STARLIMS
FOOD & BEVERAGE

STARLIMS
FOOD AND BEVERAGE INDUSTRY LIMS SPECIFICATION DOCUMENT

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INTRODUCTION

The purpose of this document is to list the main functionality and features available in STARLIMS solution for the Food and Beverage Industry.

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. • In process and 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.
Biological Samples and Containers Management - Biorepository	The Biorepository module allows the laboratory to manage biological samples separately from other laboratory materials. The new module allows users to define biological material and classifications for use throughout the system. The Biorepository module is extremely important for customers within the Pharma/ Biotech and Agricultural Crops Sciences industries that need to manage biological samples, containers, storage locations, testing, chain of custody and disposition.

FEATURE / FUNCTIONALITY	DESCRIPTION
Chain of Custody	Display any inventory transactions for the sample (view history of how a sample has been handled).
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. • 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
Stability Study (Cont.)	• 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.
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.
Analyst Certifications	Track and manage analyst training and certifications for tests and methods, scheduled courses and re-certification.
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 allow 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 graphical format.

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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.
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.

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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.
Samples Zones	Define Sample Zones and provide the sampling points on which environmental monitoring or other type of sampling has to be performed, such as water systems, clothing, and surfaces or as applicable.
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.

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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.
Using Equipment With Micro Components	Associate a 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.
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.

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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.
Electronic Signatures	STARLIMS 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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	You analyze samples using tests. 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.
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

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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. By configuring sites, you can categorize your data according to service group or physical location and you can limit user access to this information according to site and team memberships.
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.
Data Archive	Configure how often to archive data based on your retention policy, schedule and improve system performance.
Instrument Integrations (DCU)	Integrate your instruments without the need for complex programming.

FEATURE / FUNCTIONALITY	DESCRIPTION
Waters Empower™ 3 FR5 CDS Interface	Bidirectional interface with Empower. Create the sample sequence on LIMS and import to Empower. Once the data is collected in Empower CDS import relevant data back to LIMS via mapping.
Chromeleon™ 7.3 CDS Interface	Bidirectional interface with Chromeleon. Create the sample sequence on LIMS and import to Chromeleon. Once the data is collected in Chromeleon CDS import relevant data back to LIMS via mapping.
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 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. For example, 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.
Chemical Structure and Chemical Reactions Interface	The STARLIMS interface with Biovia Draw and Direct for Chemical Structures and Chemical Reactions allows users to associate a Chemical Structure or Reaction to a material within Material Manager and to a folder sample within Folder Lifecycle[1].

[1] Customers must have Biovia Draw and Biovia Direct Licenses in order to use the Biovia interface available with STARLIMS Quality Manufacturing Solution QM12.2. These licenses are not included with or supported by STARLIMS.

FEATURE / FUNCTIONALITY	DESCRIPTION
STARLIMS- SAP S4/HANA Interface	We have certified STARLIMS Quality Manufacturing Solution with SAP S4/HANA. The STARLIMS interface with SAP S4/HANA is an extension of our existing interface with SAP QM-IDI and ESS. The interface allows the mapping and exchange of information between the two solutions. The STARLIMS Quality Manufacturing solution interface with SAP's Business Suite 4 HANA (S/4 HANA) Quality Management module allows customers to seamlessly leverage the benefits of both their ERP and LIMS solutions when verifying the quality of materials via inspection lots. The interface allows product material lot and specification data to be transferred directly from SAP into STARLIMS, reducing issues related to manual entry or transcription of data by automating the creation of material information and lots within the STARLIMS. Once inspection lot data is in STARLIMS, samples can be logged, results are recorded, and the usage decision is returned to SAP.

FEATURE / FUNCTIONALITY	DESCRIPTION
Multiple Systems Interfacing	STARLIMS support several standards for data sharing. 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)
Default Graphical Workflows	The Graphical workflows will guide the end user through all the required steps or optional steps in each of the lifecycles in an easy and intuitive way: Manufacturing, Contract labs, Stability Studies, Process Samples and Environmental Monitoring.
Request Management Portal	The Request Management Portal allows clients to submit test requests directly to a Contract Lab (internal STARLIMS users) to be reviewed and processed. The Request Management Portal is integrated with the existing STARLIMS applications and therefore allows clients to track the progress of their requests at all times.
QM Application Programming Interface (QM API)	The QM Application Programming Interface QM API v1.0 provides a series of pre-defined scripts to make REST API requests to the STARLIMS QM12.2 solution. The scripts provide the proper conventions that need to be followed to make these data calls/requests. This allows interaction and exchange between other software applications that need to consume data from STARLIMS. Some examples of data commonly consumed from STARLIMS include Test, Test Plans, Inventory, Methods, Materials, Folder, Project, Clients, Equipment, and Services groups. Besides requesting information regarding different STARLIMS entities, the QM REST API also provides the ability to create new folders in STARLIMS.

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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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 allow 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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 - 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. 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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. 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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. Smart cards 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.
Ability to Detect Invalid or Altered Records	S 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 Your Lab With ISO 17025 Compliance	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.
Scientific Data Management System to Support 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 to Support 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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).
Reporting and Querying	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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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
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
Laboratory Execution System (LES)	With the STARLIMS LES (Laboratory Execution System), lab users can easily document their work at the moment they are executed (in-lab execution). This helps to ensure Standard Operation Procedures (SOP) compliance, improves efficiency, prevents transcription errors, and can make some otherwise required peer-review steps in GxP regulated environments unnecessary.
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. With the HTML5 ELN design, performance, integration, and usability are improved
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.
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. . Drill down information to determine root causes and have visibility of data for decision making.
Mobile Applications	Access your lab remotely and stay connected. STARLIMS 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.

ISO 9001, ISO 13486 AND ISO 27001 CERTIFICATIONS

STARLIMS' commitment to quality is in the field of Laboratory Information Management Systems (LIMS). STARLIMS obtains certification as ISO 9001 compliant from the BSI organization.

bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 - S
South Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636368**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for various industries.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2016-05-20
Effective Date: 2021-06-26
Latest Revision Date: 2021-04-22
Expiry Date: 2024-06-25

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ISO 9001, ISO 13486 AND ISO 27001 CERTIFICATIONS

STARLIMS also has obtained ISO 13485 certification from BSI. What this means is that our systems are held to the stringent standards of medical devices, and to our customers, that commitment to quality is in strict adherence to ISO 13485 in our software systems, our management processes, our customer service, our issue resolution processes—virtually every aspect of our company.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 - S
South Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636367**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for the medical device industry.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-05-20
Latest Revision Date: 2021-04-22

Effective Date: 2021-06-26
Expiry Date: 2024-06-25

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

ISO 9001, ISO 13486 AND ISO 27001 CERTIFICATIONS

STARLIMS is ISO 27001:2013 accredited. The scope of our certification is the information security management system for the protection of proprietary information stored within the STARLIMS platform to include procedures, records, source codes and customer PII and PHI.

bsi.

Certificate of Registration

INFORMATION SECURITY MANAGEMENT SYSTEM - ISO/IEC 27001:2013

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 South
South Hollywood
Florida
33021
USA

Holds Certificate No: **IS 702430**

and operates an Information Security Management System which complies with the requirements of ISO/IEC 27001:2013 for the following scope:

The information security management system for the protection of proprietary information stored within the Starlims platform to include procedures, records, source codes and customer PII and PHI. This is in accordance with the SOA dated 2/24/2020.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2020-05-06
Latest Revision Date: 2020-12-04

Effective Date: 2020-05-06
Expiry Date: 2023-05-05

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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	Web-based HTML5 solution, for instant global deployment accessible through Google Chrome. Validate it once, and you can deploy it globally, to any authorized user with a standard web browser.
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 to transform data into actionable, impactful insights. Our LIMS solution handle complex processes, support regulatory compliance, and promote collaboration within your lab and among labs around the world. Laboratory Execution System (LES) Easily document important method execution steps at the moment they are performed (in-lab execution). Our LES helps to ensure Standard Operation Procedures are being followed, avoiding transcription errors and paper-based inefficiencies. Electronic Laboratory Notebook (ELN) ELN eliminates paper-based notebooks, forms and log books to increase efficiency, reduce error rates, and promote regulatory compliance enforcing method execution. With the HTML5 ELN design, performance, integration, and usability are improved. Documents created in the previous version of ELN can be imported into the new version Scientific Data Management System (SDMS) Our SDMS extracts information from scientific documents and laboratory instruments and places it into a structured, easy-to-access format. 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, you can confidently make decisions.

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 STARLIMS.
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 STARLIMS.
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 Google Chrome browser for the STARLIMS HTML5 forms and IE browser for the traditional STARLIMS XFD compatible forms particularly third party integrations that are not still available in HTML5 format), 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 with third party tools and lowering the total cost of ownership associated to maintaining third party integrations.
Multi -language Support	STARLIMS is officially translated in English and from QM12.3 version the software is officially translated in Chinese Language. Other languages can be supported via Professional Service engagement.

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