STARLIMS

STARLIMS QUALITY MANUFACTURING SOLUTION INTERFACING WITH 3RD PARTY SYSTEMS

Most organizations that are looking to implement a new LIMS or replace an aging one have a significant investment in a number of information systems. Some of these may already be connected to multiple applications via a centralized integration hub or via direct interfaces. When thinking about a LIMS, organizations need a complete informatics lab solution that can be interfaced with other informatics systems.

While some of the features of these other applications also exists in STARLIMS they don't necessarily meet the full set of requirements needed by most end users. This is why STARLIMS is out of the box ready to support integration with the most common types of information systems that a LIMS solution needs to integrate with. In addition, STARLIMS provides a powerful toolset to allow customers to rapidly and easily create new interfaces when needed.

A common question is "Why is it necessary for a LIMS to have this data (or access to it?)". This whitepaper highlights several areas where the LIMS typically needs access to data that can be primarily maintained in 3rd party systems. Additionally this document describes how STARLIMS provides out of the box support for interfacing with each type of system, the technologies used and examples on why the integration is necessary on a per system basis.

Another question commonly asked is "Why not just have the laboratory personnel use the other applications to accomplish this work, and not do it in the LIMS?". This is a question of efficiency. If a lab analyst must use 5 different applications to accomplish their daily work, then they are undoubtedly less efficient than if they could learn and use a single system. The wide popularity of smartphones as a phone, camera, music player, game player, mini-computer, and internet device has proven this point from a consumer level. Abbott's Informatics business has proven this point from within the laboratory with its comprehensive STARLIMS web-based solution.

Interface Mechanisms

Below is a list of mechanisms by which STARLIMS can interface with external systems:

- **Web Services** – STARLIMS supports both the hosting and consumption of web services. STARLIMS can work with both Simple Object Access Protocol (SOAP) and Representational State Transfer (REST)-based web services. Due to the ease in which STARLIMS is able to both consume and host web services this is the most common mechanism for interfacing with external systems.

- **Application Programing Interface (API)** – If an application does not support web services; it typically has an API which allows a programmer to create individual interfaces from the source system (STARLIMS). This allows a developer to build an interface to the target third party system from within the STARLIMS integrated development environment.

- **Direct Database** – For instances where there is no existing interface available, either web services or an API) STARLIMS can work directly with the third party application at the database level. In this type of interface STARLIMS and the third party application would share information via direct reads and writes to either the STARLIMS or the third party database.

- **File based** – When direct interfaces are not possible, or the target system does not provide web services, an API, or direct database connectivity, STARLIMS can operate via a file-based interface. STARLIMS makes creating interfaces of this type easy by allowing non-programers to create file parsing and recognition patterns using an easy to use wizard. STARLIMS is able to read files and process the data from a variety of file types:
  - Text (CSV, Tab Delimited, XML, etc)
  - MS Word
  - MS Excel
  - MS PowerPoint
  - PDF
  - Others

Third Party Systems and STARLIMS Interfaces

ENTERPRISE RESOURCE PLANNING (ERP) SYSTEMS

ERP systems are renowned for their ability to manage inventory and to provide high level management of quality inspections of incoming goods and manufactured product. However, these systems are not typically focused on the overall efficiency of a laboratory. ERP systems are targeted towards to the overall business of ordering material and manufacturing products.

However, since these systems control the inventory and normally have the ability to track the quality inspections required by each item, the laboratory must be able to work with them.

MASTER DATA

The first way that a laboratory system needs to work with an ERP system is with "Master" data. Master data is simply data that originates and is maintained by an external application.

STARLIMS Quality Manufacturing solution allows for materials, equipment, and even bills of material (ingredient lists for what materials are used to make materials) to be managed outside of STARLIMS. This means that STARLIMS offers out of the box web services which allow for an external application to create or update records for master data.

Below is a list of master data that STARLIMS offers standard web services for:

- Materials
- Equipment
- Specifications and Inspection/Testing Plans

PRODUCT LIFE-CYCLE ACTIVITIES

Additionally the STARLIMS Quality Manufacturing solution provides the both web services and connections to vendor specific Application Programing Interfaces (API's) for bi-direction integration of Product QC Lifecycle actions within STARLIMS.

Below is a list of Lifecycle Activities which STARLIMS offers standard web services for:

- Logging in a Raw Materials or Product Batch samples (inspection plans)
- Updating a Batches Bill of Materials or Formulation
- Logging In Samples
- Updating Sample Test Results
- Returning the usage decision or QC disposition of the batch to the ERP

SPECIFIC ERP SYSTEMS

The STARLIMS Quality Manufacturing solution is now certified to integrate with SAP's Business Suite 4 HANA (S/4 HANA) Quality Management module. 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. Once inspection lot data is in STARLIMS, samples are logged, results are recorded, and the usage decision is returned to SAP®.

SAP® S/4 HANA runs on the highly efficient SAP® HANA database and the interface with STARLIMS lets users view data and reporting in real time.

Training Applications

Within the LIMS it is often necessary to limit access to areas of the system, or to perform certain activities based upon the certification or training status of the user. The most common need is for limiting the performance of a test and method to somebody who is certified.

This means that STARLIMS needs to have access to the training records for each user. STARLIMS has the capability to track the test and method certifications by user. In addition, STARLIMS ships with standard web services which allow the following functions:

- Creation of a new training record for users

- Retiring of an existing training record for users

- Updating or extending the training record for users

In addition, STARLIMS has worked with customers to allow any changes to a user's training record within the STARLIMS system to push those changes to the external training application.

Quality Systems

Having a system to track quality events is a requirement in most industries. Most organizations have one or more applications to help them track quality related items such as:

- Customer Complaints
- Corrective and Preventative Actions (CAPA)
- Investigations
- Customer or Employee suggestions
- Adverse Events or Effects

STARLIMS has similar functionality to allow for laboratory personnel to troubleshoot problems in the laboratory.

This may include things like researching a failed Quality Control sample or a laboratory error.

Typically the type of tasks related to a laboratory investigation is more specific than what is needed in most of the standard Quality Systems. Therefore, while the laboratory may opt to use the native STARLIMS tool, there is a need to ensure that the STARLIMS investigation is visible in the external quality system(s).

To support this, STARLIMS has standard web services which allow retrieval of active investigations.

Additionally STARLIMS has worked with customers to trigger the creation and update of quality event items either in STARLIMS from the external systems, or from within STARLIMS.

Equipment Maintenance & Calibration Systems

Most organizations have an equipment maintenance and calibration system in place. These systems are most often in use by a centralized calibration or metrology team which is responsible for the recurring calibration events for each instrument.

In the laboratory there are often a number of instruments or lab equipment which needs to be maintained by the laboratory personnel. There are tasks such as routine parts replacement or daily/weekly calibrations which the laboratory personnel are responsible for. Also, the laboratory normally wants STARLIMS to ensure that the equipment that a user wants to use for an analysis is in calibration and meets service requirements prior to the analysis proceeding. STARLIMS must have access to the current maintenance status of each device in order to enforce this.

STARLIMS includes a standard web service which will allow a third party system to update the maintenance history of a given piece of equipment.

Additionally, Abbott's Informatics business has the ability to also trigger an update to a third party system when a maintenance event occurs.

This integration allows the metrology team to use their existing system for the routine calibration of all instruments in the organization, while allowing the laboratory to effectively manage the individual instruments and equipment in use in their laboratory.

User Management Systems

Most large organizations have a central tool where user accounts and privileges are managed. While STARLIMS must have functions for managing user accounts and privileges, STARLIMS recognizes that this type of account maintenance can create administrative overhead. Additionally the burden for end users to manage their central account information (and password) separate from STARLIMS can cause issues.

Therefore, STARLIMS supports creation of accounts via web services as well as the linking of those accounts to network authentication and directory systems via Lightweight Directory Access Protocol (LDAP) such as Microsoft Active Directory. This integration allows for account creation and maintenance to occur in the centralized system, and for users to take advantage of Single Sign On (SSO) capabilities when accessing STARLIMS.

Chromatography Data Systems (CDS)

Chromatography Data Systems provide direct control over a wide variety of Chromatography devices. These systems allow for the elimination of not only different software products per instrument vendor, but also for elimination of different software products and versions for a single product.

These products normally perform the full analysis process from standard calibration through result calculation.

The need for integration between the LIMS and a CDS is usually for the LIMS to send a sample set to the CDS and for the LIMS to receive the final result data from the CDS.

STARLIMS has an API for both the Waters EMPOWER™ CDS, and the Chromeleon® CDS from Dionex. The API allows for bidirectional integration (sending sample sets and receiving results) from both systems.

- STARLIMS supports Empower™ 2 and Empower™ 3

- STARLIMS supports most of the current versions of Chromeleon®.

Manufacturing Execution Systems (MES)

These applications manage the entire manufacturing process, and normally result in a fully electronic (paperless) batch record. An MES normally interacts with the LIMS by logging samples, sharing test results (bi-directionally), handling batch disposition from the LIMS to the MES, and sharing of the electronic batch record.

STARLIMS has been integrated with several MES systems via both web services, and file-based integrations.

Regulatory Compliance, Change, and Filing systems

These systems manage filings of products with different regions and countries. Typically any change to the product or the manufacturing of the product must undergo a change management process with each country that the product(s) are shipped to. When deciding upon the usage decision in STARLIMS, based upon the test results and the specifications, the qualified person or Quality Control manager may need to check for the regulatory filing status for each country the product is shipped to. In this instance, STARLIMS may allow viewing of the compliance information as it pertains to the product.

STARLIMS has integrated with systems like these via web services and file-based integrations.

Historian Systems

These systems collect data from a variety of applications to provide real or near-real time key performance indicators. Metrics from STARLIMS are often sent to the historian system for items like batch, sample, and test turnaround time tracking.

Statistical Analysis and Enterprise Reporting Solutions

Most organizations have standard solutions for statistical analysis and enterprise reporting. While STARLIMS has robust capabilities for both with Statistical Process Control (SPC) powered by NWA Quality Analyst®, and reporting features powered by SAP® Crystal Reports, those features are geared towards helping increase the efficiency of the laboratory. Therefore, when aggregated data is needed for business oriented reporting, or when a dataset of information is needed for use in detailed statistical analysis STARLIMS has the ability to support both needs. Since the STARLIMS Quality Manufacturing solution operates on a relational database, it is possible for external systems to read the STARLIMS database directly to retrieve the information needed. Many customers perform direct SQL queries against the STARLIMS database from SAS or other tools for statistical analysis.

Additionally to support standalone reporting and statistical packages, the STARLIMS Quality Manufacturing solution comes out of the box with the ability to export data to Microsoft Excel.

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