STARLIMS

STARLIMS Pharmaceutical & biotechnology solution

Support your Laboratory Operational Excellence efforts – be at the forefront with a world - class Laboratory Information Management System

ENHANCE REGULATORY COMPLIANCE

With robust presence in the drug, medical device, contract manufacturing, contract lab, and biotechnology industries, STARLIMS Pharma & Biotech solution is a scalable web based product that will allow you to connect from anywhere and anytime with full 21 CFR Part 11 compliant capable features to ensure data integrity, regulatory compliance and inspection readiness.

- Consolidate sample data and documentation
- Produce Certificates of Analysis (CoA) for samples that meet specifications
- Generate stability summary reports
- Analyze trending, handle ICH, USP, JP, EP testing standards
- STARLIMS can help your lab comply with comply with cGxP, FDA, ANVISA, ISO 17025, and other regulatory requirements and best practices
- Produce real time analysis of tested samples

STARLIMS Integrated Solution is the only product on the market to provide a completely integrated solution incorporating LIMS, LES, ELN, SDMS, Advanced Analytics and Mobility in a single application.

STARLIMS is an industry leader in providing functionality that can help you monitor and control the safety and quality of your raw materials, processes and finished products testing; providing you a platform for the documentation of results and the management of information in a secure and reliable way.

PHARMACEUTICAL AND BIOTECHNOLOGY LABORATORY MANAGEMENT

STARLIMS laboratory information management software includes powerful tools for comprehensive management of all laboratory processes:

- Instrument management, inventory control & formulation management
- Flexible calculations, reporting & data analysis tools
- Analytical batch & plate management
- Standards & reagents management
- Comprehensive audit trail/electronic signatures
- Stability and microbiology management
- Scheduling and resource planning
- Request Management Portal
- Chromatographic data systems (CDS) integration, and more.

OPERATIONAL EXCELLENCE IN THE PHARMA AND BIOTECH LABORATORY MANAGEMENT

Achieving operational excellence through innovation, operational efficiency and enhanced quality is crucial for the Pharmaceutical and Biotechnology industries.

STARLIMS supports your industry operational excellence efforts by reducing cost and error through automation, integration, data consolidation, collaboration, process standardization, streamlining, and quality compliance.

REDUCE COSTS AND TURNAROUND TIME; INCREASE EFFICIENCY AND TESTING VOLUME, BOOST LABORATORY PRODUCTIVITY
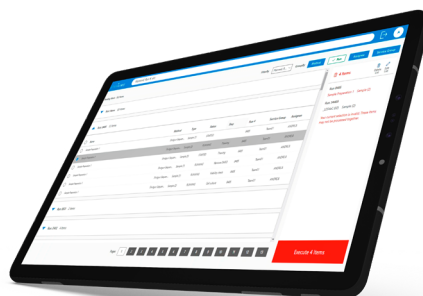
The configurable nature of STARLIMS allows you to handle many types of laboratory process or workflow without the need for programming or complex configuration, in fact, STARLIMS is able to handle different testing requirements and automate the processes from collection to report generation. With STARLIMS you can:

- Manage your data by exception rather than reviewing results that are nominal
- Automatically flag and immediately compare results in real time against defined specifications for immediate response
- Fully trace your lots and your inventory using built–in features such as lot genealogy and chain of custody
- Manage and track all auditable electronic records; have an integrated picture of all laboratory resources taking part in a specific analysis (scientists, instruments, standards and SOPs)
- Create protocols and studies, improve visibility on when an item needs to be pulled and tested and manage your product Stability
- Manage your microbiology and formulation data
- Perform trend analysis and process control charts
- Manage your external customers test requests

STARLIMS LAB EXECUTION SYSTEM (LES)
EFFICIENT, ACCURATE AND COMPLIANT IN-LAB EXECUTION

Laboratory processes are nowadays still often documented on paper. Even in laboratories that have implemented software solutions like a LIMS, this sometimes happens because the software cannot be conveniently accessed on touchscreen devices that can easily be operated by the lab technicians without disrupting their daily routines.

With the STARLIMS LES (Laboratory Execution System), lab users can easily document their work at the moment they are executed (in-lab execution). This helps to ensure Standard Operation Procedures (SOP) compliance, improves efficiency, prevents transcription errors, and can make some otherwise required peer-review steps in GxP regulated environments unnecessary.

STARLIMS ELECTRONIC LAB NOTEBOOK (ELN)
BECOME PAPERLESS, STREAMLINED, HARMONIZED & PROMOTE COLLABORATION

Laboratory workflows today can be complex and include multiple steps. Your results are important, so each step should be documented, however, documenting in paper notebooks or in Excel files stored on department share drives can be inefficient and make it difficult to maintain compliance. It is challenging to share paper notebooks with colleagues in different locations and file stored on department shared drives can be difficult to maintain and search.

Our ELN is a powerful paper notebook replacement for your lab. Whether you are looking to capture interim result data in tables, create calculations on the fly using standard Excel formulas Excel formulas, add pictures and annotate, or include attachments, the Excel- like interface provides you with a flexible canvas to capture and store your data in a central, easy to search and share repository which maintains compliance with your organization's record retention rules. You can even see the method/SOP while you are executing the steps to ensure compliance.

STARLIMS ELN allows you to focus on getting your work done efficiently, and allows you to execute your test workflow without any interruptions.

STARLIMS SCIENTIFIC DATA MANAGEMENT SYSTEM (SDMS)
INFORMATION CENTRALIZED, READILY AVAILABLE AND SEARCHABLE

Laboratories today generate many types of documents. Documents are used to ensure the lab operates to standards through SOPs and methods, and to communicate results to customers through Certificates of Analysis.

These documents need to be created, edited by team members, routed for approval, and put into effect and communicated to those impacted through passing paper/sign-off sheets around, or by storing on department share drives.

Labs also generate data from instruments such as HPLC, GC or Chemistry Analyzers, which need to be brought into the LIMS. Manually rekeying this data can introduce errors, and takes time. Our SDMS solution manages the documents and data generated by a lab. Whether to communicate lab results to customers, or put new SOPs into effect, SDMS will automatically pick up and intelligently parse documents and data, mapping it to an appropriate location in the LIMS, route through a workflow for others to review and approve and enable it to be used in the system. Set it up once, and SDMS will work silently in the background managing your data and documents, ensuring your organization is in compliance and has the appropriate controls in place. Save money and time on printing and managing paper and focus on getting your work done.

STARLIMS ADVANCED ANALYTICS
INFORMATION INTEGRATED FOR FAST DECISION-MAKING

Have a clear picture of your laboratories efficiencies, bottlenecks and trends. Laboratory managers are faced with many decisions today. It can be challenging and time consuming to gather data to make informed decisions. The great thing about the LIMS is that it stores large amounts of data about each day's lab activity. Analyzing this data, looking at trends and patterns over time can provide insights for root cause analysis, such as bottlenecks causing performance issues, identify opportunities for improvement. Laboratory Managers need data to make decisions and help build a business case for new resources. Put the power of STARLIMS Advanced Analytics to work to quickly provide you with the data you need to make effective decisions to run your lab.

STARLIMS MOBILE SOLUTION

CONNECT TO YOU LAB DATA FROM VIRTUALLY ANYWHERE WITH A SMARTPHONE OR TABLET

There are many functions and areas of operation both inside and outside of the lab. For example, you may be performing testing at workstations, perhaps in different rooms, or you may have samples that were collected outside the lab and sent in, and inventory may be stored in multiple locations. The challenge is that desktops and laptops may not be readily available everywhere you need to perform tasks. Sometimes you may need to use paper or other third party solutions.

With our solution, you can use the mobile app available on an iOS or Android device to continue your work wherever you are. Whether you are in the lab, on the go or out of the lab collecting samples you are now free to continue your work regardless of the computing device you are using. There is no need to deal with paper, or other third party solutions - STARLIMS Mobile Solution will automate your workflow.

STARLIMS REQUEST MANAGEMENT PORTAL

Manage your customers' requests for testing. STARLIMS Quality Manufacturing solution provides a single point for collaboration and exchange of information such as results and Certificate of Analysis (CoA). The Request Management Portal allows your customers to create and submit test requests directly to a Contract Lab (internal STARLIMS users) – submit material tests, approve, reject and request more information. Our Request Portal allows customers to track the progress of their requests at all times.

SAP S/4 HANA INTERFACE

We have certified STARLIMS Quality Manufacturing Solution with SAP S/4 HANA. The STARLIMS interface with SAP S/4 HANA is an extension of our existing interface with SAP QM-IDI and ESS. The interface allows the mapping and exchange of information between the two solutions.

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