



## WinLIMS – Out of the Box Functional Overview

The WinLIMS Web Client is a revolutionary, second generation web-based LIMS that is the culmination of QSI's 25 years of successful LIMS implementations in over 1000 labs using both traditional client/server software and QSI's first generation web product; WebLIMS. WinLIMS™ was built from the ground up using the Microsoft's object-oriented .NET development toolkit which promotes rapid, modular development and smoothly integrates into modern corporate environments. WinLIMS is right for any sized lab.

WinLIMS contains a wealth of functionality that has been developed based on the actual requirements of our extensive user base. Our clients are from all sectors of industry, so we have created functionality specific to each industry to supply a complete solution to any company requiring a new or replacement LIMS. In our endeavour to provide a comprehensive laboratory management system we have also taken great care to adhere to the principle of an uncluttered, simple to use interface to ensure end user acceptance. Each functional component has been assessed to determine its general utility. General functionality is included within the OTS (Off-The-Shelf) WinLIMS and industry-specific functional components are offered as optional modules that seamlessly integrate with the WinLIMS core.

WinLIMS OTS provides you with the functionality you require, without compromise, and benefits your LIMS project by reducing both initial and ongoing costs and ensuring trouble free upgrades. This document provides a brief description of the various WinLIMS software components.

### Off-The-Shelf Features

The following is a set of basic features that are included in the basic OTS WinLIMS. In most cases, these are all of the features that are required to fully implement your WinLIMS system.

#### Dynamic Page Designer (OTS)

One of the key features of allowing WinLIMS to be so effective is the ability to configure the system's pages to reflect the nomenclature and workflow of each client. All of the pages are edited using the WinLIMS Dynamic Page Designer. To jump-start the implementation, the pages are designed by your QSI Project Manager; however, you will be trained to use this powerful tool to allow you to make modifications to your system as needs arise. The tool allows you to add and position data elements (e.g. data fields) and their associated properties to the screens. You decide if a field is a manually entered text, a lookup, a checkbox, etc. The limitless nature of the Dynamic Page Designer is the key component that allows WinLIMS to accommodate the needs of virtually any laboratory.

#### Test Method Templates (OTS)

Test Method Templates permit you to enter the information required for all of your laboratory's analytical methods in a complete, well structured, and version-controlled 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...



### Specification Management (OTS)

In most laboratories test methods are assigned to samples based on the type of sample submitted. Hence specification management enables the assignment of methods to the sample type specification and sets of limits for each of the methods parameters in a version-controlled environment.

These limits will be used to check the results entered for the specific sample type being tested. Specifications can be created for the following types of samples.

- Raw Materials
- Finished Products
- Environmental Samples/Locations
- Research and Development
- And more...

### Confirmatory Testing (OTS)

The WinLIMS confirmatory testing option permits users to automatically assign supplemental tests to samples when a result on a previous test falls outside specified limits. This allows you to "chain" tests together so that if the initial test fails then the confirmatory test is automatically assigned to the sample.

### Reduced Testing (OTS)

The WinLIMS reduced testing & audit functionality provides manufacturing companies the functionality to define reduced testing schedules for samples or batches.

The system will keep count of samples or batches logged into WinLIMS for each raw material. Within the testing schedule the user can define the testing regime, i.e. test every 5th batch/sample and also what tests should be applied, hence when the count reaches the number defined within the reduced testing schedule the batch or sample would be tested.

### Supplier & Customer Records (OTS)

The WinLIMS 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 WinLIMS applications to avoid additional data input, such as sample and batch login.

### Project Management (OTS)

WinLIMS 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 WinLIMS samples or batches can be assigned against the project.

### **Compounds Management (OTS)**

The compound manager allows the laboratory to establish a standard nomenclature for all chemical compounds and measured result parameters, and it allows the tracking of the fundamental characteristics of each compound. Furthermore, these basic characteristics may be used within results calculations and/or may be used to generate chemical safety sheets.

### **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.

### **Batch Sample Login (OTS)**

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 Sample Login page normally represents the set of samples that are associated with a production Lot. When implemented in research or analytical services laboratories the Batch Sample Login page represents the group of samples that are associated with a specific Request, Job or Submission.

### **Automatic Scheduling (OTS)**

This permits the scheduling of samples or reports based on a pre-defined time frequency. This is an ideal tool for scheduling environmental monitoring samples, routine calibration samples, management reports, etc. Scheduling frequencies can be simple (e.g. once every 'x' hours, once a day, once a week, etc.) or complex (e.g. the 2<sup>nd</sup> Tuesday of each quarter), so even the most complex scheduling rules can be accommodated.

### **Sample Receipt (OTS)**

Confirmation of sample receipt is essential whenever samples to be logged into WinLIMS by users who are not physically located within the laboratory or when samples automatically via automatic schedule or MRP/ERP interface. When this occurs WinLIMS will record when the laboratory receives the samples since testing cannot begin until the lab actually has the samples in-hand. The sample receipt function enables the laboratory to record when the sample was received and by whom. This information may be used to calculate laboratory turnaround times within management reports.

### **Barcode Sample Receipt (OTS)**

This performs the same function as the Sample Receipt function; however, instead of clicking on a form to identify the sample, a barcode label containing the sample's unique identifier would be scanned, to confirm receipt in a quick and efficient manner.

### **Work Allocation/Assignment (OTS)**

WinLIMS may be configured to automatically assign tests to lab groups or individual analysts. Tests that are automatically assigned may be easily re-assigned to by authorized users using a simple drag and click interface.

### **Analytical Worksheets/Test Batching (OTS)**

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.

### **Results Entry By Method (OTS)**

When laboratories assign their work to analysts by test method, the WinLIMS results entry by method function may be used. This function permits a user to select a specific test method and be instantly presented with a spreadsheet-like form that contains all samples for which results for the selected test have not been entered. Users then enter results for a large number of samples in an efficient manner.

### **Results Entry By Sample (OTS)**

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. WinLIMS 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 Crosstab (OTS)**

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 Crosstable 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.

### **QA/QC Batch Processing (OTS)**

The WinLIMS QA/QC option enables users to set up templates for automatic insertion and recording of quality control items such as blanks, spikes, duplicates and standards. This tool is used when it is essential that all analyses that are performed are organized within analytical batches that group series of samples together. These analytical batches are uniquely identified and associated with the instrument used to acquire the data. Within the batch, the positions at which all calibration, control, quality assurance and unknown samples are recorded and results are time and date stamped to provide a complete audit trail for analytical batches. The quality data is automatically associated with the selected instrument to provide a continuous control charting for all analytical equipment.

### **Results Validation (OTS)**

In many laboratories it is standard operating procedure to require results that were entered into WinLIMS 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.

### **Sample Approval (OTS)**

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 organisation know what was determined by virtue of the laboratory's testing of the sample.

### **Batch Approval (OTS)**

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



### **Product Re-grade (OTS)**

Product re-grade in association with 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.

### **Customer Specification Matching (OTS)**

Many companies manufacture bulk products, which are then sold on to a number of different customers. Many of these customers have differing specification and certificate of analysis requirements for the same bulk product. WinLIMS allows the creation of a QA manufacturing specification which is used for the release of the bulk product and then allows the creation and assignment of customers specifications to the QA specification. When an order is received for a bulk product, the customer can be selected and WinLIMS 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.

### **Statistical Graphing (OTS)**

Statistical graphing is available within WinLIMS. For example when reviewing a sample the user can highlight a result parameter and click the SQC Graph 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.

### **Instrument Calibration & Control (OTS)**

WinLIMS 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.

### **Document Control (OTS)**

The document control function is designed to integrate essential documents into any of the WinLIMS 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: spreadsheets, 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.

### **Automatic Email and Text Messaging (OTS)**

The LIMS Events feature allows emails, text messages and/or reports to be automatically issued whenever the status of a record changes. This feature greatly enhances the speed of information dissemination and eliminates time-consuming tasks. For example, LIMS Events can be used to inform staff members when a product fails to meet product specifications. It can also be used to automatically issue reports to customers and submitters when all testing has been completed and data review has been performed.

### **Full Audit Trails (OTS)**

WinLIMS complies with (FDA regulation 21 CFR Part 11) requirement for audit trails. Audit trails can be applied to any of the tables within WinLIMS 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.

### **Sample & Batch Certification (OTS)**

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.

### **Security & User Privileges (OTS)**

The security and user privileges manager allows the system administrator to determine the level of security that will be used by their WinLIMS 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 – Mandatory
- Layer 2: WinLIMS Application Access – Mandatory
- Layer 3: Site-Specific Access – Optional
- Layer 4: Training-Specific Access – Optional

### **LIMS Event Triggers & Actions (OTS)**

WinLIMS 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

### **Report Generation (OTS)**

QSI provides integration for Crystal Reports due to its ability to work with all of the WinLIMS supported databases, its powerful functionality and its affordable price. By virtue of utilizing an open architecture database, WinLIMS allows each laboratory to select the report generator which best suits their needs. Currently the report writers that are being used with WinLIMS™ includes IQ Objects, Business Objects, Access, Report Windows, Report Smith and more.

### **Sample & Batch Archiving (OTS)**

Although there is no limit to the size of a WinLIMS database, it may become prudent to remove data that is infrequently accessed from the active WinLIMS database in order to optimize database performance. WinLIMS includes a data archive function, which enables users to select samples for removal based on any sample identification field. This means that samples may be archived by date, product, project, etc. or any combination thereof.

### **Barcode Label Printing (OTS)**

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 WinLIMS user, the labels can contain both human readable text as well as barcodes.

### **WinLIMS Administration Tools (OTS)**

WinLIMS provides the system administrators with the following administration tools:



- Logins monitor
- License monitor
- Systems settings
- Privileges management

#### **Data Import & Export (OTS)**

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

#### **Derived Results Calculation Engine (OTS)**

Virtually all mathematical functions are supported, including Boolean algebra: functions such as [IF], [THEN] etc, especially useful when working in the GLP or GMP environments. The software's exceptional flexibility allows calculation routines that can use numeric values from anywhere within the WinLIMS tables, enabling techniques such as "cross sample" calculation, i.e. the ability to incorporate results from one sample in the calculation of results for another. An example of this might be the application of correction coefficients tracking the performance of an analysis against calibration standards to correct results "on the fly" at any time in a series of measurements.

#### **Batch Template Manager (OTS)**

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

#### **Mobile Apps (OTS)**

WinLIMS includes Mobile applications that can be used on any handheld device that supports a browser. Mobile applications make it possible for field samplers to create samples and enter results and readings that are taken during the sampling process. This feature is ideal for environmental labs as well as production facilities. Mobile Applications adds efficiency by eliminating duplication of effort while eliminating transcription errors. Labels (including barcodes) and worksheets can be pre-printed as the samples are remotely registered to eliminate the backlog of paperwork that is experienced upon sample delivery. In addition, by logging samples and field readings, the lab is given forewarning of incoming samples to efficiently schedule testing.

#### **Optional Modules**

Some features of WinLIMS are only required based on industry-specific needs. To accommodate these needs, several modules are optionally offered in order to reduce the system 'clutter' for those clients who do not have the need for these features. The following is a list of the optional modules. Some of these are simply 'switches' that turn the options on and off while others are purchased options.

#### **Results Entry By Instrument Acquisition (Optional)**

Interfacing instruments to WinLIMS™ improves the efficiency of laboratory staff members while reducing or eliminating data transposition errors. QSI's instrument interfacing software enables end users to configure their own interfaces to instruments or to files that are produced by instruments, spreadsheets or 3rd party data acquisition tools. This cost-effective option often provides the payback required to justify the purchase of your WinLIMS software.

#### **Shelf Life/Stability Study Management (Optional)**

Many laboratories test their products to see how they stand up over time when stored in a variety of environmental conditions. This type of testing is routine for within the pharmaceutical, food and beverage industries; however, chemical companies often have the same requirements. The WinLIMS stability testing





function is used to define testing protocols for both research and standard release products. Pull schedules, inventory reports, schedule adjustments and other useful functions are built into the WinLIMS stability to provide an effective means to manage the most demanding stability testing laboratories.

#### **Materials Stock Control (Optional)**

The consumables or materials that are used in the laboratory can be recorded within the materials table, including who the suppliers are, the costs, opening stock numbers, 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. For example, when preparing samples the consumables used will have the stock levels reduced accordingly. Once re-order levels have been reached, the user will be prompted by WinLIMS using the LIMS Events tool.

#### **Formulations & Recipe Control (Optional)**

Product and intermediate product formulations can be created within WinLIMS. 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 WinLIMS functions such as blend corrections or recipe pre-weigh.

#### **Training & Qualifications (Optional)**

The document control function is designed to integrate essential documents into any of the WinLIMS 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: spreadsheets, 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 cataloged automatically into the document manager rather than registered manually.

#### **Quotations & Invoicing (Optional)**

The quotation and invoice functionality 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.

#### **Complaints & Corrective Actions (Optional)**

The WinLIMS ccomplaint and ccorrective aaction ooption provides additional database tables, functions and reports that are used to log complaints from customers or to file problems associated with the production of products. Once logged, corrective actions, which have been implemented to resolve the complaint or problem, may be logged until the problem has been resolved.

#### **Centralized Multi-Site & Multi-Laboratory Control (Optional)**

The WinLIMS multi-site option is designed to enable a single WinLIMS implementation to restrict access to information and functions to individual laboratory groups. This is especially useful when operating multiple sites within a single database over a Wide Area Network.

#### **Site/Location Manager (Optional)**

The Sites/Location Manager assists with sample collection by recording the details and GPS co-ordinates of the sites and locations from which the samples are collected. The user can then assign a site from this list when registering a sample or batch.

#### **Materials Safety (Optional)**

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





### **Production Control Viewer (Optional)**

A stand alone WinLIMS application designed for plant personnel to quickly view laboratory data and statistical trends.

### **Electronic Signature (Optional)**

WinLIMS complies with (FDA regulation 21 CFR Part 11) requirement for electronic signatures. The electronic signatures 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 Split (Optional)**

The WinLIMS sample split 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. This is especially useful when a sample may be too large to test all at once, or may be required for testing at multiple laboratories.

### **Sample Merge/Composite (Optional)**

Sample collation enables users to manage many samples by merging them into one single sample. Sample must be part of the same batch in order to be collated into a single sample. This may be required where batch sample size are quite small and a more relevant and usable result could be acquired from a larger sample size.

### **Sensory Testing (Optional)**

The sensory functionality will hugely reduce the quantity of paperwork that is often involved in processing sensory results and virtually eliminate the transfer errors and bias that can be introduced when data is communicated verbally. "Data" in sensory testing is not just numerical – "degree of difference" etc.- but can also be panellists' comments, and both types of information can be collated, interpreted and ultimately reduced to a single result. Parameters are fully flexible and user defined, so it is easy to accommodate company or industry rules and conventions within the interpretation and reporting process.

### **Bi-directional Interfacing to MRP/ERP (Optional)**

Interfacing to third party applications such MRP/ERP is a common requirement; hence WinLIMS has interfacing capabilities which allows bi-directional links between the applications and WinLIMS. These interfaces can populate or share data with WinLIMS such as product formulations, product specifications, raw material and works order batch information, etc. Then WinLIMS can send data back to the systems such as batch status, batch additions, sample results, concessions, etc. WinLIMS has been successfully interfaced to SAP, JDE, Prism, Progress, and more.

### **Used Oil Analysis (Optional)**

The used oil analysis function maintains a tiered historical record for each piece of equipment and can monitor its condition against its own unique set of specifications. Totally flexible specification handling means that the system can accommodate different rules for different customers, changes in plant operations and other variables.



Reports can be generated to show current and historical data in tabular or graphical form, highlighting any out-of-spec results together with engineers' comments and any recommendations for maintenance action. In addition to the engineer's free text comments, predefined comments can be added to the report automatically when a parameter is outside specification limits, significantly speeding up sample processing.

### **Blending Control (Optional)**

The QSI blending module allows production departments to optimise a blend, not only in terms of product specification variables – like viscosity, for example – but also in terms of raw material cost, and can then use the laboratory testing data to perform blending corrections if necessary. These corrections can be carried out manually or automatically. At all times the production departments are able to interface directly to the optimizer via their own input screens, to define parameters like batch size and maintain overall control of the process.

### **GoToMeeting Demonstrations & Support**

The latest productivity enhancement from QSI, probably the most innovative of all the LIMS providers, is internet-based support via GoToMeeting. Unlike traditional modem-based on-line support, which can be slow, unreliable, and requires dedicated communications resources, GoToMeeting offers a browser-based, real time support solution that is fully interactive and provides fast problem resolution – effectively a support engineer on call immediately.

Files and applications can readily be exchanged between user and engineer – invaluable for tracking down bugs and those obscure problems that obstinately refuse to materialize on the supplier's copy of the system! The engineer can take control of the user's system or the customer can run applications for the engineer to view and diagnose problems.

In such situations security is obviously paramount, and the service works with existing firewall technology, enforces password protection and offers encryption to protect sensitive data.

The speed of interaction also facilitates training operations and the demonstration or implementation of software upgrades. Provided a user has access to a standard Windows™ browser, setting up the service takes only a couple of minutes.

### **QSI Corporation**

Quality Systems International is a leader in the supply of innovative LIMS (Laboratory Information Management System) software and associated consulting services, which together provide enterprise solutions for all laboratories. QSI believes that the success of our LIMS projects is largely due to the fact that we use no third party consultants or distributors and, as such, all divisions are wholly owned subsidiaries of the QSI Corporation. Corporate headquarters are in the USA with subsidiaries are located in the UK, Germany and The Netherlands.

Our goal is to expand our operations further around the world so that we can provide greater local support and enhanced communications to our clients. Through our research team we are continually exploring and assessing new technologies thereby advancing the capabilities of WinLIMS on all platforms.

QSI measures success not only by the number of systems sold, but also by the expansion of computing technologies within our client sites and the freedom of growth and invention that this brings.

QSI believes that the use of the modern technologies available both today and in the future will revolutionise working practices within the laboratory, and unchain technicians from their clipboard and desktop PC's. We envisage intelligent LIMS software continuing to help the integration of technology into the laboratory.



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## WinLIMS FUNCTIONAL FEATURE Functional Overview

Our commitment to continued innovation is reflected in our ongoing investment in research and development. In fact we have since 1993 allocated all profits to research and development. This commitment has continued and enhanced the development of our forms technology, and introduced web and portable technologies to the laboratory community in the form of the Web Client and Mobile Applications.

***Contact QSI today for a no obligation online demonstration!***

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