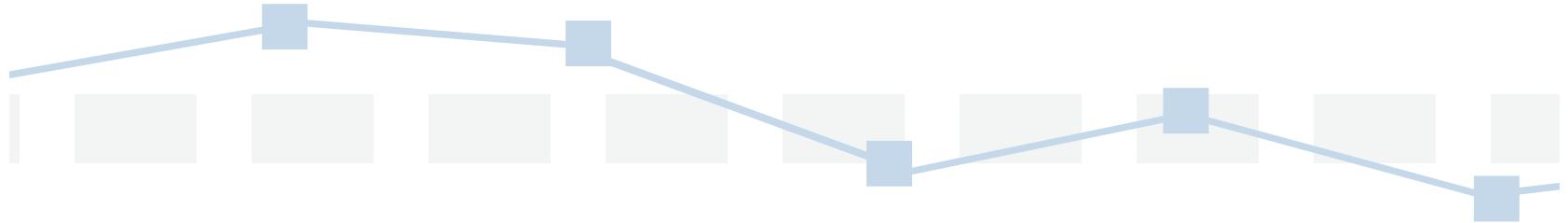


STARLIMS®
LAB DATA/ENTERPRISE ACTION



STARLIMS Version 10
Configurable Off-the-Shelf LIMS
for Laboratory and Enterprise Collaboration



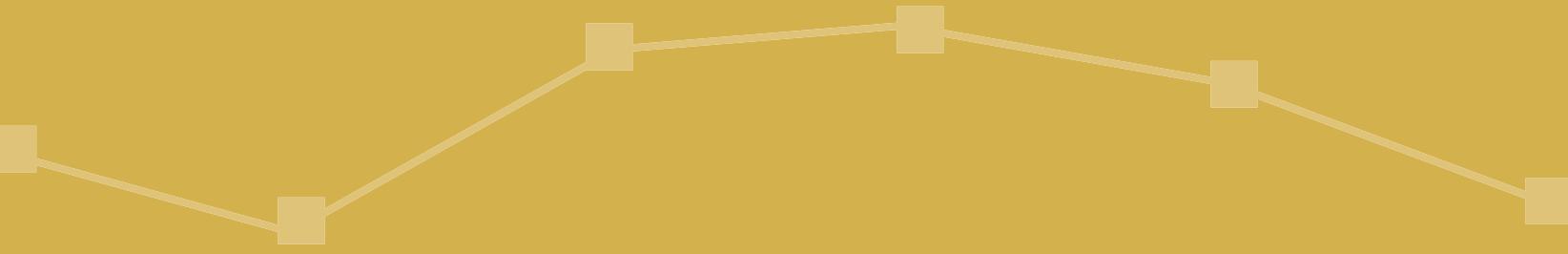


STARLIMS is the most powerful tool labs have to manage complex processes, ensure regulatory compliance and promote laboratory and enterprise collaboration.

STARLIMSV10 is a high-performance, truly web-based Laboratory Information Management System (LIMS). It provides all the features required to manage the workflow and resources of the laboratory, while providing enterprise-wide access to lab data. STARLIMS V10 helps optimize laboratory efficiency levels, while also ensuring that laboratory information is available throughout the organization in a timely way. STARLIMSV10 sets the standard for LIMS by offering a future-proof web architecture, rapid global deployment, minimal learning curves and unlimited browser-based access.

STARLIMSV10 can be deployed with the STARLIMS fully integrated Scientific Data Management System (SDMS), to create a single multi-purpose platform that manages not only structured lab data, but also unstructured information largely inaccessible to other LIMS (documents, instrument data files, PDFs, product specifications, etc). Such integration leads to optimal use of valuable lab data, and protects the value of historical data. It enables organizations to create knowledge, and make decisions, based on a combination of accurate, up-to-the-minute data and relevant historical information.

Based on two decades of experience in hundreds of organizations, STARLIMS supports most lab requirements straight out of the box with a rich true-to-life GUI, while powerful configuration tools are available to help meet specific needs. STARLIMS has a proven track record in R&D, Analytical Services, Process Operations and QA/QC environments; and operates in the public health, pharmaceutical, petrochemical, forensics, food and beverage, environmental, water and chemical industries.



STARLIMS was built from the ground up as an entirely web-based solution. Leveraging XML and other advanced Internet technologies, STARLIMS enhances overall operational excellence in all types of laboratories and organizations.



An Integral Part of Enterprise Systems

STARLIMS is a collaborative web-based tool which is an integral part of enterprise-level business systems. Seamlessly interoperating with other systems, STARLIMS generates and disseminates quality data that is used by other software systems or personnel to make business decisions. Depending on the type of organization, timely STARLIMS data can help an organization to:

- Procure additional raw materials when incoming lots fail inspections;
- Accelerate shipments after final quality control;
- Implement timely product recalls; or
- Raise alerts to officials responsible for managing Public Health threats.

The Flexibility Dynamic Labs Require

STARLIMS' flexibility is manifested in multiple levels of the system--from automated workflow and records management to closed-loop traceability. STARLIMS offers multiple ready-made tools and wizards, vastly reducing reengineering requirements. Fine-tuning STARLIMS to meet the needs of any lab is easy and convenient, thanks to a rich true-to-life GUI based on intuitive drag&drop functions. STARLIMS guides operators through defined steps and makes appropriate recommendations based on entered data, raw data or a resource reference. STARLIMS mimics manually implemented procedures, recording business logic within the automated system.

Advanced Document Management Capabilities

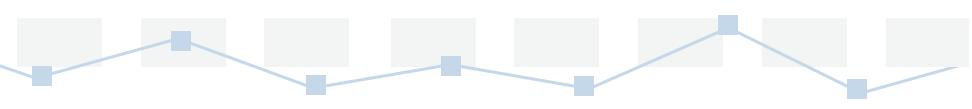
In addition, STARLIMS offers exceptionally flexible electronic document management capabilities. STARLIMS securely stores textual and graphical documents (instrument-generated graphics such as chromatograms or spectra; raw data files; standard operating procedures (SOPs); analyst certifications; electronic training materials; investigation reports and others). With full documentation readily available, organizations can ensure the integrity and validity of results, enjoying a high degree of confidence in the analysis process.



The quest for a true web-based application came about from real needs for increased efficiency and remote global access.

Limited resources in IT departments have driven demand for systems with zero client-side installation and maintenance.

Redesigning STARLIMS as an entirely web-based application is a major step in meeting these challenges.



The Road to a True Web-based Experience

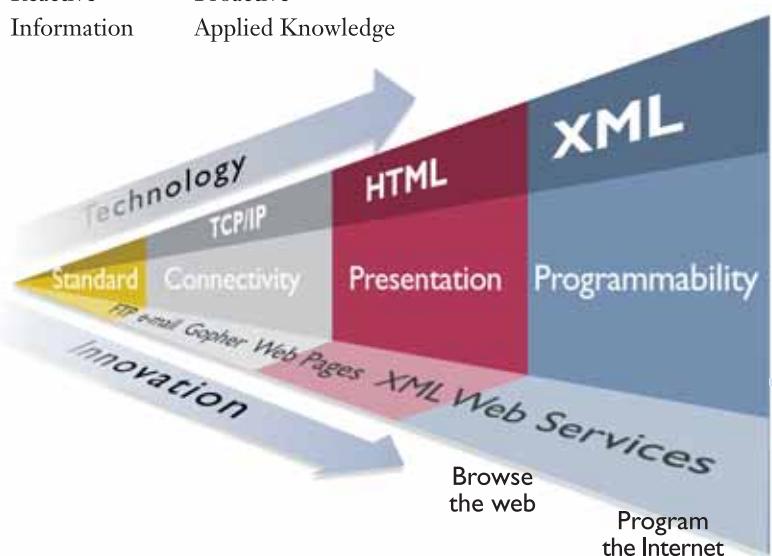
Over the last decade, laboratory regulations have become far more stringent, requiring laboratories to record dramatically larger volumes of data. In addition, laboratories and companies are seeking to accelerate response times, improve profitability and enhance decision-making processes. To achieve these aims, vast amounts of generated data must be converted into useful information—and effectively distributed throughout the organization.

With the advent of new technologies, better security and leaner systems, LIMS has moved out of the laboratory and on to the desktops of laboratory data consumers, such as research personnel, process engineers, satellite laboratories and field workers. At the same time, web service applications facilitate a paradigm shift that enables interconnection and integration of disparate business applications, resulting in shared functionality across different systems and platforms.

Going beyond traditional web-enabled solutions, STARLIMS is built from the ground up as an entirely web-based application. STARLIMS leverages XML and other advanced Internet technologies to facilitate data management and decision-making within the lab, throughout the plant and across the enterprise. At the same time, it offers a ‘rich’ true-to-life GUI that vastly streamlines configuration and deployment. STARLIMS requires no client-side installation or maintenance, and offers an accelerated learning curve.

STARLIMS advanced features, including the dashboard, are changing the way data is utilized and the way processes are executed.

From	To
Monitored	Optimized
Reactive	Proactive
Information	Applied Knowledge



Evolution of Internet technology

Web-Based Architecture

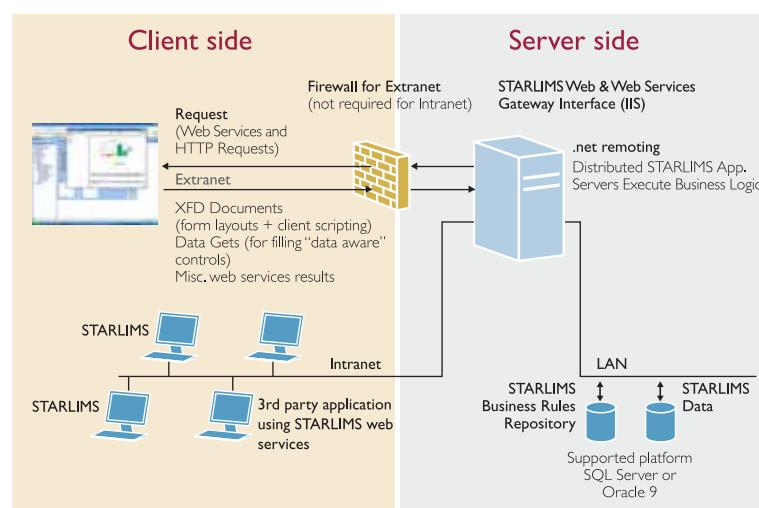
Benefits of STARLIMS Web-based Architecture

- Intuitive true-to-life GUI for a rich user experience
- Built according to Internet standards for an accelerated learning curve
- No client-side software installations
- Scalable for easily configured hardware resources and load balancing algorithms
- Unified application for design and runtime
- Full enterprise integration
- Full separation of user interface from business logic
- Predictable response times
- Easy-to-use tools for enhancing and modifying system functionality

STARLIMS architecture incorporates standard web-based features, with a scalable and extendable web browser client-side application and a database server “farm.” Communications between client and server are achieved through standard web service messaging over hypertext transfer protocol (HTTP). Alternatively, a secure HTTP (HTTPS) can be used for a more secure environment.

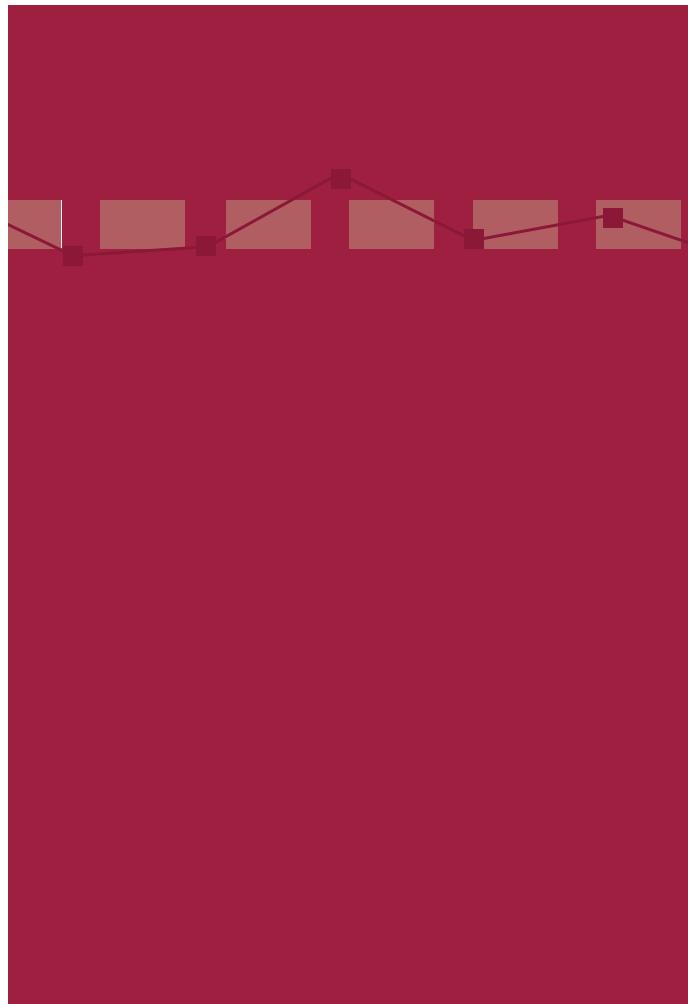
To take advantage of all the available processing power and allow for a rich user experience, STARLIMS splits code into business logic (which is executed on the server side), and presentation code (run by a .NET control on the web client). The result is predictable response times and a far superior user experience.

The STARLIMS application servers provide true scalability, allowing the LIMS to grow and meet the changing demands of the laboratory and organization. STARLIMS provides fail-safe capabilities to help ensure 100% availability of the LIMS.



STARLIMS Version 10 architecture

The STARLIMS client is a standard web browser that hosts a .NET control that dynamically presents the user interface. The STARLIMS XFD Renderer Controls are automatically deployed on the client when a new version is released. In addition to the classic GUI controls (labels, buttons, textboxes), this technology supports more complex controls, such as hierarchical data grids, tab controls, and selection boxes. For data-aware components, termed data providers, are used to interface between the GUI and the data model residing on the server. For increased security, client-side scripting code is run in an isolated (“sand-boxed”) environment, and the server-side business logic code is separated from the client-side. The STARLIMS XFD Renderer uses the local machine’s computational capabilities, resulting in reduced server and network load.



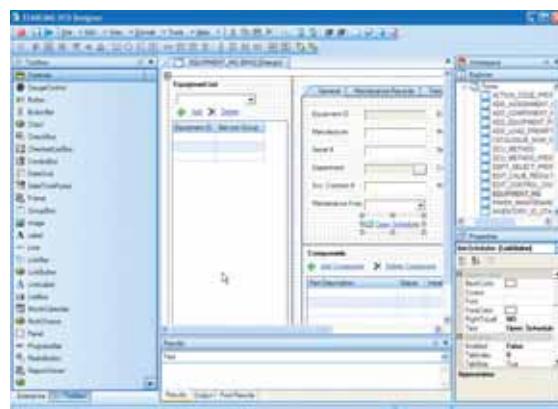
Web-Based Architecture

STARLIMS XFD Designer

The STARLIMS XFD Designer enables authorized users to configure, enhance and modify the system as business requirements change. Designed to make GUIs and Internet protocols entirely transparent to the user, STARLIMS allows users to focus solely on creating optimized business rules.

Using intuitive graphic drag & drop design tools, authorized users define the processes they need. XML forms containing layout tags are used in a declarative way to describe the user interface. JScript.NET code is used to programmatically handle these elements and corresponding events, and to make remote calls to business logic services located on the server.

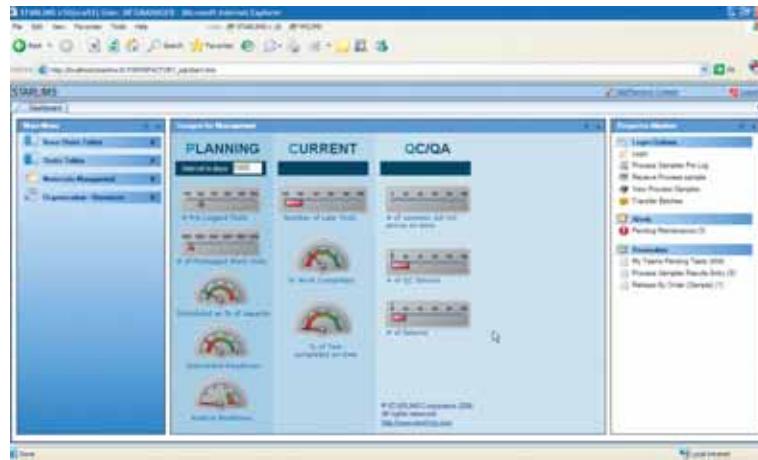
Communications between the GUI and the business logic are achieved via standard web services. The STARLIMS XFD Designer is also used to create web services made available to third-party client applications, for seamless interoperability between STARLIMS and a host of enterprise applications.



Sampling to Reporting



STARLIMS' flexible configuration tools allow system administrators to easily establish and maintain their laboratory's unique workflow and business rules through ad hoc or pre-defined lifecycles. The STARLIMS Dashboard automatically monitors the flow of data—providing targeted, real-time information personalized according to each user's role and authorization level.



THE STARLIMS DASHBOARD

GOOD LABORATORY PRACTICES CONTINUOUSLY MONITORED

Sample Login

- Login by Sampling Program
- Double Data Entry
- Barcode Labels - Printed
- Sample Receipts - Issued

Work Assignment

- Samples - Organized
- Work Lists - Issued
- Instrument Parameters - Sent

Results Entry

- Manual or Automatic Calculations
- Integrated Data Capture Utility
- Non-Numeric Data Archival
- Online Validation and Flagging

Review and Approval

- Resubmit for Testing
- Re-sample / Investigate
- Release with Electronic Signature

Reports and Queries

- Intuitive Query by Example
- Integrated SQC
- Trend Analysis
- Performance Testing
- Integrated Crystal Reports
- Export to Desktop Application
- Enterprise Updates

SAMPLE COLLECTION AND STORAGE MANAGEMENT

SAMPLE RECEIPT AND PREPARATION

SAMPLE TESTING

QUALITY ASSURANCE

ELECTRONIC DATA DELIVERABLES

The Workflow

Traceability

STARLIMS' flexible workflow tools provide complete traceability in a manner compliant with the strict standards of the US Food and Drug Administration Regulation 21 CFR Part 11. All this is possible with no compromise in process versatility.

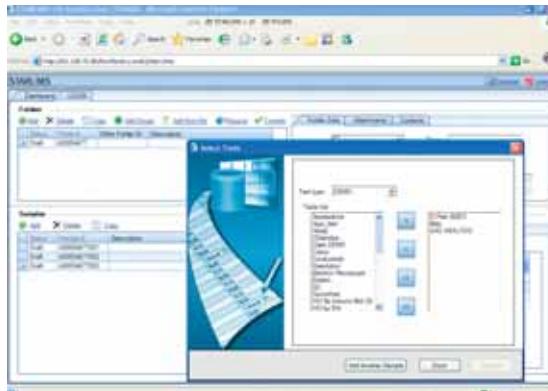
The core of the STARLIMS application is the automated electronic record-keeping function. An electronic signature is maintained in a relational database--encompassing test results, equipment settings, and all movements and activities.

STARLIMS also implements very strict controls including: stringent access rules, document and data change controls, transactional or silent audit trails and password security.



Sample Login

During Sample Login, users describe each sample using a set of meta-data fields and request tests. Test assignments and meta-data vary according to the sample type. The sample login process is extremely flexible. All meta-data fields, their pop-up list properties and test assignment methods are easily configured and associated with the sample type.



STARLIMS offers several sample login methods to accommodate diverse testing protocols: batch, routine, time-based, event-based, calendar and ad hoc. STARLIMS facilitates assigning disparate workflows and testing protocols based on login content.

Pre-Log Samples

Lab efficiency is enhanced through the ability to pre-log samples, alerting the lab and enabling it to prepare for rapid sample processing upon arrival. This eliminates errors and confusion due to misinterpretation of hand-written log-in forms.

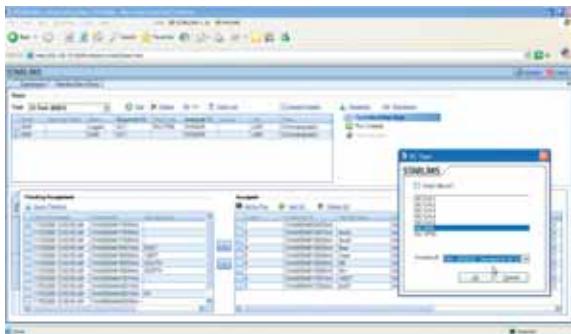
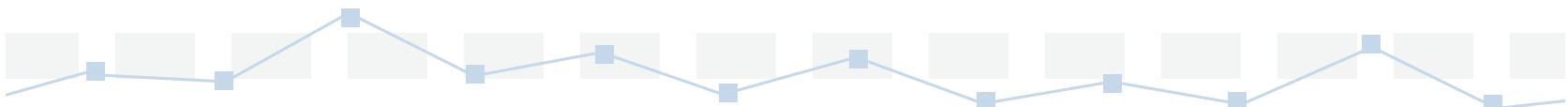
Several pre-login methods are available:

- Via a Pre-login screen accessed via Microsoft™ Internet Explorer
 - Via portable devices that use active synchronization services
 - Via web services that are accessible from third-party systems (ERP, MES, Clinical Trial Management Systems, PIMS, etc.)

Receive in Lab

Barcodes and handheld devices can be utilized to generate sample labels and receive samples in a rapid error-free manner.

The Workflow



Work Assignment

Depending on laboratory-specific business rules, tasks are assigned to analysts and teams. The Test Design Wizard enables configuring some tests so they will be assigned solely to certified analysts. Samples can be grouped into runs (batches of samples intermingled with QC samples). Utilizing the STARLIMS Instrument Work Assignment interface, work lists and instrument control parameters can be sent to analytic instruments or laboratory robotics systems.

The built-in Work Scheduler calculates the time needed to complete the tests on the work list. The STARLIMS Dashboard dynamically displays Key Performance Indicators (KPI) that indicate current capacity, percent of work completed and other critical parameters.

Results Entry

The type of result patterns that may be stored range from simple single-number or text responses, to arrays of data such as Elisa and chromatography data sets. STARLIMS' tight integration with Microsoft Office™ also supports unstructured results (e.g., notes describing an electron microscope image).

Built-in calculations, including QC calculations, automatically determine bias, precision, accuracy, sensitivity and other pre-determined parameters. Validations based on specific QC requirements can automate "reflex testing" or retesting.

Automatic Data Capture Utility (DCU)

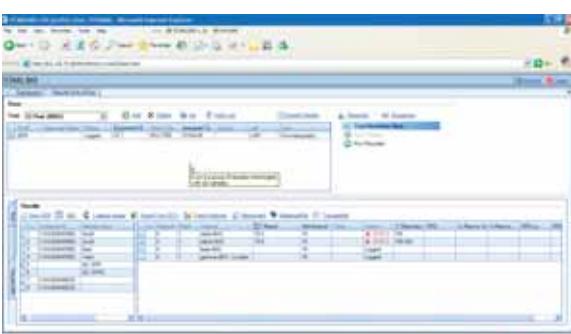
Automatic result entry of test data is facilitated through the DCU, a built-in parsing utility that enables data capture from multiple instruments or systems. Virtually any lab or enterprise system can place result files onto the network, or communicate with STARLIMS via a standard API. Upon bench approval, results are transmitted to the DCU, triggering additional calculations and validations prior to final database storage.

The STARLIMS Data Capture Utility efficiently eliminates transcription errors, creates a traceable closed-loop environment, and makes lab data available throughout the enterprise.

Manual Data Capture

In manual mode, result-entry screens lead the analyst through the required workflows. STARLIMS automatically prompts the analyst to record the necessary data at each step of the preparation and testing workflow. The screens are easily configured to reflect the specific test workflow and the information that needs to be captured.

The STARLIMS Dashboard dynamically provides the analyst KPIs regarding the workload, as well as QC KPI's (e.g., reflex tests, retest, and QC rejects).



The Workflow

Customer Access

Based on a secure web services layer, STARLIMS enables authorized users to obtain virtually any type of lab data over the Intranet—from results of analytical services to sample status and billing information.

By giving lab data consumers direct access to the information they need, STARLIMS helps labs:

- Accelerate response times
- Minimize status queries
- Reduce manual handling of analytical services
- Lower costs
- Improve customer satisfaction



Review & Approval

When all results have been entered and approval is required, the STARLIMS Dashboard Workflow console alerts the appropriate personnel to review and approve pending results. Laboratory-specific business rules determine what electronic signatures are required before final release. During the release process, all information related to the reviewed samples is accessible via the Traceability viewer. This includes:

- Instrument maintenance records,
- Analyst training records
- Records pertaining to the standards that were used
- Audit trail records and signatures gathered at the different workflow steps

Reports & Queries

Many laboratories are facing increasing demand for more and more personalized, services. Typically, customers are demanding improvements in:

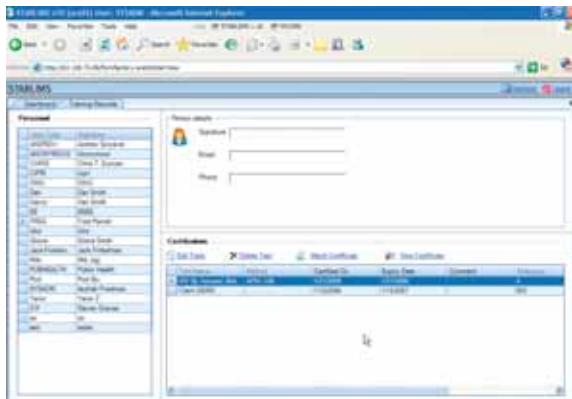
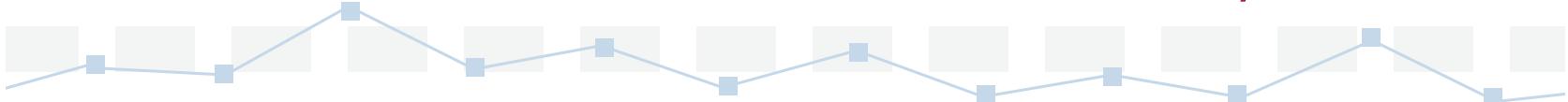
- Report formatting
- Rates, terms and conditions
- Turnaround times
- Sample collection services
- Kit management
- QC requirements

The exceptional flexibility and data filtering capabilities of STARLIMS are important factors that enable laboratories to meet these requirements.

Depending on their authorization level, data consumers can obtain any type of lab data: trend analysis, proficiency testing, turnaround time, laboratory resource planning, QC charting, laboratory output, billing and invoices, and more. STARLIMS can issue reports that are personalized for a specific user, role, instrument, group, laboratory, or location. Any report can be sent to a workstation screen, routed to a network printer, sent via fax or e-mail, or published on the organization's Intranet.

STARLIMS uses Business Objects' Crystal Reports, an industry standard SQL reporting tool offering complete flexibility in report design and layout. Other off-the-shelf desktop applications such as Microsoft Office™ can also be used to create reports.

Good Laboratory Practice



STARLIMS helps lab establish and maintain Good Laboratory Practice (GLP) documentation procedures for closed-loop traceability and regulatory compliance. Among other functions, STARLIMS facilitates maintaining versions of test methods, training certifications for analysts, logbooks for instruments and standards, control charts, MSDS and more.

The Materials Manager maintains the inventory of standards, reagents, containers and other materials used in the sampling and testing processes. In addition, the system provides tabs to maintain additional information such as links to MSDS, material recipes, etc.

The Instrument Management Module helps ensure regular ongoing maintenance, by establishing schedules, tracking completed tasks (including real-time annotations on actions taken) and flagging incomplete tasks. Depending on lab-specific configurations, certain requests may be disabled until the required maintenance task is completed.

STARLIMS ensures the highest standards of integrity and quality, in conformity with GAMP, ISO 17025, GLP, EN requirements for audit trails, security, data integrity and data archiving. This includes customer compliance with 21 CFR Part 11 requirements for electronic records and signatures.

Security

STARLIMS' security configurations allow users to determine the functions and content accessible for a given role. For instance, the functions of analysts would typically include entering results and performing peer approval. Using the STARLIMS Role Design Wizard, system administrators rapidly create multiple roles, and assign them to various users.

Likewise, access to content can also be limited to specific groups and individuals within the organization. For instance, members of the chromatography group may only be able to view their own group's data, but a lab manager may access data from various groups.

The Dashboard Parts Manager provides tools to configure different dashboards for different roles, so the appropriate content is delivered according to each person's job description and organizational affiliation.

Audit Trail

The automatic audit trail function records all changes in the audit log, indicating the nature, user and reason for the change. The system administrator can limit the fields subject to the audit trail, and the conditions required to implement changes.

Good Laboratory Practice



Version Control

STARLIMS safeguards data integrity by disallowing changes to critical information such as test plans, specifications, test methods and other controlled procedures. Critical information can only be modified by creating new versions.

Document Management

STARLIMS offers laboratory document and scientific data management in a single platform that fully complies with 21 CFR Part 11. STARLIMS Document Management functions are fully integrated into the STARLIMS workflow, for automatic simultaneous presentation of STARLIMS content and captured documents enterprise-wide. Routed content and documents may include SOPs, analyst certifications, electronic training materials, investigation reports, captured instrument outputs, COAs (Certificates of Analysis) generated by the laboratory for users, scanned COAs received from suppliers, and more.

Altogether, STARLIMS provides scientists and lab users the ability to securely store and share complete scientific reports in various textual, graphic and audio visual formats. This provides rich and complex data extraction during data querying and analysis.

Multi-Lab Capabilities

As an Internet-based system, STARLIMS V10 enables using a single database to run multiple laboratories operating at different geographical sites. Access to data is defined for each user. Some users may only view local data, while management may access a wider view spanning multiple sites and labs. Alongside these functions are capabilities that allow for transfer of samples between labs to accommodate for conditions such as capacity overflows, etc.



Add-On Modules

Stability Studies – The stability studies module provides a workflow for the creation, review and approval of stability study protocols, which are converted to studies. The Pull stability studies functions provide reminders as to when samples need to be pulled from storage and sent to testing. Built-in inventory management capabilities provide real-time information about the stored samples, their location and storage conditions. The reporting and analysis module provides tools to extract stability data and perform calculations (expected shelf life, etc.)

Future-Proof Investment

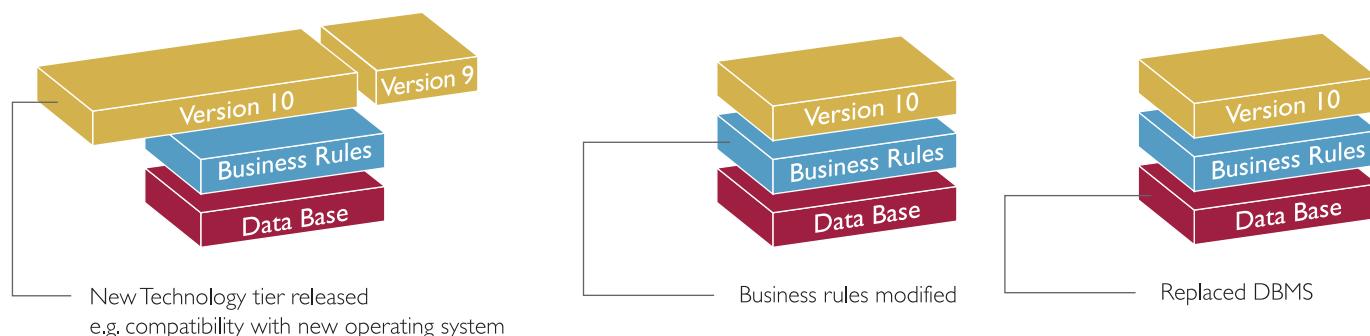


In most legacy and first-generation LIMS systems, the technology and the business rules components are compiled together and cannot be separated. Often, custom code is developed to meet dynamically changing lab and business needs. In parallel, vendors make modifications to their product code to incorporate new IT technology.

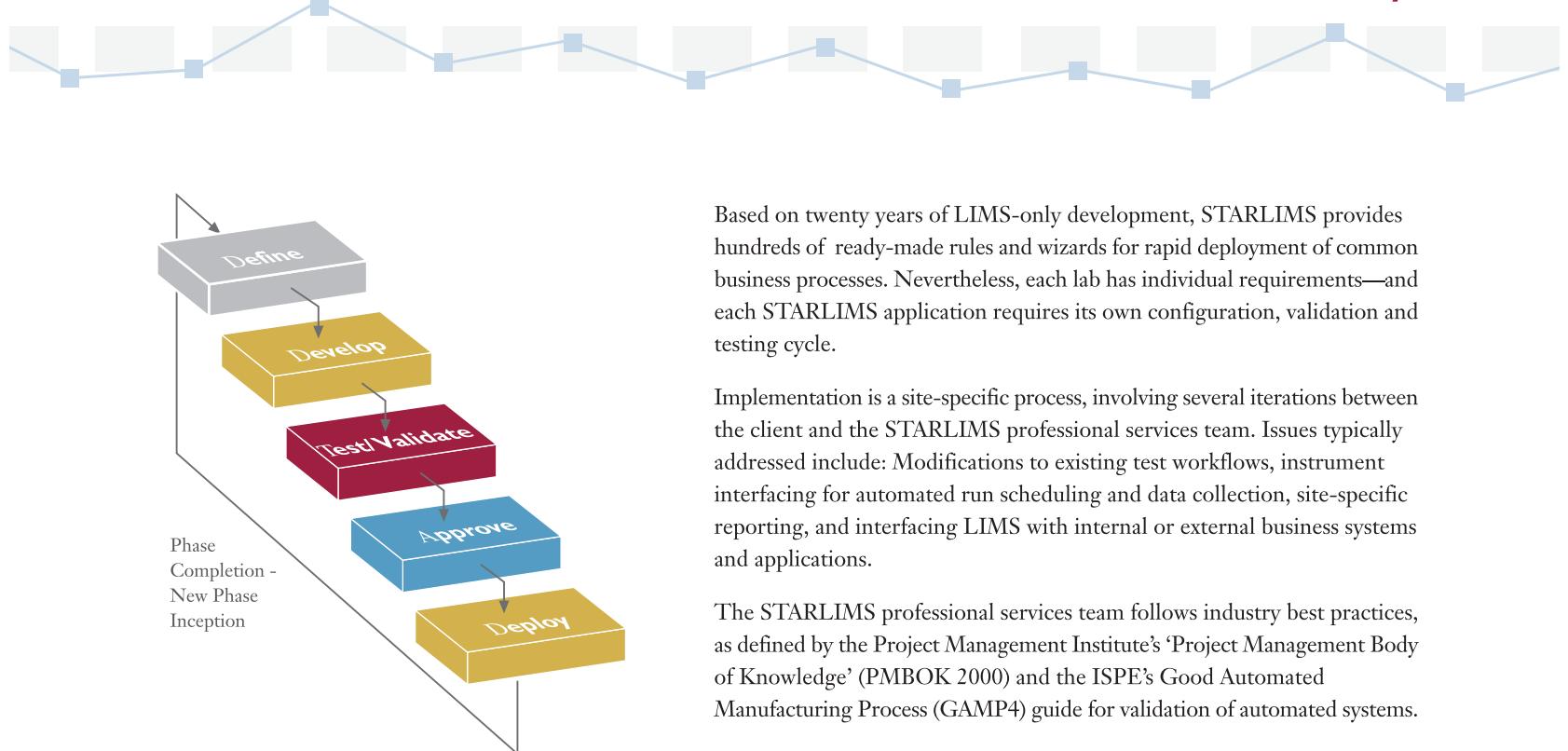
These parallel developments are normally incompatible, so users must forgo their customized applications if they wish to upgrade to newer versions of the vendor's LIMS. Deviation from the vendors' development path makes it more difficult to modify business rules. Over time, the laboratory finds itself using a system that is far behind the latest technologies, and also falls short of the laboratory's own requirements. STARLIMS Corporation believes that the long-term effectiveness and ROI of LIMS solutions can only be improved by using a single technological platform, which preserves existing business rules while allowing for ongoing configuration.

STARLIMS does just that, by using a multi-tier system that partitions development and maintenance tasks. The new and advanced features developed by STARLIMS Corporation are rapidly integrated, validated and distributed enterprise-wide, without compromising business rules or database components. In this way, we help ensure a high level of technological adoption. Conversely, users modify business rules to meet evolving requirements, without departing from STARLIMS's overall development path. This approach increases adoption of ongoing upgrades, while bringing annual ownership costs down to the level of ongoing maintenance costs.

STARLIMS represents a new paradigm for LIMS cost/performance. Easier to implement, validate, certify and maintain than comparable solutions, it lowers total cost of ownership throughout the LIMS life cycle.



Delivery



Project Definition

The project definition phase involves a kickoff meeting to define project goals, objectives and staffing requirements. The STARLIMS professional services team prepares detailed documents to define the project scope (Statement of Work, Project Plan and Work Breakdown Schedule).

Delivery



STARLIMS Corporation is entirely committed to quality processes. The company holds ISO 9001:2000 certification, reflecting our continuing efforts to offer laboratory information management systems that consistently exceed our customers' expectations.

Iterative Development

In each phase of the project, STARLIMS

- Gathers end-user requirements and develops a detailed User Requirements Specification.
- Develops a detailed Functional Specification that shows how the application will meet end-user requirements.
- Establishes a test plan and a documented Factory Acceptance Test.
- Assists the customer to develop a site-specific Site Acceptance Test to ensure the application is working correctly onsite.
- Develops a Traceability Matrix that will trace requirements through functional specification to testing.

This development cycle is repeated at each phase, depending on the scope of the application.

Project Wrap-Up

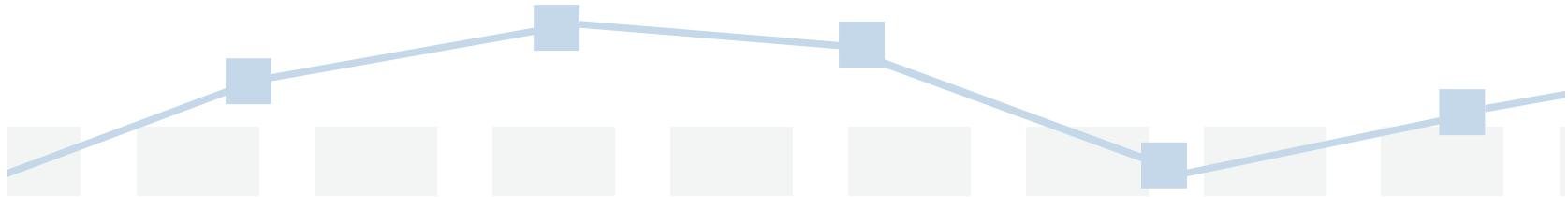
Once the project is completed, a wrap-up meeting is conducted to review the project and to evaluate its success in meeting all goals and objectives.

Ongoing Maintenance

A STARLIMS Support and Update Contract provides customers unlimited remote support and software updates on a regular basis, ensuring that systems remain current and equipped with the latest technological and functional developments. STARLIMS has built-in backward compatibility, so that customers' investment in internal logic is never compromised.

Global Support

A global network of experienced specialists deliver STARLIMS state-of-the-art solutions directly to customers, with professionals located in the US, Canada, Europe, Asia, Africa and Latin America.



About Us

STARLIMS Corporation delivers cost effective, easy-to-use collaborative LIMS solutions to organizations within the public health, pharmaceutical, forensics, food and environmental industries.

The STARLIMS full featured, flexible, multilingual laboratory information management system provides complete traceability leading to regulatory compliance, without compromising process versatility.

The company's 20-year track record together with STARLIMS' architecture have earned us recognition for "future proofing" our customers' investments in internal know-how and for straightforward conversions of disparate legacy systems.

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