

STARLIMS™



ABBOTT INFORMATICS

# STARLIMS INTEGRATED SOLUTION AND PROFESSIONAL SERVICES

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Industry faces the everyday challenge of managing cost efficient operations, producing high quality, safe products and having visibility of the operations and data. Ensuring the cost of quality adds value to the operations, becoming lean, streamlined, improving process and complying with the industry regulations are at the top level priorities.

**Support your laboratory operational and lean excellence efforts – One Partner, One Powerful Solution – STARLIMS!**

STARLIMS solution is a scalable web based product that will allow you to connect from virtually anywhere any time with compliant features to ensure data integrity, traceability, regulatory compliance and inspection readiness.

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

- Perform resource and test planning
- Consolidate product sample data and documentation
- Produce flexible reports as well as Certificates of Analysis (CoA) or General Certificates of Conformity (GCC) for product and/or samples that meet specifications
- Analyze trending, support testing standards and compliance efforts, e.g. International Conference of Harmonization (ICH), United States, Japanese, European Pharmacopeias (USP, JP, EP) and others
- Support compliance with FDA 21 CFR Part 11, EMEA Annex 11, ISO 17025, ISO 9000, Good Manufacturing Practice (GMPs), Consumer Product Safety Act (CPSA), and other regulatory requirements and best practices

**About us**

We are a leading provider of laboratory information management solutions with more than 1000 implementations in over 40 countries.

Since 1987 STARLIMS has specialized in what it does best – delivering industry-leading laboratory information management solutions that enable organizations to respond to day-to-day challenges. STARLIMS manages the collection, processing, storage, retrieval, and analysis of information generated in laboratories.

While configuring our solutions to the needs of our customers, our team has accumulated industry-specific know-how and best practices, earning us a reputation for high quality service.

Our global activities are managed from our headquarters located in Hollywood, Florida. With over 48 offices globally we serve our customers in Europe, Middle East and Africa, North and Latin America, and Asia Pacific.

The regulated and non-regulated industries that we serve are:

|   |                          |   |                 |
|---|--------------------------|---|-----------------|
|  | Pharmaceutical & Biotech |  | Chemical        |
|  | Consumer Goods           |  | Food & Beverage |
|  | Clinical Research        |  | Biorepositories |
|  | Environmental Sciences   |  | Forensics       |

Our primary disciplines are in quality assurance and quality control, testing and monitoring, and research and development.

## STARLIMS INTEGRATED SOLUTION

### Secure, reliable, integrated

Our latest modern technology provides a completely integrated solution incorporating LIMS, Electronic Laboratory Notebook (ELN), Scientific Data Management System (SDMS), Advanced Analytics and Mobility in a single application, eliminating the need for building and maintaining custom interfaces to third party tools.

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

STARLIMS laboratory information management software includes powerful tools for comprehensive management of quality laboratory processes: Configurable workflows for different laboratory types, flexible order management, resource and test scheduling, instrument and test standard management, flexible calculations, reporting and data analysis tools, comprehensive audit trail and electronic signatures. STARLIMS offers in addition a comprehensive formulation/recipe management, stability study management, environmental monitoring, Chromatographic Data Systems (CDS) integration, and more. Connect with Enterprise Resource Planning Systems (ERP), Product Information Management Systems (PIMS), Manufacturing Execution Systems (MES) and other enterprise systems via web services, file transfer and direct database communications.

### Reduce costs and turnaround time, increase efficiencies and testing volume, boost quality laboratory productivity

The configurable nature of STARLIMS allows you to handle many types of laboratory processes or workflows without the need of programming or complex configuration, handle different products testing requirements and automate the sample collection, logon, receiving, assignment, testing, result entry, approval, release and report generation process.

With STARLIMS you can:

- Manage your data by exception rather than reviewing results that are nominal
- Automatically visually 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 support improving regulatory compliance
- Manage and track auditable electronic records, have an integrated picture of your laboratory resources taking part in a specific analysis (scientists, instruments, standards and SOPs)
- Manage your product development data
- Create your protocols, studies and have visibility on when and what needs to be pulled and tested, manage your product shelf life (Stability Management)
- Perform trend analysis and process control charts

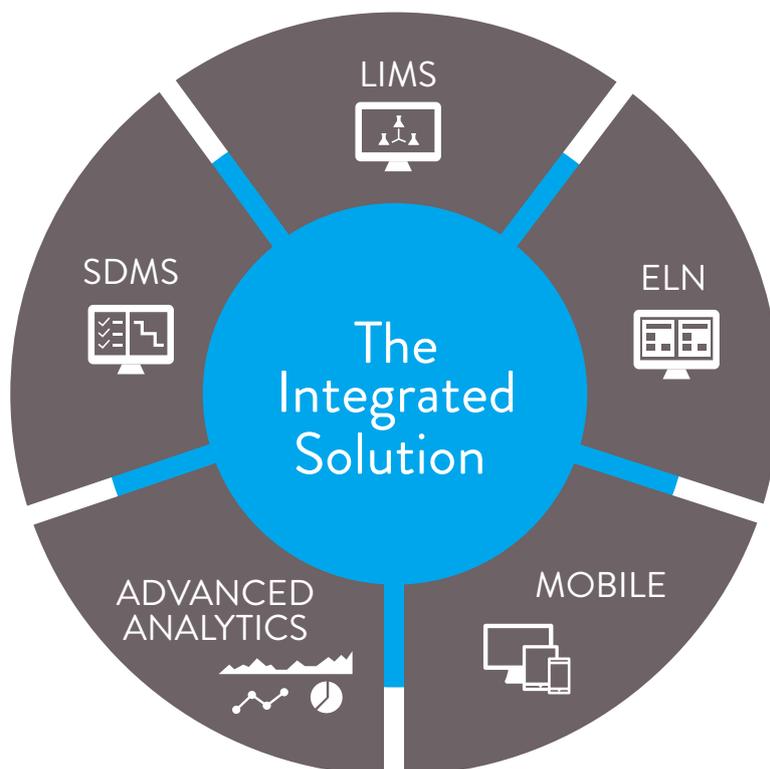


Fig. 1 - Optimize data management accessibility and integrity with our single platform

## STARLIMS 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 communicating results to customers through reports and 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. This can be difficult and expensive to do manually, either through passing paper/sign-off sheets around, or by storing on department share drives. Labs also generate data from testing instruments which need to be brought into the LIMS. Manually rekeying this data can introduce errors, and takes time.

STARLIMS SDMS solution manages the documents and data generated by a lab. SDMS will automatically pick up and intelligently parse documents and data, mapping it to appropriate location in the LIMS, route through a workflow for others to review and approve and enable it to be used in the system, whether to communicate lab results to customers, or put new SOPs into effect. 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 on printing and managing paper, save time and focus on getting your work done.

### Increase efficiency

- **Consolidate islands of data**

Consolidate your data into a single repository (one place for all your scientific data), saving your lab personnel time lost looking for information and the cost of maintaining different information stores

- **Automate data entry**

Reducing and automating data entry improves quality and saves you time

- **Reduce cycle review and approval time**

Use strong workflow and automation features for business process centric documents



Fig. 2: SDMS overview

### Promote collaboration

- **Capture files and extract data**

Capture and use information in unstructured documents including keywords, tables and charts

- **Use data**

Enable global users to access your lab documents using a standard browser regardless of its source and format

- **Store files**

Use up-to-date storage and storage management solutions

- **Search data**

Eliminate “lost data” and duplicate searches

- **Reuse data**

Repurpose the existing data for other usages

### Ensure compliance

- **21 CFR part 11**

It is designed for 21 CFR Part 11 compliance

- **Reduce use of hard-to-control tools**

Allow uploading multiple file types from multiple sources automatically

- **Workflow management**

Allows for workflow management for document creation and approval

- **Instrument raw data**

Allows backup of instruments’ raw data

## STARLIMS ELN

### Become paperless, streamlined, harmonized & promote collaboration

Laboratory workflows today can be complex, including multiple steps. Your results are important, so each step is documented. But documenting in paper notebooks, forms, logbooks, or in Excel files stored on department share drives can be inefficient and difficult to maintain compliance. It is difficult to share paper notebooks with colleagues in different locations. Files stored on department shared drives can be difficult to maintain and search.

STARLIMS ELN is a powerful paper notebook replacement for your lab. Whether you are looking to track information about reagents and standards, capture interim result data in tables, create calculations on the fly using standard Excel formulas, add pictures and annotate, or include attachments, the Excel-like integration provides you with a flexible canvas to capture and store your data in a central repository which is easy to search, easy to share and 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.

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



## STARLIMS MOBILE

### Access your lab from virtually wherever you are

Work in the lab operates in different areas. You may have samples that are collected outside the lab and sent in. Within the walls of the lab, you may have testing done at workstations, perhaps in different rooms. Inventory may be stored in a multiple locations. The challenge is that desktops and laptops may not be available everywhere you need to do work. Sometimes you may need to use paper or other third party solutions.

With STARLIMS Mobile solution, you can use the STARLIMS Mobile App available on an iOS or Android smartphone or tablet to continue your work virtually wherever you are. Whether you are out of the lab collecting samples, or in the lab, moving from your desk doing work in other areas, continue your work regardless of the computing device you are using. Automate your workflow.

Our approach to Mobile Apps:

- **Tailored to screen size**  
The user experience is tailored to match the appropriate screen size
- **Focused on specific tasks**  
As opposed to having all the functionality, the apps provide tasks which are typically done on the go
- **Touch friendly interface**  
Uses an intuitive interface with larger buttons
- **Cross platform**  
Supporting both iOS and Android smartphones and tablets
- **Supports offline mode**  
Allows mobile apps to be used in offline situation and synced back when network connection is restored



Fig. 3: STARLIMS Mobile and Advanced Analytics dashboards

## STARLIMS ADVANCED ANALYTICS

### Have a clear picture of your lab 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 a large amount of data about each day's activity in a lab.

Analyzing this data, looking at trends and patterns over weeks, months, years, can provide insights into the operations of a lab.

It can help answer questions for root cause analysis, identify opportunities for improvement, identify bottlenecks causing performance issues, and help build a business case for new resources. Laboratory managers need data to make decisions.

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.

### Advanced visualization

Advanced Analytics solutions allow for data to be visualized with charts relevant to the data. There are many types of charts available and the solution auto guides you to pick the best visualization based on the data set you have. E.g. data with a geographic location may be best visualized on a map. Scatter plots are useful for visualizing large data sets and looking for outliers in that data. Bar charts and pie charts are useful for comparison. Seeing data in these types of visualizations allows the user to see insights which jump out at them and are difficult to see in a spreadsheet or detailed view. Using color, shape and size allow further insights.

Moreover, laying out these charts in a dashboard, which assembles two or more charts allows the user to see relationships between data sets, as well as use filters to focus in on the data they are specifically interested in. Finally, dashboards allow the user to drill down through different data sets, allowing them to tailor their search and see details of a summary data set.



## STARLIMS PROFESSIONAL SERVICES

### Personalized implementation and support for LIMS operational excellence

We're not just an informatics provider, we're your long-term partner. As an extension of your lab organization, our dedicated team will make sure that your LIMS solution not only meets your lab goals of today, but also supports your lab's future needs.

### Exceed your lab's goals with a dedicated partner

Every customer is assigned a team of Abbott Informatics consultants with capabilities in project management, business systems analysis, technical design, quality assurance, and much more. No matter the size, requirements, or industry that your lab operates in, our Professional Services team will configure a LIMS solution to fit your lab's needs.

### A powerful framework for the future

From reducing costs, ensuring quality, or enabling a paperless lab, our Professional Services team will tailor a solution that supports your lab's goals today and for years to come. Built on the powerful .NET framework, our solutions enable your lab to upgrade to new versions or integrate other technologies and instruments as needed. Mobile, Advanced Analytics, and Cloud Services capabilities ensure that your LIMS streamlines productivity and efficiencies with the up-to-date technologies.

## World-class industry domain expertise

Our team members have an average of 20+ years of prior experience or operational expertise in various domains. This specialized knowledge helps us determine the optimal system configurations for your lab and meet distinct, industry-specific standards and software regulations.

## Proven implementation methodology

Our thorough and proven implementation methodology helps ensure that your software implementation happens on time and on budget, with no surprises. Throughout the process, our Professional Services teams will act as a true extension of your lab to ensure a successful implementation.

Our approach consists of the following:

### Discovery & requirements definition

- We get to know your business from the inside out. First, we'll learn about your goals and business needs. An application training will ensure that your team fully understands STARLIMS out-of-the-box solution.
- A gap analysis and review of your lab workflow and instrument integrations will help us identify areas of improvement and opportunity.
- And finally, alongside your IT infrastructure team and other lab stakeholders, we'll work together to define software requirements and plan for a successful data migration (migration strategy, data source analysis, migration design, implementation and testing, revisions and maintenance).

## System installation, configuration & quality assurance

- Using the project plan as a roadmap, our software engineers configure and implement the solution, collaborating closely with your team throughout the process.
- Our development goes through comprehensive quality assurance testing to ensure that your solution is of highest quality.
- Transparency and effective communication is key during this time, so we'll constantly share the project's progress, preview features, and make adjustments as needed.
- Hands-on training will ensure that your team fully understands how to operate and maintain the system for future enhancements.

## Validation & deployment

- Once the solution is installed and tested, we will assist you through validation processes for industry standards before deployment.
- We will be on-site at your facility during deployment to ensure that the rollout of your solution happens smoothly and efficiently.

## Training & support

- After your solution has deployed, we'll still be here to help answer your day-to-day questions, provide ongoing technical support, and plan for your future needs.
- We offer multiple in-person training sessions in four of our global offices, in addition to online training. Our comprehensive training offerings will ensure that your team is armed with the skills needed to get the most out of your LIMS solution.

## Adheres to the following standards & memberships

- GAMP5
- ISO 9001
- PMBOK 2000
- HL7
- ITIL v3
- ASTM International
- Project Management Institute
- American Society for Quality
- International Society for Pharmaceutical Engineering

Our success is your success. We are committed to building long-term relationships with every customer and focused on delivering customer satisfaction and quality results. We are passionate about what we do, and we believe in your lab's work, in whatever environment you are in.

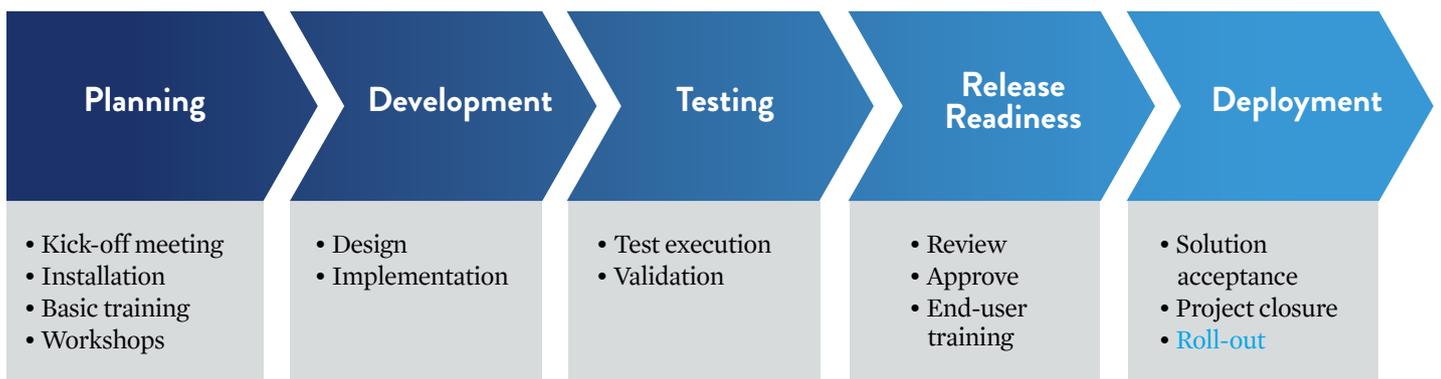


Fig. 4: Professional Services Process - Overview

# informatics.abbott

## **ABBOTT INFORMATICS**

Tel: +1 954 964 8663

4000 Hollywood Blvd, Suite 333 South, Hollywood, FL 33021-6755 USA

## **UNITED KINGDOM**

Tel: +44 161 711 0340

## **GERMANY**

Tel: +49 2302 915 245

## **FRANCE**

Tel: +33 1 61 37 02 00

## **SPAIN**

Tel: +34 91 663 67 64

## **NETHERLANDS**

Tel: +31 72 511 8100

## **ASIA PACIFIC**

Tel: +852 2793 0699

## **LATIN AMERICA**

Tel: +1 954 964 8663

## **CANADA**

Tel: +1 888 455 5467

## **AUSTRALIA**

Tel: +61 3 9670 0678

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