QLIMS v8.3 Functionality

Acknowledgments

This document includes information about QLIMS v8.0

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Contents

Off-the-Shelf Functionality

Sample Manager

Provides a management system for individual samples that offers:

Single Sample Login

Enables users to register a single sample. The registration process allows the user to identify a sample and automatically assign tests and their product-specific limits (if desired) using simple point and click operation.

Sample Approval

The sample approval step is used to confirm that the sample's testing cycle has ended and the laboratory management has given the sample a final disposition. The disposition of samples will differ from lab to lab; however, most laboratories assign disposition statuses, which include Approved, Rejected, Reworked, Cancelled, Concession, etc. This lets the rest of the organization know what was determined by virtue of the laboratory's testing of the sample.

Results Validation

In many laboratories it is standard operating procedure to require results that were entered into **QLIMS** to be reviewed by a peer or a supervisory staff member. This is often the case within pharmaceutical, food or any other regulated laboratory. When this level of data review is not required, or if data is only reviewed when it does not meet its specification requirements, the results validation step may be bypassed.

Batch Manager

Provides a management system for lot processing that offers:

Batch Sample Login

Provides a means for registering multiple samples using a single form. This is normally used when a series of samples are to be associated with each other.

Within production facilities the batch is normally based on a production Lot; whereas, in research or analytical services laboratories the samples may be associated based on a specific work Request, Job or Submission.

Batch Approval

Where companies process batches such as raw materials or manufacturing orders, batch approval routines exist to attach final disposition statuses. The final disposition would be based on the results of all the samples attached to the batch.

Browse Sample

This offers an alternate method for viewing and searching through samples along with offering multi-sample approval functionality.

Results Entry by Sample

Within some laboratories it is convenient to view all of the sample information while entering analytical results. Laboratories use this mode of results entry when it is beneficial to have a full perspective of the sample being tested at the time of results entry. QLIMS provides a mode of results entry whereby the user may select a single sample using one or more of its descriptive identifiers. When the sample is selected a listing of all of the required results will be presented for data review and entry.

Results Entry by Cross Table

A powerful tool for quality and process control laboratories or any other laboratory where it is desirable to view results from a number of related samples. Results Entry by Cross tables allows the user to select the identifiers that associate a number of samples. Upon making the selection, the results of all of the related samples will be presented on the form in a cross tabular fashion for data review and/or results entry.

Supplier & Customer Records – Address Manager

The **QLIMS** address manager enables the creation of contact information for any individuals or companies that interface with the laboratory.
The following are the contact categories that can be recorded:
- Suppliers
- Customers
- Subsidiary Companies
- Sample Submitters
- Etc...

These contact records are then made available throughout the other **QLIMS** applications to avoid addition data input, such as sample and batch login.

Methods Manager

QLIMS Method Manager permits you to enter the information required for all of your laboratory's analytical methods in a complete, well-structured format.

The following are some of the details recorded:
- Result parameters
- Instrument (if any) used to perform the analysis
- Detection range for which the parameters may be detected
- Calculations used
- Sample preparation method
- Resource management information associated with the method
- SOP that describes the "cookbook recipe" for the test method and more…

Methods records are fully version controlled.

Sample Type Development

Sample Type development permits you to enter the information required for all of your laboratory's sample types in a complete, well-structured format. Sample Type records are also version controlled

The following are some of the details recorded:
- Market Synonyms
- Associated Methods
- Customer Specifications
- Parameters and Limits

Project Management

QLIMS enables the creation and control of projects. The project information can contain the following information.
- Project Number
- Project Name
- Project Description
- Project Leader
- Project Team

Once a project has been defined within **QLIMS** samples or batches can be assigned against the project.

Instrument Calibration & Control

QLIMS provides integrated functions, which allow users to define and closely monitor each of the instruments that are used for analysing samples. The function provides an on-line means for recording all instrument maintenance records for instant scheduling of maintenance events and on-line recall of past events.

In addition, the function also enables users to record results from all calibration and QC samples that were run on each instrument in order to maintain data on-line for monitoring both usage and performance. Instant SQC charts for each instrument may be presented to provide a clear, graphic illustration of instrument performance to detect trends and take a proactive role to prevent instrument-related problems.

QLIMS Event Triggers & Actions

QLIMS allows the users to define specific events and what actions are required when the event is triggered. Typically, events are sample or batch status related, for example, a sample being out of specification could be the event trigger and the action an email notification to selected people.

The following are typical actions:
- Automatic email notification
- Running a report
- Executing a database procedure

Chain of Custody

The Chain of Custody Manager is used to select Test Methods (that are not analyzed by the laboratory that has received the sample) to either send to another department/lab or to an external contract lab to perform the desired tests.

This tends to occur in some labs that have a central point for sample receival and they process the sample at different labs at the same site, or, they may not have the expertise or the equipment to perform the analysis and as such they send the sample to an external lab to perform these tests.

QLIMS Administration Tools

QLIMS provides the system administrators with the following administration tools:
- Logins monitor
- Licence monitor
- Systems settings
- Privileges management

Data Import & Export

Data can be imported to and exported from QLIMS in all the normal formats. The commonly supported formats are ASCII, CSV and Excel.

Security & User Privileges

The security and user privileges manager allow the system administrator to determine the level of security that will be used by their QLIMS system. The security management system retains an easy to use interface, while adding the features of 128-bit password encryption and great refinement in user access.

The security system is multi-layered:
- Layer 1: Underlying Database Access
- Layer 2: QLIMS Application Access
- Layer 3: Site-Specific Access

Report Generation

OnQ recommends and provides integration for Microsoft Reporting Services and/or Crystal Reports due to its ability to work with all of the **QLIMS** supported databases, its powerful functionality and its affordable price. By virtue of utilizing an open architecture database, **QLIMS** allows each laboratory to select the report generator which best suits their needs. Currently **QLIMS** makes use of both Crystal Reports and Microsoft SSRS.

Sample & Batch Certification

The production of certificates of analysis for both samples and batches can be controlled by the certification functionality. Once samples are certified the required certificates of analysis are printed

automatically and the samples statuses updated to indicate that they have been certified and the certificates printed.

Statistical Graphing

Statistical graphing is available within **QLIMS**, for example when reviewing a sample, the user can highlight a result parameter and click the graphs button. This action will select results for the method parameter highlighted for the product being tested and then graph those results and calculate standard statistics based on the results. This tool can be used for trend analysis, SQC, and SPC.

Barcode Label Printing

Barcode labels can be printed automatically on the login of batches or samples. The design of the labels to be printed is under the control of the selected **QLIMS** user, the labels can contain both human readable text as well as barcodes.

Full Audit Trails

QLIMS complies with (FDA regulation 21 CFR Part 11) requirement for audit trails. Audit trails can be applied to any of the tables within **QLIMS** and will audit any addition, update, or deletion of the records within the table. Audit trailing can be transparent to the user automatically recording user date and time or can prompt the user for comments.

Materials Safety

Material safety data can be created and maintained within QLIMS. It is associated with raw materials and product specifications, hence when processing a sample the safety information is attached to the sample, warning the technician of any dangers and handling precautions.

Document Control

The document control function is designed to integrate essential documents into any of the QLIMS applications. Examples might be standard operating procedures or health and safety documentation, normally held as PC files or even hard copy. Documents can be in any format: spread sheets, word processor files or html files. Special tools for document management not normally found in LIMS systems are available. For example, documents located on a server can be catalogued automatically into the document manager rather than registered manually.

Text Block/Comments Manager

The Text Block Manager is used to manage the general lookup values that are made available throughout QLIMS but whose source is not related to a specific table within the system. The Text Block manager allows authorised users to create, select, update and delete records in the QLIMS TEXTBLOCK Table, which is the repository of these values.

Worksheet Production

A wide variety of worksheets are available which may be used to help the laboratory efficiently process samples. Worksheets may be organised by lab, by individual, by instrument or any other logical criteria. The worksheets may be presented on the screen, printed to hardcopy or passed to an analytical instrument for automatic run generation.

Add-on Functionality

Sample Scheduling/Autoschedular Module

Due to their business practices, regulatory requirements, or simply for a better integration with other applications, many laboratories need to schedule the automatic login of samples into the database. With the Sample Schedule module, QLIMS allows the user to easily create sample schedules for the short or long term, reducing maintenance, and time-consuming operations. On the date that the samples are due for testing the sample is 'pulled' and becomes available for receipt and/or results entry.

The automatic login of samples is performed on the basis of sample type (or product specification). Tasks are assigned through a simple table entry on the basis of time, date, week or month. Samples will be automatically logged into QLIMS at the specified time & day and given the status of N (New sample logged, but not received in the laboratory) specifications to the QA specification. Hence when an order is received for a bulk product, the customer can be selected and QLIMS can automatically compare the QA results to the customers specification and if in specification automatically print the certificate of analysis in the format required by the customer.

Corrective and Preventative Actions (CAPA)

The Corrective and Preventative Actions (CAPA) module provides a means for recording and managing incidents, right from the detection stage to it being sufficiently resolved. It allows the user to record corrective actions that need to be taken to resolve the incident and preventative actions to ensure it does not take place again.
Once an incident is logged into QLIMS, the user can review which stage the incident is in currently:

- Detection Stage
- Correction Stage
- Review Stage
- Sufficiently Resolved
- Incident Resolved

Customer Specification and Product Re-grading

The Customer Specifications provides a logistics tool. This tool enables the user to check when a product batch is out of specification whether the product will still meet the requirements of any of the customer's specifications for that product.

If the batch does meet the requirement of one or more customers, then the batch can be re-graded and a disposition made against the batch to indicate resale only to those customers.

Multi-Site/Laboratory Module

It is possible for a user to be associated with multiple labs. With the Multi-Lab option, QLIMS can grant users access to multiple laboratories and/or sites and the data is automatically filtered based on the laboratory or location. This is especially useful when operating multiple sites within a single database over a Wide Area Network.

This feature ensures that access to data is automatically identified based on its origination without any user intervention. Selection of data such as products, tests, instruments etc. is restricted to those that are logical for the current location.

Formulation Module

The Formulations Module allows for product and intermediate product formulations to be created within **QLIMS**. The formula for a product is associated with the product specification, and contains the component list and quantities for each component and all the process steps taken during manufacture. This formulation information is then available for other **QLIMS** functions such as blend corrections or recipe pre-weigh.

Training Management Module

The Training Management module can be used to create Training courses, ensuring users have access to certain methods and enter in results only once training has been satisfactorily completed. This is especially useful in ensuring that lab staff follow standard operating procedures and conduct testing and only enter results for those test methods which they have only completed the relevant courses with relevant training. Re-Training of staff can also be defined if needed.

Material and Inventory Management

The materials or consumables that are used in your laboratory can be recorded within the materials manager, including the suppliers; the cost, opening stock amount, and re-order levels. The consumables and quantities that are used in the execution of a method can be defined as part of the method. Hence when a method has been performed on a sample the consumables used will have the stock levels reduced accordingly. Once re-order levels have been reached, the user will be prompted by **QLIMS**.

Business Manager

The Business Manager provides the production of quotations and invoices for samples or groups of samples. Customer specific pricelists can also be maintained, which are then available for the quotations and invoices. Currency conversion and taxation functionality is also available.

The **Pricing Manager** provides users with the ability to create multiple price lists to suit individual client requirements. This can be based upon a number of various factors, such as bulk discounts,

specific projects, default price lists or the ability to define an individual price structure to suit a specific Company and Contact that you may wish to create.

The **Quotation Manager** allows you to create New Quotations and Update existing Quotations that can be used internally or to send out to customers.

The **Invoice Manager** allows you to create both interim and final invoices based upon the completed work (i.e. Samples).

Worklist (QA/QC) Module

The QLIMS Worklist Module has been designed to ensure that results that are obtained from your analytical techniques are performed according to the appropriate protocol. This system organizes analysis into 'Worklists' which do the following:

- Associates the samples that were run within the group
- Automatically registers quality samples and ensures they are run according to your established QA protocol.
- Provides 'in context' results entry pages and data review
- Automatically updates the status of the samples, tests and batch
- Associates the instrument and user that performs the analysis
- Provides control charting for any combination of: Standard, Parameter, Instrument, Analyst

Electronic Signatures (21 CFR Part 11)

QLIMS complies with (FDA regulation 21 CFR Part 11) requirement for electronic signatures. This functionality allows the administrator to define what transactions require electronic signatures. Electronically Signed Functions can include:

- Sample identification and/or update
- Entry and/or modification of results
- Entry and/or approval of test methods
- Entry and/or approval of product specifications
- Assignment of release status of samples
- And more…

Sample Splitting and Collation Module

There are occasions where laboratories have received a sample and they need to send samples either to multiple departments/laboratories for testing as it is not performed by a single laboratory or samples must be sent externally to another laboratory - either because they do not have the expertise internally or the dedicated equipment needed to perform the testing.

To cater for this requirement, the QLIMS split sample functionality enables users to select a sample and split it into multiple samples. A Sample template is used to define details including Number of Samples, Sample Type, Test Date and Sample Collection Date.

Bottle/Container Manager

The Bottle Manager enables the user to create bottles for which samples are collected and transported back to the laboratory. Bottles can be re-used as such you can define cleaning and re-use ability of the bottles as well as disposal of the bottles.

Batch Template

The QLIMS Batch Template Manager enables users to pre-define batch details and sample types for quick insertion of batch samples.

Site Module

The main purpose of the Site Manager is to provide the facility to configure the relationship between the Site and the Sampling Points (Locations). This will ensure that sampling points will be consistent throughout the testing schedule.

The Site Manager will allow administrators to define the address, contact information, GPS and GIS coordinates of all Sites and Locations.

The module has the ability to define Sites using a one-to-many relationship and has been applied in conjunction with the ability to register samples per site and to automatically generate these samples for sampling.

The Site Manager is generally used for environmental monitoring. However, it can also be configured to be used for a number of different purposes. For Example:

- Mining Applications - ability to identify all bore holes where samples are generated.
- Tank farm management - ability to identify all points at a Tank Farm where samples are collected.
- River Stream - ability to accurately define all points along a river stream for sample collection.
- Defining sampling points for automatic routine collection and identification of samples.
- A refrigerator - all the shelves of the refrigerator and for each shelf there may be one or many compartments where samples can be stored.

Repository Manager

The Repository Manager has been designed to allow QLIMS to control where samples are stored and manage the disposal of items when they are no longer required in the laboratory. This screen can also be used for auditing purposes to ensure that the expected samples in each repository are the same as the list of actual samples.

A report can also be created which shows the list of samples in each repository. This is to allow users to do manual auditing of the repository i.e. check expected samples against actual samples and then match this against the list in the Repository Manager screen.

Stability Manager

The Stability Manager is designed to allow quality control testing and evaluation for samples created in the Sample Manager. To create a new record an existing testing protocol (created on the Stability Protocol page) and a base sample will need to be created.

One a Stability record has been created, Samples can be added to the record automatically using the Protocol template that was added when the record was first created. This is designed to allow easy testing using the same set of parameters repeatedly or allow quick modifications to the sample records to add additional testing.

Bridge Manager

The Bridge Manager module is used to upload files to the QLIMS server (if operating with a cloud-based solution) and to modify the Bridge configuration file. It also has the option to export the configuration file as an xml document that is saved locally.

Customer Portal

The QLIMS Customer Portal is a secure digital channel that allows testing laboratories to communicate with customers/manufacturers, through a simple submission of samples which are loaded directly into the QLIMS System.

Each client is provided with secured and restricted access to the portal, seeing only what they need to see/what is allowed by the lab. As the customer portal is directly linked up with the QLIMS database used by the laboratory, once the samples are submitted through the portal they turn up in QLIMS ready to be received, tested and the results churned out. Once the testing has been completed by the lab, the staff in charge can then directly fill in the results or attach a report which when published is automatically accessible to the customer on a read-only basis.

Business Intelligence Suite

The QLIMS Business Intelligence Suite is powered by Qlik Sense, a next-generation self-service data visualisation application that empowers everyone to easily create a range of flexible, interactive visualisations that drive exploration and discovery through intuition.

It provides users with the following capabilities:

- Pre-configured intuitive and interactive visualisations highlighting key laboratory metrics such as, batch, sample and test turnaround time's, customer work analysis, cost analysis, site sampling analysis, cost per sample, error rates and more.
- User-Driven Creations with the ability to build your own visualisations to tailor information to your lab.
- Ability to connect to other systems and aggregate data alongside QLIMS. For example; Financial/ERP Systems.
- Quickly displaying information for operational and management reporting
- Provides a centralised information hub for collaboration and communication, sharing of relevant analyses in an organised controlled manner
- Anytime, anywhere access to all capabilities on any device

Reduced/Audit Testing and Sample Planning

In order to gain efficiency, some laboratories reduce the amount of testing that is performed on either the product(s) marketed or on the raw materials received from suppliers. This is done by systematically performing basic identification tests on all samples and by implementing more rigorous testing on some samples, based upon the number of samples received.

The Reduced Test Frequency is used for the Reduced Testing module and is the frequency at which the test Method will be performed for the Sample Type currently being defined. With the Reduce Test Frequencies option, QLIMS can easily accommodate all sorts of scenarios and improve testing efficiency.