STARLIMS™
CONTRACT SERVICES

ABBOTT INFORMATICS

STARLIMS CONTRACT SERVICES INDUSTRY LIMS SPECIFICATION DOCUMENT

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INTRODUCTION

The purpose of this document is to list the main functionality and features available for the Contract Services and Contract Labs.

DEVELOPMENT

FORMULATION DEVELOPMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
Formulations and Recipes	Create recipes and development batches associated with recipes, and test them through standard STARLIMS workflows.

MANUFACTURING

FEATURE / FUNCTIONALITY	DESCRIPTION
Product Life Cycle - Lab Processes	Manage your typical lab processes encountered in manufacturing plants through pre-defined processes and functionality: • Raw material release - Testing and validation of purchased raw materials that are used in the manufacturing of a certain product. • Continuous process monitoring - Sampling of a continuous scheduled process at different sampling points and the testing and validation of samples. • Batch (Lot) and release testing - Testing and validation of samples obtained from different stages in the process of manufacturing a product.

FEATURE / FUNCTIONALITY	DESCRIPTION
Product Life Cycle - Lab Workflows	Manage typical manufacturing workflows with pre-defined steps or define which of the pre-defined steps apply to your operations. • Plan - A batch, which is a group of samples and associated tests belonging to a continuous process, or a Raw Material, is created and assigned a Planned status. The batch may be created manually or electronically from a 3rd party system such as Manufacturing Execution System (MES) or Enterprise Resource Planning (ERP). Planned work is reflected in the dashboard and will allow lab management to prepare for the anticipated work load. • Start - The batch is assigned a Start status to indicate that it is now being manufactured. This triggers alerts, typically in the form of a label printed in the production floor. This reminds personnel responsible for sampling to collect the sample from the appropriate sampling points. • Receive in Central Receiving (CR) - Samples may be received in a central receiving unit that can aliquot, sort, and deliver the samples to different labs and service groups. • Receive In Lab - Collected samples are received in the lab, the labels are scanned and an actual receive date and time are recorded. • Testing and Recording Results - Testing in itself can be a whole workflow of steps. Upon completion of testing, results are recorded. The system performs required calculations and compares the entered results to pre-set limits. An out-of-specification result may require the sample to be sent for retesting or forwarded for sample disposition. • Releasing Tests - Tests are released following results entry. Upon completion of each of the above steps, reporting and messaging tasks are triggered, such as notification of an Enterprise Resource Planning (ERP) system regarding a batch release. Some of the steps are optional and can be configured using the static tables configuration tools.
Product and Sample Life Cycle Management	Product and Sample Life Cycle (Includes Login, Receiving, Results entry, Review and Approval).
Batch Inspections	Perform acceptance sampling using standards defined by the American National Standards Institute. Define inspection levels and acceptance criteria in ANSI Tables.

FEATURE / FUNCTIONALITY	DESCRIPTION
Sample Group Template	Sample Group Templates are structures that provide a way of grouping samples to handle manufacturing requirements determined by plant/site or by stage in a manufacturing process. The grouping of multiple samples in a template is done according to a common characteristics. Sample Group template allows you to define material, testing and workflow information to accommodate different manufacturing processes.
Equipment Management	Manage equipment lists and components list, manage and track scheduled and/or ad-hoc maintenance events such as repairs, preventative maintenance, calibrations, and QC's. Set up standards used in the calibration of equipment, calibration curves, and templates containing standards. Identify instrument that is used by a laboratory to perform analyses or prepare samples for analysis.
Material Management	Define the materials used in your facility and maintain comprehensive information related to the material (i.e. safety instructions, chemical/physical properties, vendor details, recipes, and component concentrations and container information). Group together materials with similar characteristics using Material type functionality.
Inventory Management	Manage laboratory materials and consumables. Manage the consumption, restocking, relocation and disposal of materials at your facility.
Storage Location Manager	Manage the storage of samples and storage locations and sub locations. Store your samples in hierarchical storage containers and view the contents of each level of the storage hierarchy. Storage locations are in rooms in buildings at a site. You can configure this information to track and manage the movement and storage of containers at a physical site.
Chain of Custody	Display any inventory transactions for the sample (view history of how a sample has been handled).

FEATURE / FUNCTIONALITY	DESCRIPTION
Stability Management	Manage protocols, sample inventory, stability studies, pulling schedules, conditions and locations, all within the system. Stability studies may be run during product development, but are also run on production batches. Simulate extended periods in a shorter time span with accelerated stability testing.
Stability Study Lifecycle	STARLIMS allows you to set up a study workflow where you can assign specific users and/or roles to perform workflow steps such as Create, Review, and Start. A study runs through a series of steps. Some steps are performed one time for starting and finishing the study. Others, such as pulling samples, are performed during each designated interval or cycle. Some steps are optional.
Pre-Defined Stability Study Lifecycle	STARLIMS offers a Stability Study Lifecycle where certain steps can be defined as option depending on your study. The following steps can be included in the following sequence for starting and performing a study: 1. Log a draft stability study - Required. 2. Create, Review, or Start Study - You must include at least Create and Start Study in the General Workflow Manager steps. 3. Process Stability Cycles - Required for cycle-based studies, but never used for interval studies. 4. Pull Stability Samples - Required. 5. Receive samples - Optional. 6. Enter results – Required 7. Manual releases - Optional. Releases are included by default. 8. Release Stability Interval - Optional. Time point or interval approval is included by default 9. Complete the study - Optional.

FEATURE / FUNCTIONALITY	DESCRIPTION
Stability Study	To support the requirements of stability studies, STARLIMS allows you to: • Create a Study Layout Design. Lay out testing schedules according to environmental conditions and intervals and tabulate product test results according to the intervals. • Assign backups for selected intervals according to condition. • Create multidimensional studies. Multidimensional studies group two or more studies which are identical in all but one factor, such as packaging. • Set study duration and time intervals. Set up the durations of studies and the available test intervals in each study using a variety of time units, such as months, days, or hours. STARLIMS also supports long term studies. • Include tests that are highly configurable. For example, tests can include calculations to convert findings, require materials such as reagents, specify test methods (including SOPs and specific instruments), and open electronic lab notebooks. • Assign acceptance criteria according to region. • Detailed information for storage locations. Designate locations for the product samples according to storage conditions such as the temperature, humidity, and so on. • Designate storage positions. These can be orientations such as upright, sideways, inverted, in full sun-light, in darkness, and so on. • Link samples to batches or lots. Indicate batches or lots to which the samples belong and other relevant details. You can also create additional fields to contain details for a particular study (configurable metadata fields). • Pull sample reminders. Automatically display reminders to the appropriate personnel to pull samples when testing is due at each interval. • Sample receiving. Require that a service group receive the samples in the system when the samples have been pulled and moved to the site. • Retesting samples. Retest samples or pull new samples (resample) to repeat tests when results are questionable. • Results review and approval. Send test results for review and approval by someone, such as a manager, other than the analyst who entered the results. • Audit and trace sensitive information. These features support compliance with Code of Federal Regulations (21 CFR Part 11). For example, changes are recorded in an audit trail. Additionally you can require signatures for changes. You can trace records and certifications for equipment and analysts involved in performing tests. • Sample labels. Create labels at various stages, such as when initially storing samples or when pulling samples for the test site. • Generate reports and charts. Create reports, such as a report of the layout schedule of tests/intervals by condition, cross-tabular reporting typically used in reporting information to the FDA, or graphical results/trend reporting for comparison of results in multidimensional studies.

FEATURE / FUNCTIONALITY	DESCRIPTION
Customer and Project Management	Manage your customer information, and set up projects for laboratory testing, including test pricing, invoicing and schedules for sampling and testing.
Client Invoicing and Billing	Bill clients for samples tested, create invoices that reflect the price list and other payment terms that your facility has set for the clients. Bill clients for the tests performed according to prices set for the tests and the materials used. Issue invoices after samples are logged for testing or materials are shipped. Change the price of an individual test, a package of tests or a material in the invoice.
Client Categories	Group clients into categories (i.e. internal, external, supplier, etc)
Client Lists	Provide information about all organizations that receive services from your facility. This includes information such as mailing addresses, phone, fax, a list of contacts, attachments, and metadata, if associated.
Price Lists	Configure price lists for your clients and projects. Typically, facilities bill clients for the tests performed according to prices set for the tests and the materials used. STARLIMS provides tools to add, update, copy, release, print, and retire price lists used in project management. You can also keep a repository of test prices which you can use to update price lists.
Contact Groups	Create groups of contacts of similar type.
External Contacts	Create a list of external contacts, who have no access to the LIMS, but who should be notified of events regarding a client's project.
Turnaround Times	Turnaround time (TAT) is the number of working days from the day that the analysis of the samples can begin to the day that results are reported to the client. The TAT (turnaround times) module makes it possible to add a premium for accelerated testing or offer a discount/surcharge for longer turnaround times.

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Base Test Prices	Use the Test Price Definition functionality to keep a repository of test prices. You can update price lists that are in a draft state using these test prices with the SYNC with Price List feature. This feature can update all or selected price lists with a Draft status in the Price Lists application with the selected prices. Note: There is no “undo” for this action.
Client Projects	The Client Projects application contains data about specific projects associated with clients. The information includes terms, contacts of personnel involved, project samples, results, metadata, project orders and invoice information.
Terms Within Client Project	The Terms tab contains the arrangements for handling project samples. These arrangements can be set from this interface for new projects and reviewed or changed for existing ones. Track who created the project, Status of the project (Won, Lost, Rejected, etc), project star and expiry date, notes associated with the project, Price List ID Tests / Price List ID Materials associated with the project.
Project Contacts Within Client Project Applications	Add or remove contacts associated with a project.
Project Samples Within Client Projects	Track details about the locations at which samples are stored, the schedule for pulling samples out of storage, and the tests to be carried out on the samples.
Project Sample Groups With Client Projects	Project sample groups contain samples that can be collected together according to some logical grouping. For example, several samples may be taken at a point in time during a process, such as the culturing stage of a cheese making process, or from the same site, such as a water reservoir.
Business Rules and Sample Login Automation	After a sample group is added, you can configure a business rule, which is an SSL script that is executed by the STARLIMS Manager Service, also called the batch processor, during the automatic samples login and that returns the next execution date when associated samples are logged.
Invoices Within Client Projects	Cross-references invoicing for the selected client and display the total charges for tests conducted for a project. View the client’s invoices, special charges, and related reports.

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Project Orders With Client Projects	Order materials such as sampling kits for collecting a client's samples using the Project Orders tab.
Client Projects Query and Reporting	Use Reports to display various distribution reports, unpaid invoices, or work in progress for clients. Query using a date range and select from the types of reports available.
Volume Base Discounts Within Client Projects	Apply a discount based on the total dollar amount from the invoices currently being processed for a client. Note: These calculations are user-defined SSL scripts created at your facility. Calculations must include logic to apply the discounts associated with the ranges. The base system will include one script without any special calculation logic in the Designer that you can select to apply the range-related discounts.
Login Billable Samples	Since there is no invoice without performing a billable test, you must log in a sample for testing before viewing the charge for it in the Invoice Manager. Sample(s) for which you want to bill must be marked as billable. Log billable samples using: • Client Project Login - To associate logged samples with a project sample group. • Test Plan Login - If you want the flexibility to log samples and assign tests that are not associated with the project. If you want to bill for these tests, insure that they are included in the price list associated with the project. • Plate Login - For samples contained in a plate and processed according to a plate workflow.
Invoice Manager	After sample login or shipment of client materials, the tests and/or materials involved can be reviewed and invoiced. Release Invoices after processing such as adjusting line items and entering payments. Recreate and Print invoices.
Analyst Certifications	Track and manage analyst training and certifications for tests and methods, scheduled courses and re-certification.

FEATURE / FUNCTIONALITY	DESCRIPTION
Investigations	Start an investigation to re-evaluate a questionable result or when a manager suspects a problem. Open, view, collect the investigation details, order a re-test, confirmatory test or re-sampling for samples under investigation. Assign the investigation steps to a user or role to perform the step.
Batch/Lot Genealogy	When batches are made using materials from other batches, such as batches of raw or formulated materials, you can trace back to these other batches to view pertinent information. Lot genealogy allows you to view the different components (materials) that are used in the batch. The lot genealogy tree provides a view of a batch and its material code, material name, its associated samples and their test results. An OOS image displays when at least one sample in the highlighted batch in the lot genealogy tree has an OOS result recorded.
Statistical Controls, Control Charts and Trending	Create control charts, configure rules to track within the chart, and view the charts throughout the sample and product lifecycle. Rule violations can be automatically detected, which can drive further actions on samples and tests. Advanced SQC and control charting are powered by Northwest Analytics (NWA). Display trends and observe patterns in sample results over time in a graphical format.
Reporting and Querying	STARLIMS provides several ways to monitor and track data in your facility by generating reports and queries. Use database re-usable query templates and generate Crystal reports file from the query results. STARLIMS offers a standard set of pre-defined reports available for areas such as general results and folder status. Create a report specific to your needs by further filtering information using a query.
Report Qualifiers	Result Qualifiers are used to describe results in printed reports. They can provide more details. The report may display the qualifier value along with the corresponding text.
Formulations and Recipes	Create recipes and batches associated with recipes, and test them through standard STARLIMS workflows.

FEATURE / FUNCTIONALITY	DESCRIPTION
Contract Labs	Performs test and analyses for customers as opposed to an internal lab that does testing for a company. Client Projects application contains data about specific projects associated with clients. The information includes terms, contacts of personnel involved, project samples, results, metadata, project orders and invoice information.
Samples and Tests Outsourcing	Outsource tasks with third-party (internal or external) laboratories and document the samples for testing at an outsource lab, whether it is internal or external.
Manufacturing Life Cycle	Effectively manage your batches, from creation to delivery of a final Certificate of Analysis (COA). Dynamically control the tests performed on batch samples, based on the frequency of testing and prior test results.
Label and Barcode Utility	Generate barcode labels and read bar code labels throughout certain steps within the applications.
Environmental Monitoring	Monitor the production environment in which batches are created. Ensure that all of your scheduled environmental samples are properly collected and tested with the environmental monitoring module. Efficiently manage sample points using visual floor plans. Use this application to verify that those components in a production environment are clean and sterile.
Environmental Monitoring Life Cycle	Pre-defined Environmental Monitoring Lifecycle workflows. • **Environmental Monitoring Login** - Use to log in and schedule a batch of sample points. • **EM Samples Pending Collection** - Indicate collection of the samples is completed for sampling requirements using this application. • **Receive EM Samples** - Receive the containers of samples gathered in a sample point. • **Environmental Results Entry** - Locate environmental samples pending testing, indicate their movement to the location for testing, and enter the test results for each sample. • **Release EM Batches** - Use to approve results. Optionally, a run release step can precede this step.

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Real World Application	Real world application provide a graphical view of a process. The graphical depiction is overlaid with transparent clickable labels, each representing a sampling point.
Microbiology Life Cycle	Define a more complex, dynamic test workflow (i.e. sequence of steps that change at run-time based on results). Microbial tests work best for workflow steps that change depending on results and that are very complex.
Micro Reagents	With several configurations, reagents in micro runs can be included in sample worksheets and the system will also automatically decrement inventory of micro reagents used.
Micro Test Groups	Use the Micro Test Group base static table to associate tests to a micro test group. Records are organized by micro test group in the Micro Results Entry and Micro Run Results Entry applications
Micro Components	The Micro Components application is used to define and configure components to be used in micro testing. A range of materials and other components can be used in microbial tests. The materials are grouped into categories such as media, dehydrated media, smears, drugs, and so on. A component can also be any step/procedure/action that needs to store a result in the life cycle of a test. Some components correspond to small tests that are performed within the larger context of a multi-step microbial test workflow.
Micro Panels and Panel Conditions	Panels are used to group micro components from a component type category. You can associate as many panels as you want for the same condition.
Quality Control for a Micro Component	Quality controls (QCs) are samples that have an expected response and are added to test runs or micro workflow steps for validation. If the expected response is not met, the test results are suspect, and the run has to be repeated.
Assigning Reagents and Other Materials to a Micro Component	Components may be created using one or more materials. The Reagents tab contains the physical materials that are used for the micro component.

FEATURE / FUNCTIONALITY	DESCRIPTION
Using Equipment with Micro Components	Associate Micro Components to an equipment record.
Microbiology Workflow Manager	The Micro Workflow Manager application allows you to view all existing micro workflows in the system from one module. Within this application, you can create, modify, or delete micro workflows in the system. You can create a microbial test workflow by defining steps in which analysts can add media, create smears and cultures, conduct analyses, and enter results. Typically, the steps follow the natural workflow and decision process employed by the lab. During sample analysis, an analyst enters the results for each micro component in a panel associated with the component type through condition.
Plates Life Cycle	Samples can be added to a well plate or tube rack, tested, and results entered according to a workflow of steps. Create a plate map template, a workflow of steps, and a test to associate these elements with equipment to process the plate. After all elements are in place, samples can be logged, then the plate workflow becomes available for processing using the Plate Lifecycle Tasks application.
Plate Configurations	The Plate Configurations application window is used to create plate groups and plate templates to be used for testing samples in plate wells or racks of tubes. A plate group can contain one or more plate templates. A plate template shows the positioning of regular samples and quality control (QC) samples.
QC Management	The **QC Management** module allows you to log and track quality control samples in your laboratory. You can run tests to verify quality control of your laboratory, instruments or methods.
Electronic Signatures, Audit Trail and Traceability	Track aspects of your lab data, from the lowest level result and test information to analyst certifications. Access an entire sample history, review the training history of each individual, display full audit trails, extract e-signature information, and others.

FEATURE / FUNCTIONALITY	DESCRIPTION
Electronic Signatures	STARLIMS QM supports electronic signatures. Use electronic signatures to configure approvals and rejections. Supervisors and others can then approve actions as the samples move through the laboratory life cycle.
User Access, User Management and Roles	Assign system access (username and password) to users so they see only the interfaces to tasks they may perform. You also assign each user a role, site, and service group (also called team) access. The role determines what console branches are displayed for that user. Site and service group access determines which site the user logs into and which samples appear for the user to process. If a user is allowed access to more than one site, the user is prompted to select a site when entering the system. During the creation of a user in the system, you can assign a unique username and password. At this time, you can also assign a common signature name which is typically the common name of the user along with any professional prefixes or suffixes.
SmartCard Login	STARLIMS supports logging on using a SmartCard. After entering their credentials for the SmartCard, users can start STARLIMS without having to re-enter log on information. SmartCard SSO can also be used for other STARLIMS events that require an electronic signature.
Work Assignment	Allow laboratories to manage both human and instrument resources.
Resource Planning and Scheduling	Save time by assigning work to your analysts and equipment based on availability and their current workload. Managing the laboratory workload is important to reduce turnaround times, improve performance, and assess the use of people and equipment to balance work between the available resources. To make the most effective use of laboratory resources, the RPS module is a helpful tool in prioritizing deadlines while using available equipment and analysts.

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Dashboard Gauges (Monitoring Performance)	The STARLIMS Dashboard can visually inform users about laboratory performance or individual analyst workload by displaying gauges. There are two types of gauges you can add to the dashboard, each with their own set of reports intended for users with management or analyst roles. • Gauges for Management • User Gauges The Gauges for Management section of the Dashboard display defined Key Performance Indicators (KPIs). It shows graphically the status of a specific operations/tasks in the LIMS and lists standard reports about samples in various stages of processing. The dashboard is configured for users based on role. The User Gauges section of the dashboard graphically shows the status of specific operations or tasks in the LIMS and list standard reports about samples in various stages of processing.
Metadata Templates	Metadata is data about data. Metadata provides an area to expand information based on fields defined in a template. Templates are available to be included in an application's **Metadata** tab according to the **Usage** selected. You can configure templates of fields and captions and lay these elements out on a page for inclusion in **Metadata** tabs. Metadata tabs are used by applications that are expected to require the additional fields.
Workflow Manager	STARLIMS allows you to set up a workflow of multiple steps that can be executed by different people. Frequently, different users with different responsibilities handle the different steps of workflow. Most STARLIMS applications only recognize one workflow, that is, there is one workflow with the relevant Application Reference and Code keywords. Exceptions are Stability Study Protocols and Stability Study Management which provide the ability to select alternative workflows.
Authorization Models	The Authorization Models application can be used to obtain multiple approval signatures simultaneously, or as a notification mechanism through acknowledgment. Authorization roles are different from STARLIMS roles. Users are assigned either a Primary role or Backup role in the authorization model. The primary user will have to fulfill an action, or if the primary user is not available a backup user can be assigned to complete the action

FEATURE / FUNCTIONALITY	DESCRIPTION
Method Manager	List your methods, such as Standard Operating Procedures (SOP) or American Society for Testing and Materials (ASTM) methods. Select from available methods when configuring a test. Methods are associated with analytes within Test Manager and Sample Group Templates, Test Plan Manager, or Stability Study Protocols. Methods can be associated with electronic notebooks (ELN), which can be used to display associated SOPs while an analyst is performing tests. Within an ELN, the analyst can also be guided through a workflow of sequential steps including constraints when required data is not entered.
Specifications Manager	Specs are an important part of results entry. You can set limits (specifications) outside of which the results are considered to be positive, abnormal, or out-of range. You can configure multiple specifications for an analyte to allow for different requirements. The **Specifications Manager** displays all existing specifications in the LIMS along with the tests and profiles to which they are associated. Specifications are used to contain values for comparison with results to determine if the results entered exceed limits.
Ad Hoc Multi-Spec Evaluation	The **Ad-Hoc Multi-Spec Evaluation** application allows you to evaluate sample test results against different sets of specifications. The Multi Spec command allows you to compare your current results against other specifications aside from the primary spec in your test plan or template. Within this application, you can evaluate any set of sample results available in the LIMS against any set of specifications defined in the system.
Test Manager	Test Manager lists the tests that can be performed by your laboratory. The test configuration includes analytes used, spec schema to be used on results entered for each analyte, methods used in analysis, the equipment used for measuring results and preparing samples for analysis, the specifications (limits) to which the results are compared, reagents that are used when a test is performed, and other test parameters. Test Manager contains the Test Workflow Diagram in which each box contains a separate step in the workflow that you can configure as necessary.

FEATURE / FUNCTIONALITY	DESCRIPTION
Test Workflow Diagram	STARLIMS includes a pre-defined test workflow, however, for those instances in which a test requires a series of steps, the STARLIMS Test Workflow Diagram allows you to view or configure the steps to be followed in the performance of a specific test. The workflow diagram is specific to the test selected. Each box in the diagram allows you to configure a separate step in the workflow (as necessary).
Test Workflow Triggers	Triggers can initiate actions, such as retests based on results that are out-of-specification, or other triggers, such as validations. You can define triggers if the test is part of a test plan or sample group template.
Pre-Defined Triggers	STARLIMS provides a pre-defined set of Test Workflow Triggers: • Confirmatory Test - Provides the option to repeat the test when test results are out-of-specification. Results from the confirmatory test replace the original results. • Reflex Test – Provides the option to associate an additional test with the original test. All results, for initial and reflex tests, are reported. • Retest - Select this option to automatically log the indicated number of samples for retesting when the test results are out-of-specification. The final results are posted under the original Sample ID.
Test Manager Method Rules	The Rules link within the Methods tab of the Test Manager application allows you to add analyte limits per method on a given test. You can associate one test with more than one method and define a default method.
Applying Calculations To Analyte Results	Set up calculations to be automatically triggered at the time that data is entered into analyte results entry fields. The calculations may involve reading values from other analytes in the test, their replicates, or analytes from other tests, performing calculations such as averages, assigning these values to various variables, and combining the variables in a mathematical expression to return a final value, such as % label claim.

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Test Plan Manager	Organize tests according to certain characteristics, such as similar specification sets. During some login processes, a test plan is required so that particular specifications and other information such as repetitions can be provided, ensuring that processing runs smoothly. With test plans you can: • Create test profiles that are assigned to samples during login. • Configure specification limits for tests associated with the test plan. • Specify sampling requirements to define the location, amount condition, and destination of sample containers. • Configure when a report is generated in the life cycle and its formatting.
Ad Hoc Test Plan Group	The Ad Hoc test plan group comes pre-configured in the LIMS. It contains the Ad Hoc test plan. Typically it is used to log samples without a specific test plan. During sample login, users can select the Ad Hoc test plan group and test plan and then assign any test in the LIMS to the sample.
Spec Schemas	The Spec Schemas application is used to create spec schemas and schema groups. Spec Schema can be used to apply calculations, validations, or otherwise define results of tests. For example, use a spec schema to perform a calculation on several measurements and then validate that the final result is within a specified range. The schema can be used to define the information displayed or used for a test in the Results Entry window such as: • The characteristics of expected analytes: high and low values, list of possible values, % recovery, and others. • The set of fields that will be required to enter measured data or to display calculated data for an analyte. • The properties of each field displayed: field caption, width, etc. • Calculation formula used to validate or calculate a result.
Units Management	Define and categorize units of measurements into types, define its conversions.
Alert Management	Alerts are used to send messages through the LIMS to other users. You can create an alert, send the alert, and someone acknowledges the alert.
Email Manager	The system can automatically send emails to alert users when events occur that are of interest to them, such as the release of a COA report. If an email does not go out as expected, it is queued in the Email Manager application.

FEATURE / FUNCTIONALITY	DESCRIPTION
Sites	Sites module allows you to define the organizational structure of your laboratory locations. After creating a site, you can define the teams (or Service Groups) that operate at each location and assign members to them. Sites can also include detailed structural information about plants, buildings and rooms which allows you to define inventory storage locations or keep track of testing locations at a more granular level.
Open Productivity Connectivity (OPC) Server	Open connectivity (OPC) Server, provides standards to facilitate communication of information such as results between systems such as STARLIMS and other manufacturing applications.
Data Archive	Configure how often to archive data based on your retention policy, schedule and improve system performance.
Importing Data Using CSV	STARLIMS provides a way to set up your organization's data in the system by importing it through .csv files. STARLIMS provide a set of pre-configured templates to upload master static data. In addition, imports are used for loading LIMS tables using .csv files when the data is already configured on another system and you want to import it into your LIMS.
Instrument Integrations (DCU)	Integrate your instruments without the need for complex programming.
Empower 3 CDS Integration	STARLIMS interacts via a bidirectional interface with the WATERS EMPOWER Chromatography Data System. This software works with High Pressure Liquid Chromatography (HPLC) and Gas Chromatography (GC) equipment. STARLIMS supports EMPOWER software up through EMPOWER 3. The interface allows STARLIMS to send a list of samples together with QC samples to EMPOWER creating a Sample Set Method in the EMPOWER project. Once the data is collected in Empower CDS import relevant data back to LIMS via mapping. You can use the electronic notebook to retrieve instrument results. ELN can be used with systems such as EMPOWER (interfaces are bi-directional). The STARLIMS -CDS integration, increase automation, minimize data entry errors and eliminate redundant data entries.

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Chromeleon 6.8 and Chromeleon 7.2 CDS Integration	STARLIMS interacts via a bidirectional interface with the Chromeleon Chromatography Data System. This software works with High Pressure Liquid Chromatography (HPLC) and Gas Chromatography (GC) equipment. STARLIMS supports Chromeleon Version 6.80 SR13 Build 3967 and Chromeleon 7.2. The interface allows STARLIMS to send a list of samples and QC samples to Chromeleon and then creating a sequence or adding the samples to an existing sequence. Once the data is collected in Chromeleon CDS import relevant data back to LIMS via mapping. You can use the electronic notebook to retrieve instrument results. ELN can be used with systems such as Chromeleon (interfaces are b-directional). The STARLIMS -CDS integration, increase automation, minimize data entry errors and eliminate redundant data entries.
NWA Integration	STARLIMS allows the interaction between the system and NWA Quality Analyst third party software. The **Trending and QC Charts** interfaces differ depending on whether you have NWA Quality Analyst enabled in your system or not.
Interface Connection	The STARLIMS application can interact with external applications, such as SAP, either using an ES Bundle via Web services or other technology depending on the customer's software infrastructure. The Interface Connections application can be used to translate information between the LIMS and the third party interfaces. To minimize development time and to allow reusability of interfaces, a template named Template Interface is provided which formats and packages information from the LIMS. You can add scripts to this base template to allow the LIMS to receive a response from one or more third party applications.
SAP Integration	In the manufacturing world, quality inspections are performed against batch. SAP's module allows rudimentary result recording, but lacks sample life cycle, instrument interfacing, and many other standard LIMS features. SAP recognized this lack and offers different technologies to connect a LIMS to their quality management module. STARLIMS supports SAP interface to help companies who want to integrate their LIMS into their enterprise system landscape.

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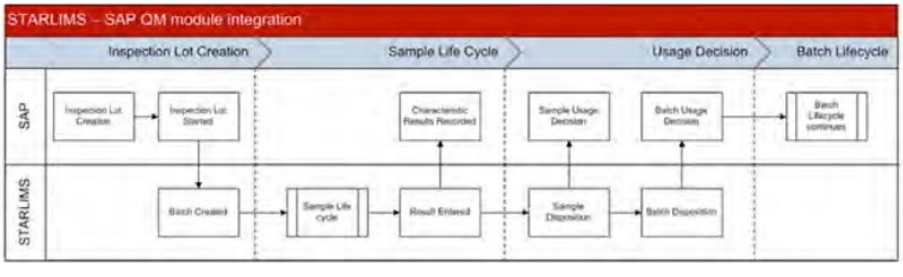
SAP Integration	In the manufacturing world, quality inspections are performed against batch. SAP's module allows rudimentary result recording, but lacks sample life cycle, instrument interfacing, and many other standard LIMS features. SAP recognized this lack and offers different technologies to connect a LIMS to their quality management module. STARLIMS supports SAP interface to help companies who want to integrate their LIMS into their enterprise system landscape. STARLIMS supports 2 different technologies for SAP, both with different prerequisites: **SAP Enterprise Services for Quality Management** • Commonly known as the "ES Bundles", this uses web services and requires SAP ECC 6.0 with enhancement packs 1 & 2. **SAP QM-IDI** • This "older" technology relies on COM/DCOM libraries to communicate with SAP RFC (remote function calls). This interface requires SAP R/3 or +, and is an integral part of SAP Quality Management module. This is typically the preferred solution when prerequisites for the "ES Bundles" cannot be met. The SAP Mapping tab in STARLIMS defines the relations between STARLIMS and an SAP interface components. This allow STARLIMS to work in conjunction with SAP systems. With the SAP and STARLIMS integration Lot information can be send from SAP to STARLIMS which can trigger the creation of a batch, the Batch samples will follow the regular life cycle as configured (receive, result entry, review, approvals or as applicable). Once results are entered in LIMS, results can be send back to SAP. In addition, once the samples that pertain to the batch are disposition as well as the batch, status of the samples and batch can be sent also to SAP. 

FEATURE / FUNCTIONALITY	DESCRIPTION
Multiple Systems Interfacing	STARLIMS support several standards for data sharing, including open connectivity (OPC). Our LIMS also has interfaces to SAP, Empower and Chromeleon. Additionally, our software can interface with a wide variety of enterprise systems via: • Simple Object Access protocol (SOAP) and Representational State Transfer (REST)-based web services • Application Programming Interfaces • Direct Database connections • File-based interfaces • Our LIMS has integrated with a wide variety of systems, including, but not limited to: • Equipment calibration and metrology systems • Enterprise Document Management Systems (EDMS) • Training or Learning Management Systems (LMS) • Quality event and management systems • Regulatory compliance and change management systems • Process historians • Statistical analysis systems • Enterprise Resource Planning (ERP) systems • Manufacturing Execution Systems (MES)

REGULATORY COMPLIANCE

FEATURE / FUNCTIONALITY	DESCRIPTION
Support 21 CFR Part 11 Compliance/ Electronic Records/ Electronic Signatures	The Title 21 Code of Federal Regulations (21 CFR Part 11) provides compliance information regarding Electronic Records and Electronic Signatures. Basically, certain guidelines are set forth to help insure security, integrity, and confidentially of electronic records and to insure that electronic signatures are as legally binding as hand-written signatures. STARLIMS has features to support 21 CFR Part 11 regulation compliance. Below are some of the features:
Authentication	STARLIMS requires a unique username and password for authentication into the system. Passwords are encrypted. In addition, StarLIMS offers the option of LDAP server authentication
Authority Checks	The system uses authority checks such as user ID and password to ensure that only authorized individual can use the system. In addition, when applying electronic signature users have to enter their credentials.
Group Memberships and Access Privileges	Access to the system is controlled by roles, sites and service groups. Roles are used to manage security access and operation of the system and to grant or revoke the user's right to perform different actions. Security measures defined by role and user information are used to control access to data and system functionality and to track system login failures and successes. System allows for creation of unlimited roles with assigned privileges, and the assignment of those roles to the users. Site and service group access determines which site the user logs into and which samples appear for the user to process.
Security and Password Policy	STARLIMS allow you to set password policies as a global setting or based by roles; among the available password policies are: grace login, password expiry date, password complexity, failed password attempt lock out, inactive timeout/lockout period, among others. Users can retrieve their password using the pin number and security questions they set the first time they logged on.

FEATURE / FUNCTIONALITY	DESCRIPTION
Audit Trail and History	STARLIMS generates time –stamped audit trails. The audit trail record the date and time of the operator entries or actions. Audit trails can be collected for creation, modification or deletion of records. STARLIMS provides you the ability to track changes made to a given field. This ability to track is critical for satisfying CFR Part 11, the Title 21 Code of Federal Regulations. STARLIMS allows you to view the login history. The History application is the access point for this information. The History window displays event logs with signatures and audit trail records. When you set auditing for a record, associated tables, controls, and events are monitored. After you start auditing, you do not have the option to stop auditing. The Audit Trail window includes a Search option.
Login History/User History	Login History - following a successful login procedure, a user will be notified of the last successful login, last successful password change, last failed login attempt, and the number of failed logins since the last successful login. User History - The User History lists login failures and successes for the highlighted user, the server to which the user connected, and at what time.
Electronic Signatures and Audit Trail	STARLIMS provides you the capability to configure electronic signatures based on workflow rules and triggers. Example you can configure sign off capabilities on a certain actions during the laboratory life cycle. It is possible to add an electronic signature to certain system events. Not all events are available to have an electronic signature added. With STARLIMS you can require E-Sig Comments, or require users to provide their user name and password when electronically signing a record. Comments made by users are added to the audit trail history. In addition, you can configure an E-signature witness - which requires another user that is a witness, to sign with his user name and password before an action takes place. Some workflows allow the automatic start of audit trail functions. Audit records are linked to the individual that performed the action through the collection of the user's electronic ID or electronic signature.

FEATURE / FUNCTIONALITY	DESCRIPTION
Electronic Signatures and Audit Trail (Cont.)	During the creation of a user in the system, users are assigned a unique username and password. At this time, the user can be assigned a common signature name which is typically the common name of the user along with any professional prefixes or suffixes. Thus, the signature field can be readily used in reports or required authorization fields where a more meaningful representation of the user's name is needed. When users sign-off on actions, the signature text is displayed in applications listing those actions, such as traceability and audit trail. Each signature record includes the username of the person who performed the task, the date and time the task was performed, and comments. Electronic signatures are linked to their respective electronic records.
Security, Data Protection and Encryption	User ID s are unique and User passwords are encrypted. User can be required to reset their password at first logon. If the customer needs all data encrypted this can be turned on at the RDBMS level. Note: Full encryption of all data may result in performance degradation. Default system accounts can be disabled as required.
Human Readable Records	STARLIMS has the ability to accurately generate or produce electronics records data in both human readable and electronic formats.
Enforcements of Sequence of Steps	STARLIMS allows you to enforce the sequence of steps via configured workflows and via the Electronic Laboratory Notebook (ELN). **Enforcements of sequence of steps through My Service Groups Runs** This results entry option is useful if you have several samples that require the same tests, or when the tests have several replicates and you want to perform a calculation of some sort (such as an average) using the replicates' results. You use a run (work sheet) to assign analysts to perform tests. Use the run window to list a group of samples on which a type of test is to be performed. Assign each run to an analyst who performs the test on the samples. In addition, you can use runs to enforce sequences of steps to be performed. These steps can include preparation, approval, run creation, results, validation, and retesting steps. As the run moves through the steps according to the step code, corresponding buttons appear. After entering data into fields and tables, you click on these buttons to move the work sheet to the next step.

FEATURE / FUNCTIONALITY	DESCRIPTION
Enforcements of Sequence of Steps (Cont.)	You can also use runs to specify the materials needed to perform tests, assign equipment, and specify the due date for the test to be completed. For the Microbiology life cycle you can configure that the sequence of steps changes at run-time based on results. **Enforcements of sequence of steps through ELN** You can apply a workflow to the ELN Template, which mean that you can control the order in which ELN sheets are completed when the ELN form is run.
Microsoft Active Directory Integration for Authentication	The system can be integrated with Microsoft Active Directory such that users are able to log into the system using their current network credentials. LDAP is also supported. STARLIMS allows users to authenticate when logging in over connections with an LDAP server. LDAP is Lightweight Directory Access Protocol, which allows users to query and authenticate with a database over TCP/IP.
Protection of Electronic Records Controls Throughout Retention Period	STARLIMS provide controls that ensure electronic records are protected and available during the data retention period. System access, data creation, modification and deletion is controlled via user id, password, service groups, roles and its corresponding access privileges. Purging or deletion required to enforce retention periods could managed using the archive module.
Archive	STARLIMS provides an Archive module which allow you to archive and restore data. With this module you can define: network locations for the archives, the type of data that gets archived, and the age of the data to be archived.
SmartCards	STARLIMS supports logging on using a SmartCard. After entering their credentials for the SmartCard, users can start STARLIMS without having to re-enter log on information. SmartCard SSO can also be used for other STARLIMS events that require an electronic signature. SmartCards provide a portable security solution for tasks such as identification, client authentication, data storage and application processing. They can provide strong security authentication for large organizations that single sign-on (SSO) to control access to their enterprise software.

FEATURE / FUNCTIONALITY	DESCRIPTION
Ability to Detect Invalid or Altered Records	STARLIMS provide the ability to detect invalid records (e.g. during data entry). You can configure STARLIMS to detect invalid record. You can define required (mandatory) fields. The system can provide visual indicators (flag) for the data that it is out of specification. Also the system can provide flags when data is entered that is beyond allowed limits. The system will prevent you from committing the sample in the following cases: • If an invalid (unapproved or expired) specification is assigned to the sample. • A test with an invalid method is assigned to the sample. • If the tests/analytes assigned to the sample do not match the tests/ analytes in the specification assigned to the sample. In this case you will still be able to commit the sample, however, the system will notify you of the mismatch. In addition, record and application access privileges are controlled via roles and service groups. Alter or modified records can be captured via audit trails. Examples of Invalid records scenarios are: • For Spec Schema groups: Attempting to populate Start Date and Expiry Date fields with invalid input (such as YYYY/DD/MM rather than MM/ DD/YYYY) will display a blinking red icon on the top right. • For Location Types blinking red icon is displayed if you attempt to update Size and Order fields with invalid input (such as ABC rather than numeric values).

SUPPORTING ISO 17025

FEATURE / FUNCTIONALITY	DESCRIPTION
How STARLIMS Supports ISO 17025	The STARLIMS product supports customers in operating their laboratories in a manner that is compliant with ISO 17025. Below is some of the ways how we support those laboratories.
Document Control	In addition to a Laboratory Information Management System (LIMS) which allows you to centralize your laboratory testing process data, our Integrated Solution includes a Scientific Data Management System (SDMS). The Scientific Data Management System extracts information from scientific documents and instruments and places it into a structured, easy-to-access format. SDMS has features, like document management, document routing, instrument data repository, instrument integration, and advanced file parsing and extraction, supporting you with document control.
Supplier Management	STARLIMS QM Suppliers application contains detailed information about vendors who provide commodities used by a facility. You can use this application to manage information about suppliers (supplier code, supplier name, phone, fax, web link). It allows you to define supplier location and contact information. Also you can add meta data fields to track supplier's certifications.
Analyst Certifications and Training/ Training and Authorization of Personnel	With STARLIMS QM you can track and manage analyst training and certifications for tests and methods, scheduled courses, and re-certification. The Organization-Resources module includes information on courses and analysts' certifications.
Courses	The STARLIMS Courses application provides tools to manage available courses, their cost, content, and the test methods they cover. This information can be used later to schedule training or set certifications within the other applications Course Schedule and Analysts Certifications.
Course Schedule	Some laboratories, especially in regulated industries, require that analysts carrying out tests be certified (or validated) to perform the test methods used in the lab. Using the Course Schedule application, training courses can be scheduled, participants selected and invited, and certifications are granted.
Analysts Certifications	In STARLIMS when you assign tests to samples, they are routed according to the appropriate laboratory service group. If your facility requires that the tests be performed in a certified lab or by a certified analyst, you can check on certifications when assigning samples to labs and analysts.

FEATURE / FUNCTIONALITY	DESCRIPTION
Equipment/Instrument Calibration and Maintenance	STARLIMS provides a full Equipment Management module to manage equipment lists, scheduled maintenance calibrations and maintenance events, QC standards, and automated alerts.
Inventory and Materials Management	The Inventory Manager allows you to manage the consumption, restocking, relocation and disposal of materials at your facility. You can manage all laboratory materials and consumables including: • Material Safety Data Sheets (MSDS) and SDS handling • Testing of received or created materials • Hierarchical storage of materials • Full chain of custody on each inventory item (reception, consumption, restocking, relocation and disposal) • Purchase order creation • Customer supply and invoicing of consumables and sample collection materials • National Fire Protection Association (NFPA), Hazardous Material Identification System (HMIS) and Global Harmonized System (GSH) labels
Environmental Monitoring Module	You can monitor the production environment in which batches are created. Ensure that all of your environmental monitoring scheduled samples are properly collected and tested. Efficiently manage sample points using visual floor plans with STARLIMS.
Statistical Process Control Charts and Trending	With STARLIMS Statistical Quality Control (SQC), Control Charts and Trending you can create control charts, configure rules to track within the chart, and view the charts throughout the sample and product lifecycle. Rule violations can be automatically detected which can drive further actions on samples and tests. With the trending tools graphically display trends and observe patterns in sample results over time. Advanced SQC and Control Charting are powered by Northwest Analyticals (NWA).

FEATURE / FUNCTIONALITY	DESCRIPTION
Reporting and Querying	The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods (ISO 17025). Calibration reports can be generated via STARLIMS. STARLIMS provides several ways to monitor and track data to manage performance in your facility: • Dashboard Gauges (Monitoring Performance) - Monitor daily activities to assess performance and workload in your facility. • QBE Manager - Use to configure database query templates and generate reports in the system. For example, you can get a report about how many samples run through a specific instrument were rejected. An unusual number of rejections may show the instrument needs more frequent maintenance. • Trend Analysis with Control Charts - Track data over time to determine potential problems in advance. • QC Charts - For viewing and configuring equipment control charts. • Labels Count - View reports of the amount of labels that have been printed for containers in various applications.
Data Visualization and Reporting	View key performance indicators via dashboards, get an indication of time and resources utilization, bottlenecks, sample turn around, number of Out of Specifications, drill down data and identify probable root causes. Perform ad-hoc queries, and create a variety of charts based upon the data. The system has hundreds of reports available out of the box and the capabilities to configure your own reports. Generate certificate of analysis and many other reports.
Product Quality Control Testing	Some of the aspects of Product QC testing covered by the STARLIMS system. • Lot Genealogy • Multi-Level and Multi-Region specifications and COA's • Workflow driven notifications and reports • Out of the box interface for SAP • Multi-Level review and release • Linked sampling and test plans

FEATURE / FUNCTIONALITY	DESCRIPTION
Sampling and Material Testing	**Sample and Test Workflow** STARLIMS supports sample and test workflow from start to finish, you can configure triggers, sample points, re-sample and re-test workflows. Link to open investigations through the integrated investigation module. Additionally, you may generate worksheet/list, result calculations, and result specifications comparisons. **Sample Storage and Sample Location Management** Manage the storage of samples, sample storage locations and areas. Store your samples in hierarchical storage containers and view the contents of each level of the storage hierarchy. **Sample Schedules and Sample Points** Set up your sample schedules to automatically schedule sampling points and QC samples based upon multiple criteria. Almost any type of sample schedule can be created, including hourly, daily, and annual schedules. Easily view sample schedules in a calendar format and visualize when samples will be logged. Samples Draws-configure batch draw profiles and its associated tests and sampling requirements.

CROSS FUNCTIONAL

FEATURE / FUNCTIONALITY	DESCRIPTION
Advanced Analytics	Accelerate your lab by transforming your data into actionable insights. From powerful visualizations that more clearly illustrate key activities to predictive analysis capabilities that help you anticipate critical events, Advanced Analytics gives you the insight you need to manage your lab.
Electronic Laboratory Notebook (ELN)	STARLIMS Electronic Lab Notebook (ELN) provides centralized electronic replacement for paper lab notebooks and other homegrown solutions used to record your lab data. Whether you are looking to 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 interface provides you with a canvas to capture and store your data in a central repository. The ELN makes it easy to search, easy to share and maintain compliance with your organization's record retention rules. The ELN also manages both structured and unstructured data and provides method execution capabilities to ensure SOPs are followed, and the method/SOP is visible while you are executing the steps to ensure compliance. Using an electronic solution enables you to transform your lab into a paperless operation and reduce paper management costs.
Scientific Data Management System (SDMS)	Scientific Data Management System for centralized management of documents, lifecycle management and automatic document routing and indexing; parsing and recognition technology that transforms a variety of documents or files into searchable structured information.
Mobile Applications	Access your lab remotely and stay connected. Abbott Informatics mobile offering gives you the ability to access some of the data of your lab on the go. The mobile solution is optimized for a wide range of screens and devices. From out-of-the-box apps to ones you can custom design to fit your lab's needs.

TECHNOLOGICAL ADVANTAGES AND COMPATIBILITY

FEATURE / FUNCTIONALITY	DESCRIPTION
Multi-tier Technology	STARLIMS technology platform is used by all of the market verticals and is the functionality that presents the user with the user interface and data which is configured in the business layer. By making the technology platform separate from the business layer STARLIMS customers can take advantage of rapid changes in IT infrastructure and gain access to novel tools like HTML5 and Mobile Application development without disrupting their business layer. The STARLIMS technology platform can be independently upgraded with little overall business and validation impact.
Web Based	Fully web-based solution, for instant global deployment. Unlike the web-enabled and partially web-based LIMS which still require some software downloads on the client side, ours is an entirely web-based system. Validate it once, and you can deploy it globally, to any authorized user with a standard web browser. Developed as a purely web-based platform.
Integrated Solution	STARLIMS is the only LIMS vendor to provide a completely integrated solution incorporating LIMS, ELN and SDMS in a single application. This eliminates the need for building and maintaining custom interfaces to third party tools. Our Integrated Solution combines all of your lab data on a single platform—optimize data management, accessibility, integrity, and provide the long-term value needed. Our Integrated Solution can include a combination of: **Laboratory Information Management System (LIMS)** STARLIMS handle complex processes, support regulatory compliance, and promote collaboration within your laboratories even if located around the world. **Scientific Data Management System (SDMS)** SDMS extracts information from scientific documents and laboratory instruments and places it into a structured, easy-to-access format. **Electronic Laboratory Notebook (ELN)** ELN eliminates paper-based notebooks, forms and log books to increase efficiency, reduce error rates, and promote regulatory compliance by helping to enforce method execution. **Advanced Analytics** Use real-time data to make critical decisions quickly. By providing an easy way to view and analyze all of your laboratory data through intuitive graphs and tables.

FEATURE / FUNCTIONALITY	DESCRIPTION
Integrated Solution (Cont.)	**Mobile** Take your lab on the go. Use your smartphone or tablet to track inventory, manage user access, view key performance indicators, and much more. By having full control of the lab at your fingertips, you can increase productivity and efficiency even when you are away or in the field.
Database Compatibility	STARLIMS is compatible with SQL and Oracle databases. Our system database conforms to Open Database Connectivity Standard (ODBC). STARLIMS Database servers can be clustered to provide failover support For additional details contact Abbott Informatics.
Operating Systems Compatibility	STARLIMS can be installed on Windows based operating systems. STARLIMS Application servers can be scalable through the use of MS Windows Clustering and Network load balancing services. For additional details contact Abbott Informatics.
Application Server Virtualization	STARLIMS application supports a virtualized environment. STARLIMS application may be installed on VM thus reducing the number of required physical servers and energy requirements. We support VMWare, Hyper-V and Xen Center.
Multiple Environments	STARLIMS integrated platform offers support for multiple environments such as PC (using as the client the IE browser for the traditional STARLIMS XFD forms and any browser for HTML5 compatible forms), smart phones and tablets (using STARLIMS Mobile capability for iOS and Android mobile operating systems).
Total Cost of Ownership	STARLIMS is the only LIMS vendor to provide a completely integrated solution incorporating LIMS, ELN and SDMS in a single application. This eliminates the need for building and maintaining custom interfaces to third party tools and by consequence lowering the total cost of ownership.

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