in the LIMS to ensure only trained methods and calibrated instruments are enabled

- Complete sample, test and result workflow management
- Calibration and maintenance of instruments down to component parts
- Operator training records with expiry alerts
- Dashboards provide snapshot of lab status to management

- Secure, future-proofed data archival and retrieval
- Support for various instrument types from different vendors
- Vendor neutral XML for future-proofed storage
- View data from different techniques on a single system without original software

ENABLING COMPLIANCE IN HIGHLY REGULATED ENVIRONMENTS

Certified System
Quality
ISO 9001
SAI GLOBAL

The Digital Science business of Thermo Fisher Scientific operates a Quality Management System (QMS) certified to ISO 9001: 2015 for the 'design, development, sales, implementation and support of computer based laboratory information automation systems'.

References

1. The FDA states that paper printouts of chromatograms fail to be a true copy under 211.180(d) of the electronic records used to create the paper chromatogram.

Learn more at **thermofisher.com/samplemanager**