

Laboratory software

Adding a LIMS to advance your bioanalytical workflows

Introduction

In the rapidly evolving world of bioanalysis, laboratories across the globe are constantly seeking solutions that can streamline their workflows, enhance efficiency and support compliance with stringent industry regulations. One such solution that stands at the forefront of this technological revolution is a laboratory information management system (LIMS).

A LIMS is more than just a software package; it's a comprehensive system designed to manage and control the complex requirements of bioanalytical laboratories. It offers an innovative approach to efficiently manage your bioanalytical data, promote compliance and create efficiencies in small- or large-molecule bioanalytical workflows for both clinical and non-clinical studies.

This eBook provides an in-depth understanding of how implementing a LIMS, specifically Thermo Scientific™ Watson LIMS™ software, can advance your bioanalytical workflows. From study initiation to closeout, Watson LIMS software helps ensure complete traceability and control, enabling compliance and adherence to industry regulations. With a proven track record of successful implementations, Watson LIMS software has been instrumental in bringing thousands of drugs to market across the world.

Whether you're a small laboratory focusing on specific biologics or a large institution with a mixed portfolio of small and large molecules, Watson LIMS software offers a complete solution to power your bioanalytical workflows. From method validation and sample analysis to data processing and reporting, Watson LIMS software is designed to streamline every step of your bioanalytical process.

Join us as we delve into the world of LIMS and explore how it can revolutionize your bioanalytical workflows, save time, eliminate customization and help ensure successful implementation with expert support. Discover the power of Watson LIMS software and get ready to transform your bioanalytical laboratory into a hub of efficiency, compliance and success.



Contents

Enabling data integrity in bioanalysis

Gain insights on the importance of data integrity in bioanalysis as scientific demands continue to evolve. In this whitepaper you will learn the key elements of bioanalytical data integrity, the role of a LIMS, the impact of evolving scientific demands and the cost of non-compliance.

Experiencing Watson LIMS software

Dive into the world of Watson LIMS software, a tool designed to manage and streamline bioanalytical studies. With Watson LIMS software you will not have to compromise on quality or accuracy. Our software is designed to unlock your laboratory's full potential, empowering you to achieve your goals with ease and confidence.

Cloud services with AWS

Discover the benefits of deploying Watson LIMS software in the Amazon Web Services (AWS) cloud. From the robust security measures, including encryption, intrusion detection, and strict access controls, your data is protected. Realize the value of Thermo Fisher Scientific managing your AWS deployment, providing end-to-end support, including disaster recovery and change management.

Standardizing bioanalytical workflows with Watson LIMS

Learn about one of Europe's largest oncology-focused, integrated discovery and development companies introducing Watson LIMS into their labs to manage process statistical data related to ELISA experiments. Discover why Watson LIMS was their software of choice and how the solution plays an instrumental role in delivering drug approvals through exceptional study management, while promoting regulatory compliance.

Achieving LIMS implementation success

Elevate your LIMS experience by partnering with a dedicated team to ensure seamless implementation. With over 400 employees specifically dedicated to digital science solutions, Thermo Fisher helps ensure minimal downtime and successful project outcomes. Our approach includes future-focused solutions, punctual rollouts and no hidden costs. You also benefit from early planning, a deep understanding of lab processes and continuous communication.



Laboratory software

Enabling data integrity in bioanalysis

Evolving scientific demands

There is continued growth in emerging scientific modalities, particularly the use of monoclonal antibodies and cell and gene therapies. Cell therapies are considered as “next generation” or “novel biologics” and are growing in quantity across development pipelines. A recent search in clinicaltrials.gov with the term “CART”, “TCR”, or “monoclonal antibody” yielded 106, 84, and 1049 active/recruiting studies respectively. With such rapid growth, novel bioanalytical assays had to be developed and validated with only a draft guidance available as reference – stressing the importance of data quality and the ability to recreate a bioanalytical study.

While there has been substantial growth within large molecule development, several trends have also emerged in recent years in regards to small molecule bioanalysis. One significant trend is the increasing demand for sensitivity and selectivity in small molecule analysis. Scientists are constantly striving to detect and quantify lower concentrations of analytes in complex biological matrices. This requires the development of more sensitive and specific analytical methods, such as **liquid chromatography-mass spectrometry (LC-MS)** and **gas chromatography-mass spectrometry (GC-MS)**, as well as innovative sample preparation techniques.

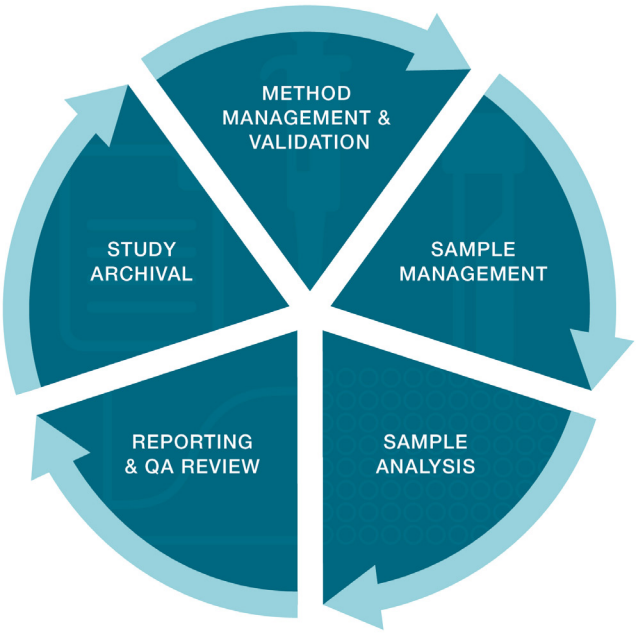


Across all molecule types there is an increasing need for the **integration of high-throughput automation systems**. With the common industry need to analyze large numbers of **samples efficiently, automated sample handling systems, robotic platforms**, and **laboratory information management systems** have become essential tools. These advancements help streamline the analysis process, reduce human error, improve quality, and increase productivity in laboratories. We partner with our customers to **address all of** these specific challenges to bioanalysis – ***informatics, automation, sample prep and storage, antibody creation, instrumentation, and bioanalytical services***.

Producing data of high quality and integrity throughout bioanalytical studies

Laboratory analysis is just one component in controlling and ensuring data integrity during a bioanalytical study. Data integrity in a bioanalytical laboratory goes beyond non-clinical and clinical data capture, it stems into many other processes such as record keeping, sample and analyte shipping, stability, study and sample management, method and instrument validation, training, and documentation. The data produced by bioanalytical laboratories is vital in supporting BLA and NDA submissions, as well as phase 1-4 clinical trials. The failure to adequately document GLP studies, can result in regulatory agencies rejecting pieces of a submission and asking the Sponsor to re-conduct studies, or more seriously a Refuse-to-File (RTF) as outlined in the guidance to industry "Refuse to File: NDA and BLA Submissions to CDER,", causing a significant impact to the timeline and budget of a project. Section 21CFR601.2(a) states "An application for a biologics license shall not be considered as filed until all pertinent information and data have been received by the Food and Drug Administration".[4]

The challenge for bioanalytical laboratories is ensuring that they are complying with the latest regulatory documents set forth by regulatory agencies in each of the countries where they plan to file in. The most reliable way to ensure the integrity of these components is by incorporating a dedicated bioanalytical LIMS such as Thermo Scientific™ Watson™ LIMS software.



Quality is not optional

The Food and Drug Administration reported that in FY 2022 out of the 29 nonclinical inspections conducted, significant observations were noted resulting in the issuance of a Form FDA 483 Inspectional Observation during 13 inspections, with 78 significant observations noted. The trends and themes identified were:

- Inadequate training at multiple levels
- Failure to follow written procedures
- Lack of Study Director oversight[1]

Significant direct and indirect costs are accrued as a result of receiving a 483; the financial impact varies depending on the severity of the findings ranging in costs from millions to multi-millions of dollars to reconcile. Examples of direct costs include: hiring of consultants to mitigate and reconcile findings, government fines, re-validation of methods, loss of patient sample (particularly important in cases of rare disease), and repeat of clinical trial –on average an individual pivotal trial for a new drug cost $19 million USD.[2]

In addition to the direct costs of receiving an FDA warning letter, there are indirect costs as well, including:

- A damaged public reputation
- Competitor opportunity
- Severed contracts
- Distractions from growth
- Decreased employee morale and increase turnover

Theses direct and indirect costs can be mitigated by implementing a Laboratory Information Management System (LIMS) that is ***trusted by regulatory bodies and pharmaceutical Sponsors***. LIMS provide bioanalytical labs with a mechanism to ensure that their scientific data is captured, documented, stored, witnessed, and archived in a safe and secure manor.

> **"Good science requires good record keeping. Good record keeping promotes both accountability and integrity."**
>
> – National Institute of Health[3]

Bioanalytical laboratories are required to comply with regulatory guidance documents such as, Guidelines for Bioanalytical Method Validation (EMA and FDA), 21CFR58, and 21CFR11, from method development through study archival. Procedural elements for data integrity in a bioanalytical laboratory can be broken down into three elements: integrity of the analyte and data produced, integrity of the sample identity, and integrity of documentation.[5] Integrity of the analyte or drug product needs to be maintained from manufacturing of the drug product, to handling, shipment, and storage procedures. This includes tasks such as ensuring that the product certificate of analysis is attached to each analytical run and that the same lot of drug product is used from method development throughout sample analysis, providing consistency across data sets. Without complete knowledge of the conditions that an analyte has been through, the accuracy of assay data will be called into question by an inspector. It is crucial to have full chain of custody for any movement that is made to the analyte, for example, temperature monitoring records must be included with shipping records, and all movements into and out of storage must be tracked and monitored. Failure to accurately track these methods can jeopardize the credibility of the bioanalytical study as incorrectly following procedures can affect the stability or change the composition of an analyte.

Ensuring integrity in the sample identity and sample data encompasses many different bioanalytical processes such as instrument validation, method validation, sample management, and laboratory analysis. Validation of computerized systems and laboratory equipment is a key factor in ensuring the accuracy and reliability of data that is generated or produced from those systems. Laboratories must conduct validation of systems according to 21 CFR Part 11, this provides assurance that the system is consistently producing expected results and complies with security requirements, enabling high data integrity.

The Guideline for Bioanalytical Method Validation explicitly details all analytical methods that must be conducted for assays used in clinical analysis. The rigor of the method validation guidance provides credibility and integrity in the data that is generated from clinical assays. If a method fails to comply with the bioanalytical guidance, then the results produced in clinical analysis cannot be fully accepted by auditors due to a lack of confidence in the performance of the assay.

It is vital that a Study Director in a bioanalytical study can walk an auditor through the complete life cycle or chain of custody of a non-clinical or clinical sample. This allows the auditor to review the sample accessioning process which must comply with Good Laboratory Practices (GLPS) and Good Clinical Practices (GCPs). Auditors must be able to see documentation related to how the sample was received and stored, documentation of any discrepancies in the shipment or sample manifest, and each freeze/thaw of the sample, including movement for analytical runs (i.e. time at benchtop and temporary refrigerator storage). Without a complete chain of custody, the credibility of the sample and therefore the analytical results can be called into question. GLP studies must be fully documented, including training records on all SOPs for instrument use, reagent creation, analytical methods, and data analysis



So why leave data quality up to chance? Leave it to the experts

Ensuring compliance with many different regulations is a challenging task for the bioanalytical community, but with the right partner these challenges turn into strengths. Thermo Fisher has been serving the bioanalytical community for over 20 years and has the regulatory acumen and domain expertise required to effectively drive success. We support bioanalysis in many different avenues – whether its integrating data analysis with Watson LIMS software, running an assay on a Thermo Scientific™ Orbitrap™ Mass Spectrometer, storing critical reagents in a Thermo Scientific™ Ultra Low Temperature freezer, purchasing an antibody, or utilizing our best-in-class bioanalytical laboratory services.

Watson LIMS software is the market leading bioanalytical LIMS that has been trusted by top pharmaceutical Sponsors and CROs for decades. Complete traceability from study initiation through study closeout is maintained in the software – and has withstood many regulatory inspections. The software supports both small and large molecule development – and incorporates best bioanalytical practices into the product. Unlike the competition, Thermo Fisher can tap into the bioanalytical expertise of our more than 100,000 colleagues to create industry trusted, reliable solutions.

We help our customers accelerate innovation and enhance productivity, underpinned by quality, always.

References

1. United States, U.S Food and Drug Administration, *FY 2022 Good Laboratory Practice FDA 483 Observation Trends*. https://www.fda.gov/media/172783/download
2. *"Cost of Clinical Trials for New Drug FDA Approval Are Fraction of Total."* Johns Hopkins Bloomberg School of Public Health, publichealth.jhu.edu/2018/cost-of-clinical-trials-for-new-drug-FDA-approval-are-fraction-of-total-tab. Accessed 8 Nov. 2023.
3. National Institute of Health. "Guidelines for Scientific Record Keeping." Https://Oir.nih.gov, oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-scientific_recordkeeping.pdf.
4. "Cost of Clinical Trials for New Drug FDA Approval Are Fraction of Total Tab." Johns Hopkins Bloomberg School of Public Health, publichealth.jhu.edu/2018/cost-of-clinical-trials-for-new-drug-FDA-approval-are-fraction-of-total-tab. Accessed 8 Nov. 2023.
5. United States, U.S Department of Health and Human Services, *Applications for Biologics Licenses; Procedures for Filing*. Vol. 7, 21CFR601.2, 2017.
6. James, Christopher A, and Howard M Hill. "Procedural Elements Involved in Maintaining Bioanalytical Data Integrity for Good Laboratory Practices Studies and Regulated Clinical Studies." *The APPS Journal*, vol. 9, no. 2, ser. 14, 27 Apr. 2007. 14.

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

© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **WP80984-EN1123**



Watson LIMS software

Built for bioanalysis, trusted by industry leaders

Thermo Scientific™ Watson LIMS™ software has been widely recognized as the industry standard in bioanalytical support with over 8,000 users worldwide. It manages your bioanalytical data, creating efficiencies and promoting compliance for small- or large-molecule bioanalytical workflows for clinical and non-clinical studies. Watson LIMS enables complete traceability and control throughout your bioanalytical study, from initiation through study closeout, while enabling compliance and adherence to industry regulations.

For more than 20 years, Watson LIMS has helped bring thousands of drugs to market across the world. As the world leader in serving science, Thermo Fisher Scientific is committed to growing with the bioanalysis market and the continuous evolution of Watson LIMS software.

Power your bioanalytical workflows

Manage and build study designs
Upload sample manifests using templates with the aid of Import Study Protocol to reduce metadata transfer errors.

Maintain sample chain of custody
Record all sample shipments and monitor sample movement, define storage locations down to plate position, and track freeze/thaw cycle and sample stability. Easily provide chain of custody records to auditors.

Ensure traceability throughout a study
Get complete study records and reports from study initiation through study closeout, including sample chain of custody, assay verification, and reconstruction events using the audit trail.

Connect lab instruments and software
Reduce the risk of manual transcription errors by automating data capture and management processes. Watson LIMS software integrates easily with instrumentation through established interfaces (e.g., SCIEX™ Analyst™ software).

Streamline method validation and sample analysis
Perform concentration evaluations to assess pharmacokinetics (PK) along with an assessment specific for anti-drug antibodies (ADA) assays. Set acceptance criteria and identify results that fall outside the expected range.

Execute efficient reporting and QA review
Generate a full study report including method validation experiments, assay performance, and study data. Report your data in CDISC, SEND, and SDTM formats to help streamline submissions.

Get built-in security and audit trail
Benefit from maximum flexibility and configurability while preserving data integrity. System and study access are granted to authorized, role-based users, in accordance with Good Laboratory Practices (GLP).

Simplify compliance
Generate study-specific labels that meet the necessary requirements. Implement storage facilities that include visible labels and barcodes for easy identification and traceability. This helps enable compliance with 21 CFR Part 11, FDA Bioanalytical Method Validation, and EMA guidance to facilitate audits.

Streamline data processing and reporting
Easily generate a variety of graphs, tables, and statistical calculations from study data. Sort, find, filter, and reorder grid contents for a quick way to review a specific sample's data.

Minimize quality review time
Get real-time snapshots of data quality and easily transfer study data between sponsor and CRO using pre-defined assay performance and summary tables.

Manage your bioanalytical study from initiation to study archival



Method Management
Review and optimize methods through collaboration.

Study Design
Model flexible study designs and apply amendments.

Method Validation
Perform quantitative measurements for:
- Precision and accuracy
- Selectivity, specificity, and carryover
- Matrix effect and dilution integrity
- Stability and recovery

Sample Receipt
Create new or import existing barcodes to identify samples and help ensure traceability.

Sample Management
Define storage location down to plate position, track freeze/thaw cycles, and prove chain of custody.

Routine Assays
Get support for LCMS and quantitative and qualitative ELISA essays, including Multiplex, ADA, and NAb assays.

Data Acquisition
Utilize pre-defined data exchange with many data acquisition systems. Secure and scalable bi-directional instrument communication preserves data integrity.

Regression & Data Review
Analyze data using several models (linear/non-linear), annotate anomalous results, and facilitate accept/reject decisions using run acceptance tool.

Manage Reassays & ISR
Identify reassays, automate reassay decisions, report reassays and Incurred Sample Repeats.

TK/PK Analysis
Manage non-compartmental analysis on individual or pooled data, bioavailability calculations, and data export in SEND PP domain format.

Immunogenicity
Calculate assay cut-points and guide users through the tiered approach to performing ADA assays.

Report & Data Transfer
Customize data export to client requirements and report in SEND format. Generate industry-standard reports and store using Watson LIMS software's secure Document Management System.

QA Review
Review the history of attributable changes in the audit report.

Standardizing processes

Watson LIMS software is ready to help manage bioanalytical studies, from initiation through archival, working to support industry and regulatory standards. The software was designed with a deep understanding of the bioanalytical workflow and regulations. Principal Investigators, scientists, and analysts are all able to move logically through each step in their workflow, simplifying bioanalytical support for nonclinical and clinical studies.

Compliance throughout the entire workflow

- The **Reassay Decision Matrix and Run Acceptance Template** assists users to comply with SOPs, reducing the risk of non-compliance. Decisions are automated according to pre-configured criteria, but allow the user to override when required.
- System and study access is granted to authorized users only. Role-based access ensures only authorized actions can be performed by users, in accordance with Good Laboratory Practices.
- The database stores audit trail records, which can be easily retrieved for review. These records outline all events that have been performed in the system. To facilitate an unambiguous and efficient review, a purpose-built audit records viewer is available, which enables categorizing and organizing audit events.
- Electronic signatures are designed to meet the requirements of 21 CFR Part 11 and record user identity, time/date stamp, and reason-for-save.
- Lockout/logout timers are configurable for periods of inactivity, requiring a user to reenter their username and password to regain system access.
- Watson LIMS software was designed to enable compliance with 21 CFR Part 58, FDA Bioanalytical Method Validation guidance documents, and EMA guidance documents.

Study design and sample management

Dynamic study design simplifies study setup with groups, treatments, and biological matrices, for both blinded and unblinded studies, as well as modeling the preclinical and clinical trial process. Since bioanalytical studies evolve around real-world incidents, studies can easily be amended by adding or removing samples as required to reflect protocol amendments or unscheduled events. The Design Reconciliation feature also provides a way for Principal Investigators to document and correct sample manifest discrepancies all within one software system.

Compliance checks and audits are made easier, since a sample is easily identified using barcodes, which can be added from external sources as well as created by the system. Location changes can be tracked using barcodes and electronic signatures. The product facilitates the creation of labels according to study requirements, and storage facilities can be displayed and barcoded to ease identification and traceability. The product also supports the use of 2D barcodes.

Analysts can quickly and easily move samples from a sample manifest into a new storage location. Principal Investigators can recreate the lifecycle of a sample in Watson LIMS software using various entities to see where the sample was stored, who handled the sample, and report freeze/thaw cycles, demonstrating a complete chain of custody from sample receipt to archival and disposal.

Pharmaceutical companies and CROs worldwide adopt Watson LIMS software as it provides a standardized way to work, ensuring seamless data collaboration and reporting.

Delivering value

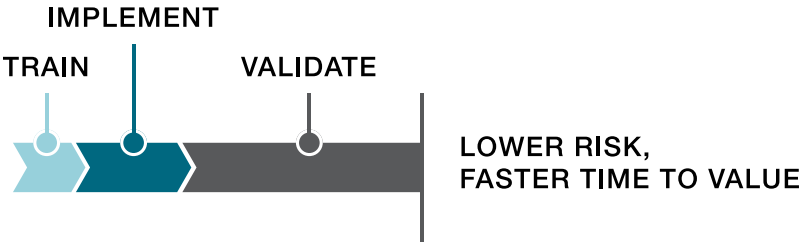
Fast implementation and expert support

Laboratories installing Watson LIMS software get more than just an industry-proven software package. Our team of experts not only understand the complex requirements of a bioanalytical lab, they also have the knowledge and experience required to ensure every implementation is a success.

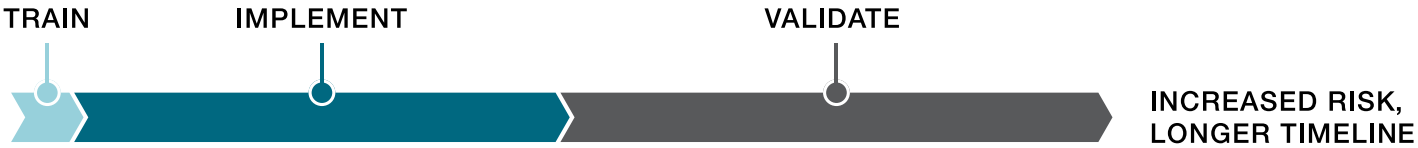
Established processes and templates mean that customers are up and running far faster than you might expect. Our teams' extensive experience in risk-based validation approaches, as well as minimal product configuration serve as catalysts for faster time to value compared to custom-built solutions.

Realize value quickly with a purpose-built solution

- Implement and validate in half the time of a traditional analytical LIMS
- Eliminate customization and lengthy configuration
- Save time with documentation that is completed, tested, and ready to go
- Leverage a proven track record of successful implementations



Watson LIMS Software



Traditional Analytical LIMS

Streamlining method validation and data analysis

Watson LIMS software supports method validation of LCMS and ELISA assays, and analysis of ADA and NAb assays, allowing scientists to perform method validation and data analysis for many different assay types within one system.

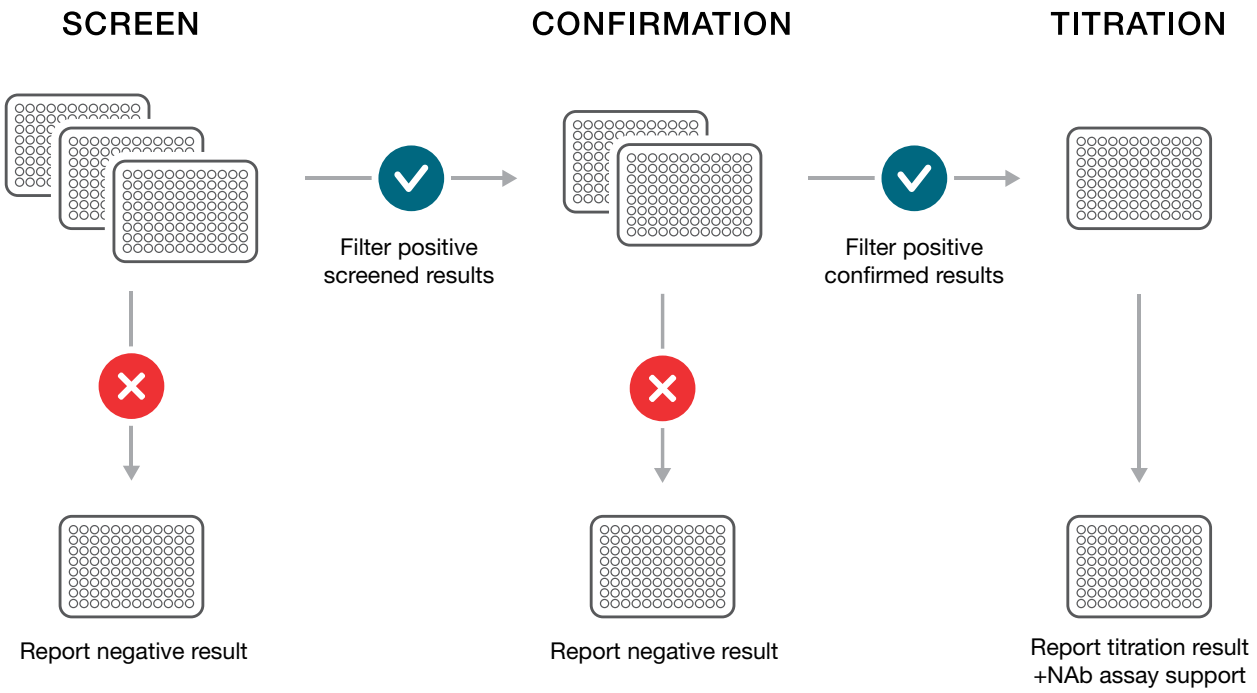
Method Validation support enables scientists to evaluate their methods for reliability and reproducibility. Predefined reports include precision and accuracy, specificity, selectivity, carryover, dilution integrity, stability (including benchtop, freeze/thaw and long-term stability), recovery and matrix effect.

The configurable **Run Acceptance Template** provides a tool to assess run performance against an SOP with defined acceptance criteria.

The integrated **Pharmacokinetics Module (PK)** allows the user to perform non-compartmental pharmacokinetic and toxicokinetic calculations within Watson LIMS software.

Enabling testing for immunogenicitys

Immunogenicity assays protect patients from potentially harmful anti-drug antibodies and provide insights into neutralizing antibodies that may inhibit the biologic activity of a drug. The **Immune Response Module (IRM)** enables a tiered approach to performing immunogenicity assessments. IRM guides its users through the tiered approach of performing screening, confirmatory, and neutralizing assays. Scientists utilize the IRM to calculate assay cut-points, create automated flags for samples outside of the cut-point and to determine if there is a reactive sample. New study-level control reports include intra/inter-run statistics, flag limits, and cut-point values reported, providing valuable data in one location.



Reassays and ISR

Reassays can be queued both from the PK and IRM modules and on review of statistical study data. Results are linked to the original for comparison, including the reason for reassay and reanalysis. The user is easily able to view the impact of the reassay result on the overall data.

The **Reassay Decision Matrix** enables the user to create a graphical workflow, which emulates a decision tree defined in a reassay SOP.

Built-in calculations and configurable reporting support **Incurred Sample Reanalysis**. The report can be quickly and easily configured from a set template.

Instrument and system interfacing

Watson LIMS connects with other enterprise systems, instruments, equipment, and your customers, delivering increased compliance and productivity across your labs.

With an extensive library of bidirectional interfaces to commonly used bioanalytical instruments, no matter what hardware and equipment you use or might add to your lab in the future, Watson LIMS software can speak its language.

Once an analytical run has been acquired, the raw data is transferred from the data acquisition software back into the system for review and processing. Secure connections eliminate transcription errors and preserve data integrity.

Watson LIMS has a built-in interface with numerous instrument software applications, including but not limited to:

- Thermo Scientific™ Xcalibur™ software
- Thermo Scientific™ Chromeleon™ CDS software
- Thermo Scientific™ TraceFinder™ software
- SCIEX Analyst™ software
- Waters™ Empower™ software

Watson LIMS interfaces through file-based and/or data transformation tools with common instrument software, including but not limited to:

- Gyros™ Gyrolab™ Workstation
- Luminex™ platform
- Molecular Devices™ SoftMax Pro™ software
- MSD™ DISCOVERY WORKBENCH™ software
- MSD™ Methodical Mind™ software
- Quanterix™ Simoa™ technology
- Secure Open Standard File Transfer (SOFT)
- Shimadzu™ LabSolutions™ software
- Waters™ MassLynx™ software



In the past five years, Watson LIMS software users have had over 4,500 drugs approved for use across North America and Europe.

Data processing and reports

Watson LIMS software's unrivaled data processing capability easily generates a variety of graphs, tables, and statistical calculations from study data. The software allows you to easily sort, find, filter, and reorder grid contents, enabling a quick way to review a particular sample's data. Watson LIMS also supports CDISC SEND and SDTM data standards.

Regression Analysis is centralized and automated supporting linear and non-linear models.

Considerable time is saved in collating and reporting results compared to other LIMS or laboratory data management solutions.

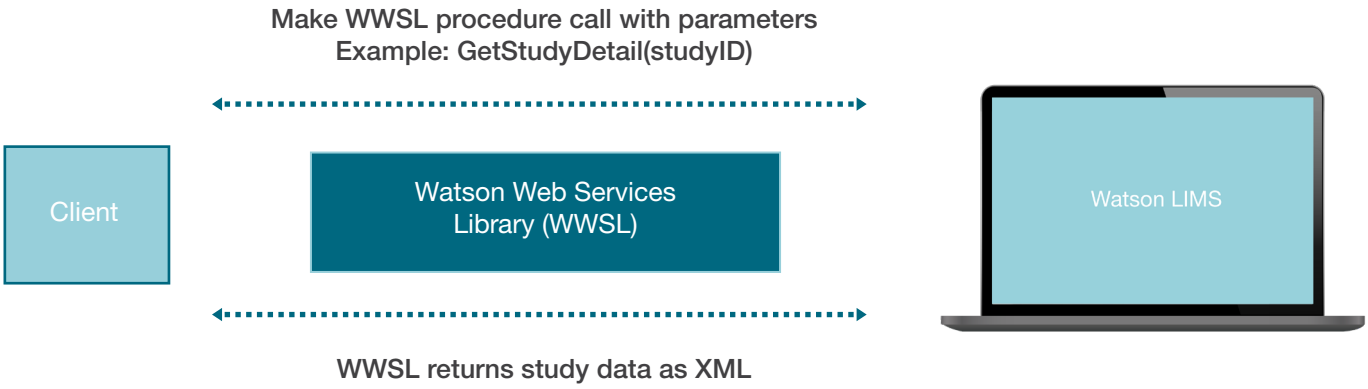
Quality review time is minimized using Watson LIMS software—the gallery of **pre-defined assay performance and summary tables** are a major benefit since the precision and accuracy of study data is very quickly demonstrated. Any new data added is automatically taken into account—providing a real-time snapshot of data quality. Standard data exchange enables easy transfer of study data between sponsor and CRO.

The powerful **Document Management System** enables you to select the documents, tables, and graphs to quickly build a full study report. All results, raw data, graphs, and reports are held in one database, which is controlled securely by user access and system roles.

Watson LIMS software is now accessible through the Thermo Fisher Cloud.

Watson Web Services Library

The Watson Web Services Library (WWSL) is a mechanism that allows external systems to seamlessly interact with Watson LIMS using web service technology. This standard approach ensures secure communication through the use of the HTTPS transport protocol. With WWSL, data validation and audit trail generation are automatically handled for any data transferred into the Watson LIMS database. Supported procedures include, but are not limited to, importing study samples, creating analytes and projects, as well as updating study details, subjects, and treatments. WWSL streamlines the process of entering and retrieving information into the Watson LIMS database, providing a seamless integration solution for your lab.





A proven partner

Experience the power of partnering with Thermo Fisher to transform your bioanalytical challenges into strengths. With over 20 years of experience serving the bioanalytical community, Thermo Fisher possesses the regulatory acumen and domain expertise necessary to drive your success. Unlike the competition, we have the ability to tap into the bioanalytical expertise of our extensive network of over 125,000 colleagues, enabling us to deliver industry-trusted and reliable solutions that bring life-saving drugs to market.

Partner with Thermo Fisher to discover the full potential of your bioanalytical workflow management capabilities.

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

For Research Use Only. Not for use in diagnostic procedures. © 2021-2024 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. BR80493-EN0324.

DISCOVERY WORKBENCH is a trademark and/or service mark of Meso Scale Diagnostics, LLC. and licensed to Methodical Mind, LLC. Gyros and Gyrolab are trademarks of Gyros Protein Technologies Group. LabSolutions is a trademark of Shimadzu Corporation or its affiliated companies in Japan and/or other countries. Luminex is a registered trademark of Luminex Corp. Methodical Mind is a trademark and/or service mark owned by or licensed to Methodical Mind, LLC. Molecular Devices and SoftMax Pro are trademarks of Molecular Devices Corporation. Quanterix and Simoa are registered trademarks of Quanterix, Inc. SCIEX and Analyst are registered trademarks of AB Sciex Pte. Ltd. Waters is a registered trademark of Waters Corporation. Empower and MassLynx are trademarks of Waters Corporation.



Cloud services

Thermo Scientific Watson LIMS software deployments in AWS

Overview

Thermo Scientific™ Watson LIMS™ software can be deployed on-premises or in the Amazon Web Services (AWS) cloud. On-premises deployments or deployments to a customer's own cloud hosting service are managed by the customer based on their infrastructure standards

Customers who contract with Thermo Fisher Scientific to manage their cloud deployment in AWS receive end-to-end support. Thermo Fisher provisions the cloud services, installs Watson LIMS software and maintains the deployment.

The following are some of the features and benefits of deploying Watson LIMS software to AWS:

- Fully managed deployment available across the globe in select AWS Regions.
- Physical access to the AWS data centers and networks is strictly controlled, monitored, and audited.
- Your data is segregated with dedicated servers and logically isolated networks.
- Your data is secured in motion and at rest with industry standard encryption.
- Your data is protected from unauthorized access or compromise with tight controls at the firewall and policy/procedure level.
- Your data is backed up and retained on a 30 day sliding window.
- Systems are managed with integrated auto-recovery from hardware failures.
- 99.5% service availability.
- Realtime intrusion detection and prevention.
- Infrastructure and user activity logging and monitoring.
- Data backup snapshots occur at least hourly.
- 2 hour response time for all critical issues with continuous effort until service is restored.
- The following sections provide an overview of the security policies and procedures applied to Watson LIMS software. Please also refer to the AWS Cloud Security site for information on the security provided by AWS.

thermo scientific

Facility security

Deployments of Watson LIMS software utilize AWS for all customer systems; there are no systems located onsite in Thermo Fisher offices. Access to the Thermo Fisher facilities is strictly controlled.

System security

Watson LIMS software customer systems are deployed and managed on AWS in line with the security policies outlined in the AWS Cloud Security site. Access to systems – corporate and customer – is controlled and limited to specific identified employees. The Technical Operations team at Thermo Fisher utilizes multi-factor authentication to secure access to systems.

Network security

Customer systems are configured and managed in a customer-dedicated Virtual Private Cloud (VPC). The VPC provides fine grained control and monitoring of all network interactions between the outside world and your managed instance, as well as internally between infrastructure components. Security policies are implemented for each customer, defining all the rules for how data flows and who has access to the systems.

The network in which Watson LIMS software is hosted is secured with an Intrusion Detection and Prevention System. It provides a high level of security, with active monitoring and intrusion detection and prevention. The IDS is configured to alert appropriate personnel to malicious activity detected and automatically update the IDS signatures.

Watson LIMS software has a dedicated highly controlled Virtual Private Network (VPN) for access to the Watson LIMS software network. The VPN is for employee use only and is actively monitored to ensure proper usage.

Data security

Watson LIMS software employs the industry standard AES-256 encryption algorithm to encrypt your data at rest. All data residing in the database or on file systems are encrypted.

Watson LIMS software encrypts data in transit, ensuring that all communication with the managed instance is secure using industry standard 256-bit encryption with a 2048 bit public key. Direct access to data stored in customer databases is restricted.

Application access

Watson LIMS managed cloud service utilizes robust Authentication, Authorization, and Accounting (AAA) capabilities. Thermo Fisher recommends the use of AAA policies that provide for the highest level of security.

Watson LIMS software customers are provided with the option of limiting access to their application instance by IP restriction or allowing access from the internet.

Secure coding practices

Watson LIMS manage cloud service is reviewed based on best practices prescribed by the Open Web Application Security Project (OWASP).

Watson LIMS software leverages tools to assess the security of the code and employs a secure coding audit as part of code reviews.

Logging

Watson LIMS software utilizes a log management system which logs IT infrastructure activity as well as user activity, including successful and failed user authentication attempts. The log management system is used to review the logged activity and alert the Technical Operations team on the detection of suspicious activity. Log data is retained for up to one year.

Monitoring

Thermo Fisher software actively monitors all systems, networks, applications, and supporting infrastructure using multiple commercial tools. AWS CloudWatch, AWS GuardDuty, AWS CloudTrail, Intrusion Prevention/Detection services, Cloud Governance and Alerting tools are used for monitoring, logging and alerting Technical Operations team members for security and health of managed services.

The Technical Operations team performs vulnerability assessments on Watson LIMS software. Thermo Fisher's Corporate Information Security (CIS) program provides guidance, oversight and continuous review and improvement of security controls for cloud deployments of Watson LIMS software managed by Thermo Fisher.

Change management

Thermo Fisher employs a Change Management Policy to record changes to systems and infrastructure. Changes are reviewed to mitigate risk and recorded for accounting purposes. Thermo Fisher utilizes CloudTrail to log all activities related to infrastructure on AWS including actions taken through the AWS Management Console, AWS SDKs, command line tools, and other AWS services.

Disaster recovery

Watson LIMS software has a standardized deployment architecture and associated procedures. This standardization allows the Technical Operations team to easily stand up new environments as needed.

Thermo Fisher manages services for customers across multiple AWS Regions and availability zones (refer to Regions and Availability Zones).

Thermo Fisher maintains backups of all customer services separate from the deployed environment (refer to “Backup and Recovery” section of this document).

In the event of a disaster scenario, Thermo Fisher will evaluate the risk and impact of the event and contact affected customers. The Technical Operations team will develop a plan to restore services, focusing on risk and impact to the customer. The customer will be notified of the plan. The Technical Operations team will execute the plan to restore services.

Backup and recovery

Watson LIMS software leverages Amazon’s comprehensive infrastructure to execute a backup and restoration process in order to maintain system availability for all hosted systems.

- Systems and data are backed up and backups are retained to meet the recovery targets.
- The backed up image is stored separate from the system using Amazon Simple Storage Service (Amazon S3). This provides a highly durable (99.999999999% durability) storage infrastructure designed for mission-critical data storage. Amazon S3 redundantly stores objects on multiple devices across a minimum of three Availability Zones (AZs) in an Amazon Region.
- All backups are encrypted using industry-standard encryption algorithms.
- Restoration due to data or system corruption or loss is deemed an incident and is managed under the Incident Management Policy.
- The Technical Operations team will restore systems and data to address unrecoverable system failure, data corruption, or data loss.
- Customer stakeholders are notified prior to a planned execution of a system or data restore.
- Thermo Fisher will verify restored systems and data. The customer is required to verify that the restoration meets their expectations.
- All restoration procedures will be executed.

Thermo Fisher has been using AWS’s services since 2008.

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

© 2022 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **PS80565-EN0822**

CASE STUDY

Thermo Scientific Watson LIMS software

Standardizing bioanalytical workflows at Nerviano Medical Sciences

Nerviano Medical Sciences (NervianoMS) is the largest pharmaceutical research and development facility in Italy, and one of the largest oncology-focused, integrated discovery and development companies in Europe. The pre-clinical development unit of NervianoMS, Accelera, began using Thermo Scientific™ Watson™ LIMS (Laboratory Information Management System) software in order to manage and process statistical data related to ELISA (Enzyme-Linked ImmunoSorbent Assay) experiments in line with GLP regulations.

Nerviano Medical Sciences and Accelera NervianoMS is a private company owned by the Congregazione dei Figli dell'Immacolata Concezione CFIC) and was incorporated following a company re-organization by Pfizer. A total of almost 700 highly skilled and experienced scientists, technicians and managers are involved in oncology R&D projects at NervianoMS, from target validation to clinical phase IIa. NervianoMS aims to discover and develop innovative medicines for the treatment of cancer, and to establish partnerships with the biopharmaceutical industry and the scientific community.

The preclinical development unit (PCD) of NervianoMS, Accelera, is committed to predicting and managing potential toxic, pharmacokinetic and metabolic issues of new compounds and to supporting all stages of drug discovery and development. Based outside Milan, Italy, Accelera has successfully developed and applied state-of-the-art technologies and ad hoc approaches to "pick the winner" among potential drug candidates for all therapeutic areas.



Currently employing approximately 120 scientists, Accelera provides a range of PCD services including preclinical discovery and profiling, development services and consultancy, clinical and preclinical bioanalysis and oncology drugs research services. Beyond the specific expertise in the design and execution of PCD programs for oncology drugs, Accelera has strong competencies to support projects across a range of therapeutic areas.



The challenge

The IT group of NervianoMS manages and maintains complex IT infrastructure architectures, information system networks and software applications and supports more than 1000 workstations across the organization. The group must also maintain processes in line with GLP and FDA Computer Validation Guidelines, as well as other regulations relevant to the pharmaceutical environment.

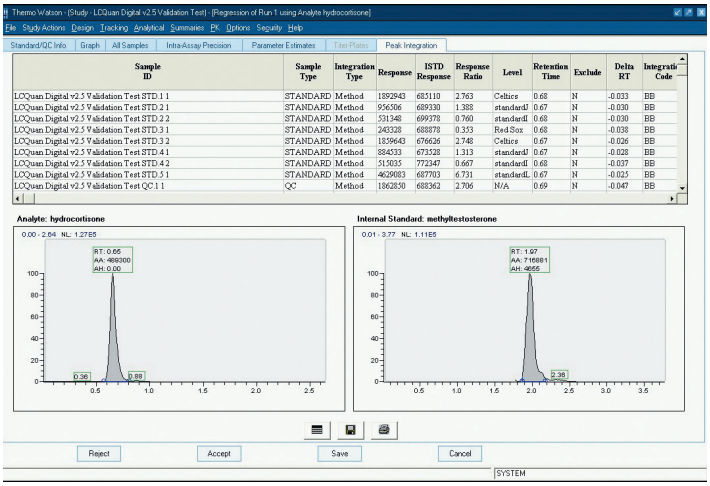
Both GLP and FDA guidelines require drug makers, medical device manufacturers, biotechnology companies and other regulated industries to implement control processes including regular audits, validation programs and full documentation of products and systems. GLP guidelines help to assure regulatory bodies that data submitted by manufacturing companies are a true reflection of the results obtained and can therefore be relied upon. In order to comply with this wide range of regulatory requirements, it is essential that companies undertaking sample analysis implement carefully validated software systems.

As part of its R&D activity, Accelera carries out ELISA experiments with a large focus on GLP compliance. Later that year the company began to receive both internal and external requests for bioanalytical support for ELISA data in preclinical and clinical regulated studies. The main business requirements for such a support system were a validated process to generate and manage ELISA data, a validated statistical tool for ELISA data, the capacity to electronically manage study information and an electronic repository for ELISA data that was compliant with regulatory guidelines such as GLP. In order to meet these requirements, the company began to look for a LIMS (Laboratory Information Management System).

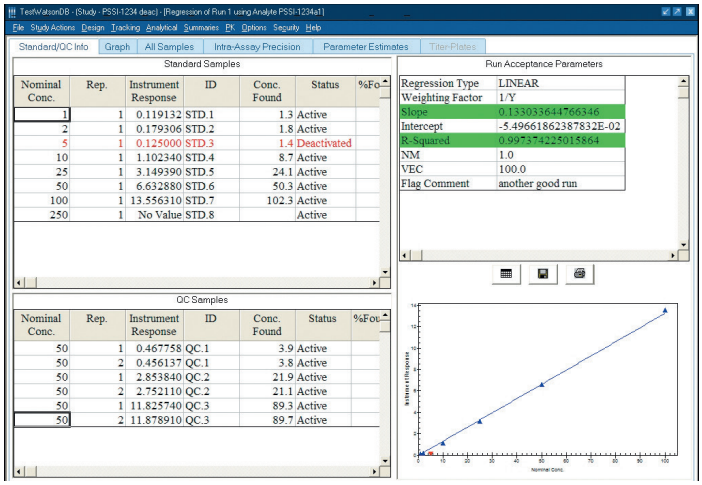
Implementation

Accelera traditionally used vendor-specific instrument analysis software for the management of ELISA data, as well as Microsoft Excel and paper-based procedures. When they realized the need for a LIMS, NervianoMS looked at several alternative systems for Accelera, but found that none matched the capabilities of Watson LIMS software in terms of integration, development for the analytical field and guaranteed GLP compliance.

Watson LIMS software is a highly specialized protocol-driven system which has been specifically developed to support DMPK and bioanalytical studies in drug development. The system was developed with input from major pharmaceutical companies and its success is a direct result of its ease of use and the high level of service offered to assist in implementation. Watson LIMS software is installed in the top 20 global pharmaceutical organizations and is widely used in leading biotechnology and contract research organizations worldwide.



The advanced, bi-directional digital interface between Watson LIMS software and LCQUAN™, the data acquisition system for the Thermo Scientific™ TSQ™ Quantum mass spectrometer series, enables the secure transfer of worklist information and results data, together with integrated peak viewing in the Watson LIMS software.



Watson LIMS software analyzes calibration curves from standards and back-calculates concentrations for QCs and unknowns. Configurable parameter flags alert the user to acceptability criteria. Color-coding enhances visual inspection of results.

NervianoMS already had an established relationship with Thermo Fisher Scientific as the organization uses a range of Thermo Scientific branded instruments. Thermo Fisher's proven track record of support for Watson LIMS software attracted NervianoMS, as well as the company's ongoing dedication to developing and integrating its systems in the analytical field. Additionally, the LIMS has been expressly built to promote compliance with GLP regulations and the 21 CFR Part 11 guidance, a significant consideration for Accelera when choosing a LIMS.

During the Accelera implementation, Watson LIMS software was configured to use a central Oracle™ 92 database on a Linux operating system. The LIMS offers a simple, point-and-click graphical interface that resulted in minimal training for the 50 LIMS users at Accelera. To aid GLP compliance at Accelera, the system security and audit trail are designed to provide maximum flexibility and configurability while preserving data integrity. Watson LIMS software is the ideal system for Accelera as it is capable of handling and storing complex study protocols and tracking deviations to each study.

Since its installation, Watson LIMS software has become a key driver for all GLP activities at Accelera, and as a result almost all experimental data must be organized and managed by the LIMS. In addition to implementing the LIMS, Accelera required a method to import ELISA data files directly from its PerkinElmer™ Victor2™ fluorometer into the LIMS. As a result, Accelera uses ELY4, a program compiler, to interface Watson LIMS software with the Wallac 1420 software for the Victor2 microplate reader, thus guaranteeing full LIMS support for the determination of large molecules. By interfacing with ELY4, Watson LIMS software represents the full driver for a range of activity, from study information and sequence plans to the final results reports in Accelera's fully compliant environment. The ELISA experiments constitute 10-15% of the studies managed by the LIMS.

Key benefits

Since the implementation of Watson LIMS software, Accelera has experienced considerable benefits including guaranteed regulatory compliance as well as increased laboratory productivity and accelerated sample turnaround.

As the LIMS fully supports unit management and allows data consolidation across studies and projects, it has been quickly accepted by Accelera's analytical community. By expanding the use of the electronic format across Accelera's traditionally paper-oriented environment, Watson LIMS software has had a significant impact on laboratory productivity, and enables laboratory analysts and ELISA study directors to easily consolidate sample and instrument data.

Watson LIMS software has also had a significant impact on the level of compliance of Accelera's laboratories. The system provides a clear audit trail for Accelera which guarantees GLP compliance for the execution of regulated studies.

Conclusion

In a global pharmaceutical manufacturing company such as NervianoMS it is essential that processes and practices be compliant with strict regulations such as GLP and FDA. However, newly implemented systems must be flexible in order to interface with Accelera's wide range of instruments and data used at Accelera. By using Watson LIMS software, Accelera has put in place an easy-to-use system which improves laboratory productivity and turnaround time as well as guaranteeing simple regulatory compliance in a cost-effective way.

The LIMS has fulfilled the initial requirements of Accelera and through its security control and server qualification provides a fully compliant system for the management of ELISA data. With the capability to support a validated statistical tool for ELISA data as well as being the driver of automated data processes, the LIMS is an electronic repository for ELISA data across multiple studies and projects for Accelera.

Stefano Cavanus, Watson LIMS software System Manager at NervianoMS, comments, "We initially chose the LIMS because of the development of the system within the analytical field, into which Watson LIMS software is perfectly integrated. We were also impressed by Thermo Fisher Scientific's efficient group dedicated to solving problems. Watson LIMS software is extremely easy to use and was quickly accepted by our 50 users, and we continue to devote significant time to train these users according to their roles and activity with the LIMS."

"Watson LIMS software has met all of our requirements and was easily configurable to enable interface with our instruments. Since implementing the LIMS, all of our processes have been validated and all points of the NMS Computer Validation Policies have been applied, in agreement with the FDA Computer Validation Guidelines. As a result of the increased productivity of our laboratories and the guaranteed compliance of the LIMS, we cannot do without it."

Watson LIMS software is now used as the standard LIMS across Accelera's PCD laboratories, including the development of LIMS interfaces for its key instruments.

Find out more at **thermofisher.com/digitalscience**

© 2020 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. Oracle™ is a registered trademark of Oracle. PerkinElmer Victor2™ is a registered trademark of PerkinElmer.
CS80219-EN0420



Achieving LIMS project success with Thermo Fisher Scientific

In today's fast-paced scientific landscape, laboratories require more than just robust equipment. They require future-proof digital solutions to streamline operations, enhance productivity, and help drive data integrity. As the world leader in serving science, Thermo Fisher understands the intricacies of Laboratory Information Management Systems (LIMS) and offers unparalleled expertise with a wide range of industry knowledge and experience. When it comes to digital transformation, we understand that implementation needs to be as fast and as smooth as possible with minimal down-time.

We achieve this by assigning a dedicated, highly skilled team to support you throughout your project. With over 400 employees focused on delivering top tier digital science solutions, paired with our diverse industry knowledge, we build a team to match your requirements. This ensures that you are set up for a successful and seamless LIMS implementation.

1,500+ Successful LIMS implementations

30+ Years of LIMS experience

$44B revenue

>125,000 colleagues

$1.5B R&D investment

Delivering on our promise

We're committed to providing our customers an industry best experience, not only by promising a great customer journey, but delivering on it! From the initial conversation to the post-installation high-five, we deliver on our promises, milestones, and ensure project success.

- **No hidden costs** – Our quotes are accurate to make financial planning a breeze
- **Punctual roll-outs** – Our phased approach to implementation ensures go-live deadlines are met
- **Expert team** – Engage with a team who are not just qualified, but invested in your success
- **Future-focused solutions** – We work with you to provide solutions not only for today's challenges, but for your future endeavors
- **Pre-configured solutions** – Deliver faster implementation times and minimize downtime so you can get back to doing what you do best
- **A plan for success** – Our phased approach sets realistic guidelines and provides a step-by-step guide to keep your project on track

GLOBAL PROJECT IMPLEMENTATION PROCESS



- Collaborative planning
- Workshops
- Trainings

- Build the system
- Create data
- Continuous testing

- Validation
- User training
- Go-live
- Change management support

Setting up for success

The success of each of our projects are driven by a strategic partnership and a set of common goals between you and the Thermo Fisher implementation team. Between a clear vision, early planning and a deep understanding of your lab's specific processes and objectives, the Thermo Fisher team will provide a solution that best suits your needs.

The journey does not end there. Assembling a core team that includes power users, everyday users, and occasional users is critical for a holistic LIMS adoption. Finally, open, and continuous communication, both within your organization and with the implementation team, is the key to a smooth and effective deployment.

With a global network of some of the most highly experienced LIMS professionals dedicated to delivering the best lab informatics services across a wide range of industries, Thermo Fisher is a trusted partner to unlock the full potential of your lab data.

Ready to start talking LIMS?

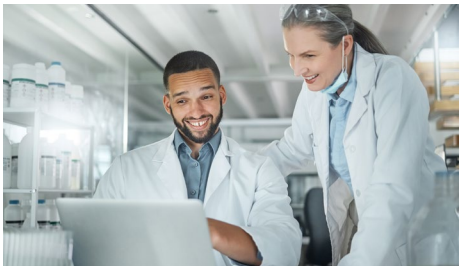
Let's start the discussion!

Scan the QR to contact us

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

© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **FL80972-EN0923**

On-demand resources and support



Additional information

Our website is the first port of call if you'd like to learn more about Watson LIMS software.

Find out more about Watson LIMS software



The Connected Lab blog

Subscribe to our Connected Lab blog to stay up to date on features relevant for scientists and researches across all industries and applications.

Subscribe to our blog



Speak to a member of our team

Thermo Fisher Scientific staff are here to support you throughout your scientific journey.

Contact us to see how we can help

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

Not for use in diagnostic procedures. © 2024 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **BR80996-EN0624**