STARLIMS
PHARMACEUTICAL & BIOTECH

STARLIMS PHARMACEUTICAL 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 solutions for the Pharmaceutical Industry.

RESEARCH

FEATURE / FUNCTIONALITY	DESCRIPTION
Storage Utilization	Plan and track the capacity in each storage location, consolidate inventory within a location, and remind personnel to perform periodic physical inventory reconciliation.
Specimen Placement and Removal	Screens with barcode scan fields and graphical tools that delineate the specific position of a specimen within a container, and the container within another container or a storage location.
Product Life Cycle - Lab Processes	By tracking the individuals responsible for each specimen and its respective storage location, user-configurable approval workflows allow the Biorepository to enforce business logic for approval of specimen usage or movement. STARLIMS tracks a specimen's home location and the due date for its return and it enables researchers to reserve specimens for a specified time interval.
Chain of Custody with Electronic Signatures	Using electronic signatures allows chronological tracking of the entire history of each specimen. This ranges from initial electronic manifest login and/or accessioning to final disposal. STARLIMS offers functions including pooling, aliquoting, freeze-thaw tracking, quantity adjustment, shipping, and disposal management, ensuring that the full genealogy and history of the specimens are maintained.
Query Capabilities	Query tools enable researchers to identify and locate specimens of interest for clinical research purposes.
Aliquot Ordering and Test Assignment	Specimen aliquots or tests can be ordered for an individual specimen or a group of specimens by Biobank personnel external researchers. Testing workflow tools manage all specimen preparation and testing including extraction and quality testing of molecular components (such as RNA and DNA).
Specimen Metadata Options	Biorepository metadata templates allows to add or modify specimen metadata attributes. The Biobank can quickly add a new specimen attribute and then researchers can immediately use that attribute in their Biobank queries.

FEATURE / FUNCTIONALITY	DESCRIPTION
Patient Manager	Track demographic, clinical, and lifestyle information about donors to support medical research efforts. View historical test results, attached files and special notes.
Consent Management	Manage the level of detail that ensures all human biological specimens are handled per IRB and regulatory requirements and in accordance with donor preferences.
Identification and Resolution of Discrepancies	The integration with Clinical Study Management enables timely identification and resolution of discrepancies between specimen/donor attributes (arrival condition, container, transit time, etc.) and clinical study requirements.
Interoperability Tools	Automated import of E-manifest, test requests, and test result files; interfacing tools including interfacing to automated specimen handling systems and analytical instruments; and system-to-system communications via web services, File (text, CVS, ASCII, etc.) transfer, and direct database communications.
Logistic Management	Configurable workflows for a wide range of lab processes- from specimen; through storage location management; to querying and referral. Real-time data facilitates inventory management, storage management, specimen usage and movement, specimen placement and removal, and test assignment.
Workflow Management Tools	Workflow tools and wizards developed specifically for biorepositories. GUI based on intuitive drag & drop functions makes it possible to easily and conveniently fine-tune STARLIMS solution to meet the needs of any lab.
Web-Based Solution for Global Deployment and Collaboration	Web-based solution, leveraging XML, the .NET framework and other advanced Internet technologies. The Web-based interface also make it possible to submit specimens, request results online, and track specimens anywhere within the enterprise—providing outreach capabilities to third parties and customers, and dramatically reducing transcription errors and queries to lab personnel.

DEVELOPMENT

ANIMAL STUDIES

FEATURE / FUNCTIONALITY	DESCRIPTION
Species and Strains Management	A centralized management for species and strains definition for each specie to be used in various clinical and research studies and / or testing.
Study Activity Management	Clinical and Research studies require activities to be performed to the animals such as body weight, dosing, caliper measurement, food consumption, water consumption, open field test, etc. STARLIMS allows the user to configure the study activities and the information needed to be captured, as well as defining calculations for certain activities results like calculated dose for the dosing activity.
Services Management	Clinical and Research studies require services to be performed to the animals, such as surgery, specimen collection, tissue extraction, storage and shipment. STARLIMS Allows the definition of a service workflow with steps that are applied to inventory items like in the case of animal studies to animals.
Study Manager	Trial Manager allows the user to create studies and maintain the following study • Study Start and End Dates • Study Sponsor, Investigator(s), and contacts • Study Milestones • Study Subjects (animals) • Study Testing or Testing Groups • Study Activities • Study Time Points • Study Schedule
Study Workflow	The user can define the workflow for their clinical studies as a series of steps and validation of required information for the study prior to move to the next step as well as rules for certain study management features available based on the study step in the workflow. Example of study workflow step are: Planning Initiate, Active, Locked, Completed and Canceled.

FEATURE / FUNCTIONALITY	DESCRIPTION
Animal Inventory Management	Tracking of animal inventory reception, movement of animals to various locations, assignment of animals to clinical studies, tracking of animal inventory status as well as chain of custody for animal inventory and history of transactions with user and date/ time stamp. Typical transactions for animals are movement of locations and cages, allocation to studies, termination of animal, and assignment of services or tests.
Dosing Compound Formula Management	Recipie definition for material used in dosing type activities.
Study Treatment Groups	Definition of the treatment or testing groups of the study and its properties such as: Group name, Blinded, Cross Blind ID, Color; definition of expected number of animals by species, strain, gender, age range, weight range definition of the type of dosing activity, dosing compound(s) to use.
Study Time Points	Study time points is the foundation for the Study Schedule. The user can define the time point´s time units in Month, Week, Day, Hour and Minute; and define early and late tolerances for the execution of activities.
Study Schedule	The user can use the study time points defines for the study to build the study schedule and assign to each time point the required activities/services to be performed as well as the treatment groups.
Study Reporting	Reporting tools to crate queries and reports of study related data such as: Study Activities results, Study Animals status, statistics of study activities results, etc.

DEVELOPMENT

CLINICAL TRIALS

FEATURE / FUNCTIONALITY	DESCRIPTION
Patient Management	Patient query tools; centralized management of demographic details, including Family genealogy; patient merge tool; patient alerts and flags that can be displayed at test ordering or accessioning. Easy access to patient history. Easy data entry with support for scanned image entry.
Rules Manager	Clinical and Research studies require activities to be performed to the animals such as body weight, dosing, caliper measurement, food consumption, water consumption, open field test, etc. STARLIMS allows the user to configure the study activities and the information needed to be captures, as well as defining calculations for certain activities results like calculated dose for the dosing activity.
Clinical Order Management	Customer-configurable, template-driven booking screens for test request and specimens; test order frequency alerts; reflex tests; delta checking and configurable reference range criteria (e.g., age, gender, clinical study, diagnosis, etc.).
Sample Tracking Management	Specimen annotation from multiple sources; query capability to identify specimens of interest; management of pull lists, specimen preparation, transfer, shipping and disposition; aliquot/derivative and polled sample tracking.
Microbiology	Decision support tools, infection control management, surveillance of antibiotic resistance and infectious disease tracking; and configurable result approval and release workflows. Support for micro-titre plate testing with interpretative reporting for reaction patterns.

CLINICAL TRIALS

FEATURE / FUNCTIONALITY	DESCRIPTION
Immunology Plate–Based Testing	Configurable well plate definition, including blanks, standards, controls, and unknowns; plate workflows management tools; visualization tools; and interfaces to plate-based instrument software.
Clinical Genetics/ Molecular Biology	Sample lifecycle management, including pre-login/ login sample registration options; extraction/normalization management, plate handling, including plate configuration and plate workflow management; patient management including pedigree. Integration with DNA sequencers and other equipment
Quality Control Management	Tools for integrated QC functionality, including QC material lot number and expiry handling, delta checking, and Levey Jennings plots.
Reporting	Report formatting that is configurable bye the lab. Support fot HL7 web-based reports. Integrated remote access for clinicians providing secure access to reports.
Remote Access	Web access for accessioning and for specimen pre-login, data entry, and test ordering at the site where the specimen is collected. Online reporting for access to specimen testing status and results.

FEATURE / FUNCTIONALITY	DESCRIPTION
Clinical Study /Trial Management	Integrated functionality for management of clinical studies/trials. Definition of study-specific reference ranges, visit/time point-based rules for testing, kit production and distribution management, specimen collection, and data validation, contact management for clinical sites, and reporting and blinding rules.
Material Management	Inventory tracking, supplier management, COA/QC testing, chain of custody, materials distribution, and traceability of test results to standards and reagents used.
Fusion	The Fusion Integration Module provides flexible based providers, which is key to the success of your lab with many different format requests for sending lab results.
Reflex Testing, Auto Approval, and Double Blind Data Entry (DBDE)	Generate specific rules that further automate processes such as reflex testing, auto approval, and Double Blind Data Entry (DBDE).
Study Management	Define the study protocols, treatment groups, subject/ sample metadata, and visit schedules. Create and track kit inventory and distribution.

CLINICAL TRIALS

FEATURE / FUNCTIONALITY	DESCRIPTION
Study Subject Management	The STARLIMS Trial Manager allows authorized users to manage distinct treatment group and recruited subjects. Define visit-specific subject metadata and consent information to be collected and verified during sample collection.
Master Schedule	Define visit elements, tolerance limits and visit sequence information. Study administrators can manage the entire study using our flexible Master Schedule application.
Kit Inventory Management	The STARLIMS Inventory Manager is seamlessly coupled with our Trial Manager to allow users to define kit components, track manufacturing, kit distribution.
Query Capabilities	Identify and locate specimens of interest for clinical research purposes with powerful and flexible query tools. Conduct queries from across the globe using the system's intuitive graphic interface, flexible query template and a standard web browser,
Specimen Placement and Removal	Delineate the specific position of a specimen within a container, even nested within another container, or in storage, by using barcode scan field and removal, and streamlines all specimen handling procedures.
Specimen Usage and Movement	Make sure that the appropriate protocols for specimen usage or movement are followed, by tracking the individuals responsible for each specimen and its Respective storage location with user-configurable approval workflows. Track a specimen's home location and the due date for its return, and enable researchers to reserve specimens for a specified time interval.

FEATURE / FUNCTIONALITY	DESCRIPTION
Specimen Meta-Data Options	Easily add or modify specimen metadata attributes with our flexible template. Add a new specimen attribute that researchers can immediately use in their clinical research queries.
Consent Management	Manage patient consent information to the finest level of detail, ensuring that all specimens are handled in accordance with Institutional Review Board (IRB) and regulatory requirements, as well as subject preferences.
Discrepancy Resolution	Close integration with clinical study management enables timely identification and resolution of discrepancies between specimen/subject attributes (arrival condition, container, transit time, etc.) and clinical study requirements.
Storage	Receive decision support for effective storage utilization, including tools to plan and track the capacity in each storage location, consolidate inventory within a location, and proactively remind personnel to perform periodic physical inventory reconciliation.
Inter-Operative Tools	Automated import of E-manifest, test request and test result files. Interfacing tools include interfacing to automated specimen handling systems and analytical instruments, and system-to-system communications via web services, file transfer (text,CVS,HL7,ASCII,etc.) and direct database communications.
Template Setup	Streamline the set-up process by enabling the use of existing studies as templates for new studies, and configuring wizards to stablish study-based reference ranges, reflexes, triggers and reporting requirements .
Chain of Custody	Track the entire history of each specimen chronologically with electronic signatures. See a specimen's history from initial electronic login and/or accessioning to final disposal. Function include pooling, aliquoting, freeze thaw tracking, quantity adjustment, shipping, and disposal management, ensuring that the full genealogy and history of the specimens are maintained.

DEVELOPMENT

FORMULATION DEVELOPMENT

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

MANUFACTURING

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
Equipment Management	Manage equipment lists and components list, manage and track scheduled and/or ad-hoc maintenance events such as repairs, preventative maintenance, calibrations, QC. 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).
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.
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.
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 certification for tests and methods, 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
Batch / Lot Genealogy	View the different components (materials) that are used in the batch (i.e. 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 thr Lost 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 chart 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.
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.

FEATURE / FUNCTIONALITY	DESCRIPTION
Label and Barcode Utility	Generate barcode labels and read barcode labels.
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.
Microbiology Life Cycle	Define a more complex, dynamic test workflow (i.e. sequence of steps that change at run-time based on results). Microbial test work best for workflow steps that change depending on results and that are very complex.
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 , smaple can be logged, then the p'late workflow becomes available for processing using the Plate Lifecycle Tasks application.
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 all 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 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.
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.

FEATURE / FUNCTIONALITY	DESCRIPTION
Workflow Manager	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 (KPI´s). 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 dashboards is configured for users based on role. The User Gauge 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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.
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 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 thought 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.
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. By configurating sites, you can categorize your data according to services group or physical location and you can limit user access to this information according to site and team memberships.
Data Archive	Configure how often to archive data based on your retention policy, schedule and improve system performance.
Importing Data Using CSV	Used for loading LIMS tables using .CVS files when the data is already configured on another system and you want to import it into your LIMS. The data from the old system is entered into a CVS file, a file format that stores tabular data in plain-text form. The information can then be imported into STARLIMS. CSV Files typically contain delimited data parsed into files to be uploaded into fields, tables and databases in a software system. STARLIMS provides template files for creating .cvs files for many applications tables.
Instrument Integrations (DCU)	Integrate your instruments without the need for complex programming.

FEATURE / FUNCTIONALITY	DESCRIPTION
Waters Empower™ 3 FR5 CDS Interface	Bi directional 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	Bi directional 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 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.
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.

CROSS FUNCTIONAL

FEATURE / FUNCTIONALITY	DESCRIPTION
Lab 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.

REGULATORY COMPLIANCE

FEATURE / FUNCTIONALITY	DESCRIPTION
Support 21 CFR Part 11 Compliance/ Electronic Records/Electronic 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 expire date, password complexity, and 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 fist time they logged on.
Security, Data Protection and Encryption	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 allow you to view the login history. The History application is the access point for this information. The History window display 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 - 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. With STARLIMS you can require E-Sig Comments, or require users to provide their 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. hus, 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 RDBM 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 Document) 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 Document to the next step. You can also use runs to specify the materials needed to perform tests, assign. 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 ELNT template, which mean that you can control the order in which ELN Documents 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.

FEATURE / FUNCTIONALITY	DESCRIPTION
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 group, role 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.
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:
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.

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.

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 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.

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: 2016-05-30
Latest Revision Date: 2021-04-22

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

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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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To be read in conjunction with the scope above or the attached appendix.
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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 solution, leveraging XML, the .NET framework and other advanced Internet technologies. The Web-based interface also make it possible to submit specimens, request results online, and track specimens anywhere within the enterprise— providing outreach capabilities to third parties and customers, and dramatically reducing transcription errors and queries to lab personnel.
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.

TECHNOLOGICAL ADVANTAGES AND COMPATIBILITY

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 HTML5 compatible forms, smart phones and tables (using STARLIMS Mobile capability for iOS and Android mobile operating systems) and IE browser for the traditional STARLIMS XFD compatible forms particularly third party integrations that are not still available in HTML5 format).
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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