Thermo Scientific Watson LIMS software

Built for bioanalysis
Watson LIMS software is specifically designed and built to support the bioanalytical workflow, allowing users to:

• Harmonize laboratory processes across all sites
• Ease exchange of information between sponsors and contract labs
• Increase throughput by automating data handling and reporting tasks
• Promote compliance throughout the workflow

• Implement quantitative concentration assays or qualitative immunogenicity assays
• Track study sample history from receipt to disposal

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**Method Development**
- Review and optimize methods through collaboration.

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

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

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

**Study Design**
- Model flexible study designs and apply amendments.

**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.

**Routine Assays**
- Support for LCMS and quantitative and qualitative ELISA assays including Multiplex, ADA, and NAb assays.

**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.

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

**Reports & 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.
Compliance throughout the entire workflow
- The Reassay Decision Matrix and Run Acceptance Template assist 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.
- Audit trail records are stored in the database, readily retrievable for review and outlining all events performed in the system.

Watson LIMS software is ready to help manage bioanalytical studies, from initiation through archival, working to 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 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, report freeze/thaw cycles, demonstrating a complete chain of custody from sample receipt to archival and disposal.

Study design and sample management
Dynamic study design simplifies study setup with groups, treatments and biological matrices, for both blinded and unblinded studies, 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.

Pharmaceutical companies and CROs worldwide adopt Watson LIMS software as it provides a standardized way to work, ensuring seamless data collaboration and reporting.
“Watson [LIMS software] is an essential element to providing a quality bioanalytical service. It is the single point of control, ensuring that samples received have a chain of custody and an unambiguous analysis pathway to deliver the final concentration results.”

– Stuart McDougall, Bioanalysis Leader, Arcinova

**Fast implementation and expert support**

Laboratories installing the 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.
“Watson [LIMS software] is unique in its ability to maintain the data for a bioanalytical laboratory in a compliant way so that we meet all of our sponsors’ expectations.”

– Chad Briscoe, Executive Director of Global Bioanalytical Science, PRA Health Sciences

Streamlining method validation and data analysis
Watson LIMS software supports method validation and data analysis for LCMS and ELISA assays including Multiplex, ADA, and NaB assays. Providing scientists, the ability to perform method validation and data analysis for many different assay types all 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 immunogenicity
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.

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SCREEN
- Filter Positive Screened Results
- Report Negative Result

CONFIRMATION
- Filter Positive Confirmed Results
- Report Negative Result

TITRATION
- Report Titration Result +NAb Assay Support
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
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 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 software provides users the ability to report data in SEND format, based on the SEND Implementation Guide.

“Watson [LIMS software] is essential for a CRO, as it allows us to import samples and output data in a variety of ways to meet our clients needs.”

– Stuart McDougall, Bioanalysis Leader, Arcinova
**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. Easily sort, find, filter, and reorder grid contents enabling a quick way to review a particular sample’s data.

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.

Find out more at [thermofisher.com/watson](http://thermofisher.com/watson)