Thermo Scientific
Integrated Informatics

Rest Assured

Get Your Lab Audit Ready with
Thermo Scientific™ Integrated Informatics

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Visits from the FDA and other regulatory bodies to check and verify processes, review appropriate use of resources and ensure data integrity are inevitable for pharmaceutical laboratories across the globe.

Many labs are unable to easily locate and provide evidence to demonstrate adherence to validated processes, show that the most appropriate and qualified resources are being used and ensure all analytical data is accurate, complete and consistent.

Laboratory data integrity in a 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 pharmaceutical laboratories at least twice a year – more if processes or substances are novel or complex. Not all inspections are announced in advance.

As outlined on US FDA Form 482, inspectors can ask to examine any records of analyses, handling, storage and shipping, staff training and calibrations – anything pertinent to the development of your drug products. So you need confidence in your ability to retrieve this data at any time.

Metadata such as chromatography column used, temperature, reagent information, solvent information, etc. are essential to provide full electronic records. Without these details your records are incomplete.[2]

Are you ready?

Focus on the importance of your lab data

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

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.

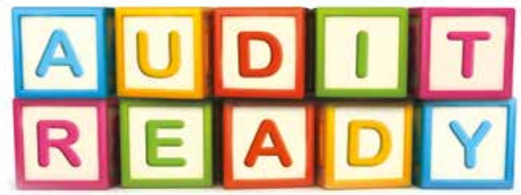
2 Furthermore, it is not a complete and exact copy of the electronic records as required by 21 CFR 211.68, as there is typically not the injection sequence, various instrument, acquisition or processing methods and certainly not the linked audit trail entries from the analytical run. The reason is that the electronic records in a CDS contain much more information than the corresponding paper printouts of the same chromatographic run.

Robert McDowall. "Review and Critique of the MRHA Data Integrity Guidance for Industry - Part 1: Overview". Published on Scientific Computing (http://www.scientificcomputing.com)

Rest assured

No more searching for documentation to show that a procedure was followed correctly. No more time spent hunting for staff training records, instrument calibration records and proof of US FDA 21 CFR Part 11, ISO 9001, EU GMP Annex 11 and cGXP compliance.

Thermo Scientific™ SampleManager LIMS™ is a fully integrated laboratory platform encompassing laboratory information management, scientific data management (SDMS) and lab execution (LES), with seamless integration to Thermo Scientific™ Dionex™ Chromeleon™ 7.2 Chromatography Data System (CDS) software.



Rest Assured – Audits Simplified

Laboratory Execution guides users step by step through laboratory methods, ensuring adherence to processes

Automatic result transfer and **full audit trail** preserves data integrity

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 & 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

Electronic signatures provide unquestionable proof of all actions completed in the lab - secure and dependable evidence for auditors

Thermo Fisher Scientific has helped hundreds of customers in pharmaceutical research and development and manufacturing 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

Understand the requirements

You are responsible for the accuracy and integrity of the data generated by your lab, including all the raw data produced during each sample test, such as graphs, charts and spectra from lab instrumentation. These records should be properly identified to demonstrate that each batch was tested and met release specifications.

GMP Regulatory Requirements for Data Integrity:

Building confidence in laboratory data management

- **Instruments must be qualified and fit for purpose –**
  The ability to maintain instrumentation and equipment and ensure they are fit for purpose at the time of use is critical, both for efficiency and to maintain compliance. Similarly you need to demonstrate that methods, equipment and instruments are only used by people trained to use them.
- **Software must be validated –**
  Any software used to manage lab processes, or the data generated in the lab must be validated to ensure data integrity and compliance.
- **All calculations must be verified and data securely backed up –**
  Data must be consistent from acquisition through to calculation, reported result and long term archival. Raw data should be stored and maintained in a secure, centralized server.
- **Reagents and reference solutions must be prepared correctly with appropriate records –**
  Stock management functionality ensures traceability from tests to the reagents and sample preparation used.
- **All actions must be documented contemporaneously –**
  Every action must be attributable to an individual using electronic signatures time stamped by both client and server, ensuring undisputable evidence of process adherence.

"The implementation of Thermo Scientific LIMS has resulted in a number of clear benefits including enhanced data quality, integrity and availability by eliminating manual, error-prone and time consuming paper-based processes."

Top 10 Pharmaceutical Customer

Auditors will check that data is accurate, complete and consistent:

- ☑ **Accurate:**
  Do records show that the results recorded by the instrument are the same as those submitted in COA's and other documents?
- ☑ **Complete:**
  Was full data recorded - including metadata, such as column or other equipment used, temperature, time of analysis, etc?
- ☑ **Consistent:**
  Where out-of-spec results were returned, were appropriate actions taken according to SOPs?

Method Execution

- Drives user through methods and SOPs in a stepwise fashion.
- Improves quality and consistency in processes.
- Configuration, not customization to create new methods.
- Automatically verifies in the LIMS to ensure only trained methods and calibrated instruments are enabled.

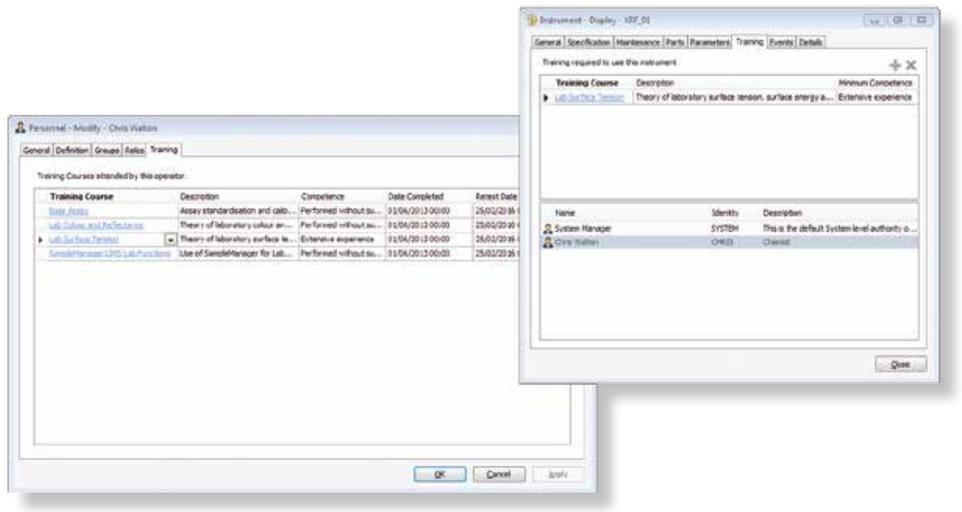
Laboratory Management

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

Data Visualization

- Secure, future-proofed data archival and retrieval.
- Support for approximately 200 instrument data formats.
- Vendor neutral XML for long term storage.
- View data from different techniques on a single system without original software.

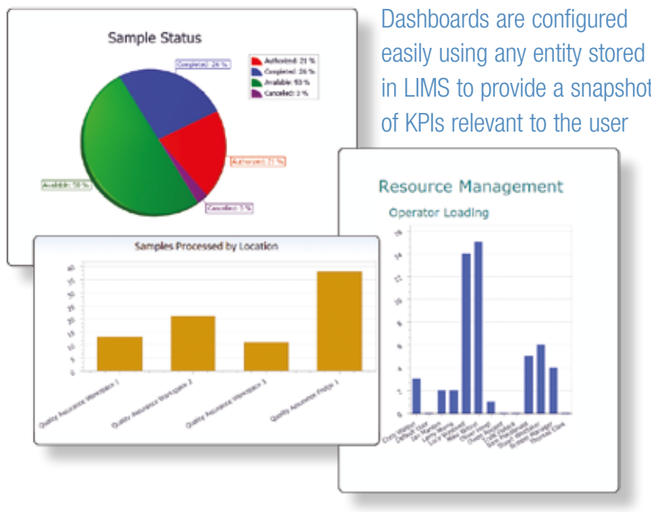
Enabling Compliance in Highly Regulated Environments



Ensure that scientists can only employ the instruments, methods and equipment they are trained to use

"Thermo Fisher Scientific was selected not only for its product's rich functionality and extensive deployment history in Pharmaceutical QA/QC, but also for its services capabilities to implement, validate and provide language support across multiple sites and continents."

Top 10 Pharmaceutical Customer



Dashboards are configured easily using any entity stored in LIMS to provide a snapshot of KPIs relevant to the user

Thermo Scientific
Integrated Informatics

A proven solution relied upon by pharmaceutical laboratories globally, Thermo Scientific LIMS has been fully validated and successfully audited at hundreds of our client sites. Here's what you can expect:

- Built-in audit reporting for FDA 21 CFR Part 11, ISO 17025, Annex 11 and other regulatory bodies.
- Control of methods and SOPs, changing workflows and continuous sample tracking with our built-in Laboratory Execution System.
- Full Connectivity and Integration with existing enterprise systems and instruments for centralized data capture, access, visualization, retrieval and reporting.
- Detect non-conformance trending before it reaches pre-defined thresholds with Statistical Quality Control (SQC).
- Comprehensive stability management including inventory management, real-time expiration prediction and linked sub-studies.

Seamless CDS Integration

SampleManager LIMS is fully integrated with Chromeleon Chromatography Data System - providing a seamless CDS link within the LIMS to streamline the laboratory process and eliminate manual steps related to sample testing and results capture and analysis. The integration gives access to LC, GC, IC and MS data within the same platform and user environment, simplifying training of personnel and reducing operating costs. SampleManager LIMS also integrates with all other commercially available Chromatography Data Systems - contact us to find out more. Visit the Chromeleon CDS Resource Center at **www.thermoscientific.com/Chromeleon**

In good company

"I've never seen a LIMS as well integrated into the QC laboratory as it is here."

An FDA auditor following the inspection of a QC lab at a global biopharmaceutical company using SampleManager LIMS

"The level of automation in this department is the best I've ever seen."

An HPRA auditor following the inspection of a pharmaceutical QC lab using SampleManager LIMS

"We made the decision to standardize on a company with proven expertise in the pharmaceutical industry. We needed a validated product that provides flexibility to deliver all the industry functionality such as data security and consistent quality data, and fast and accurate data storage and retrieval."

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The Informatics business of Thermo Fisher Scientific operates a Quality Management System (QMS) certified to ISO 9001: 2008 for the 'design, development, sales, implementation and support of computer based laboratory information automation systems'. Seven facilities worldwide are registered under this multi-site certificate for Informatics global QMS.

Certified System
Quality
ISO 9001
SAI GLOBAL

For more information about Thermo Scientific Integrated Informatics, call us at the number closest to you, email us at **marketing.informatics@thermofisher.com,** or visit **www.thermoscientific.com/RestAssured**

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