

# WinLIMS Shelf Life & Protocol Management

## INSIDE THIS ISSUE:

WinLIMS Protocol Management	1
Traditional Shelf Life Testing	1
Protocol Definition	2
Study Initiation	2
Results Entry and Data Review	3
Reporting	3
Automated Email and Reports	3
About QSI	4

## WinLIMS Protocol Management

Laboratory Informatics systems such as WinLIMS are designed to improve product quality and increase the efficiency of your staff by accurately acquiring data and converting it into information that is quickly disseminated to decision-makers and seamlessly passed to other software systems. The features provided by WinLIMS adds significantly to the bottom line of your organization by reducing production costs, eliminating bad shipments and saving countless lab, production and administrative staff hours.

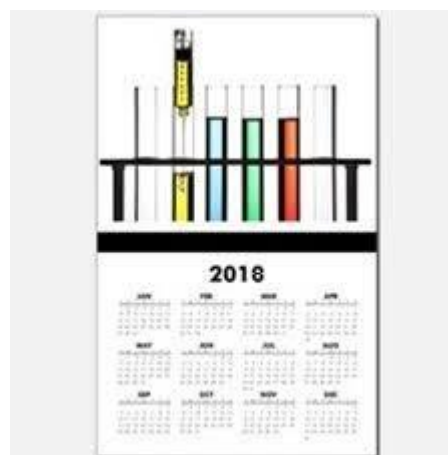
One of the industry-specific tools that can be implemented within WinLIMS is the Shelf Life & Protocol Management Option. This is a multi-purpose software tool used by organizations

that need to schedule multiple samples for testing either on a timed basis or on a pre-determined sampling cycle.

The Shelf Life & Protocol Management Option does more than schedule and organize samples for testing within labs that perform product shelf life (stability) studies in a variety of storage

conditions. It can also use the same time and condition-based protocol techniques to manage biological kinetic (metabolism) studies.

In addition, there are some protocol-driven sampling schedules that are event-based such as managing production batch testing protocols and/or managing routine field sampling protocols.



## Traditional Shelf Life Testing

Tools within a LIMS traditionally include the ability to define templates for protocols (product, pull times, storage conditions, storage quantities, etc.) that are repeatedly encountered.

When a product is ready to be placed into a stability study, it is scheduled within minutes by identifying the product, protocol, production (or research) lot number and study

start date. Upon initiating the study, all of the samples will be scheduled. Additional information such as the actual storage locations and quantities can be recorded as well.

## Special Features

WinLIMS includes the ability to manage the inventory and location of your shelf-life samples. This makes it easy to find samples when they're scheduled to be pulled for testing and you'll always know if you have enough samples available for testing.

Barcode labels can be printed and affixed to the Samples for positive identification. The WinLIMS Mobile App that runs on tablet PCs and smart phones can be used to quickly locate samples within storage facilities both on and off-site. The Mobile App can also be used to locate samples that are eligible for disposal and record disposal information.

Samples are organized by individual study using a unique identifier which allows quick access to related information for review within WinLIMS pages and/or within reports. Within each study, samples are clearly identified based on their pull time, storage condition and any other site-specific identifiers that you wish to use.

## Protocol Definition – Time or Batch Based

Test Suite	Hold Time	Time Units	Storage Condition	Plug Quantity	Storage Quantity	Storage Location	Storage Orientation
AMA (morphine)	0	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	1	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	3	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	6	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	9	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	12	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	18	MONTHS	Room Temp	2	200	Chamber #2	Vertical
AMA (morphine)	24	MONTHS	Room Temp	2	200	Chamber #2	Vertical

Protocols can be time or event based. The ability to create and approve protocol records is strictly controlled by the role-based security system. All records are audit trailed and version controlled to comply with all regulatory agencies and internal workflows.

Time-based protocols allow you to define nominal testing times in minute, hour, day, week, month or year intervals. You can define your own

storage conditions & cycles (e.g. freeze/thaw, accelerated, etc.) to accommodate your requirements. Storage amounts, locations, orientation and any other storage-related data can be included within the definition of a protocol where applicable.

The Protocol Manager also provides the ability to change the test assignments for each pull time and storage condition and also allows you to

change the allowable testing limits at specific pull times for those products where spec changes are permitted to as the product degrades over time.

Event-based protocols provides the ability to pre-define a set of samples that are always taken when performing a specific task such as the start of a production batch or a sampling pickup run within a plant or for a set of environmental samples.

## Study Initiation

Study initiation is a simple, time-saving process that creates multiple sample records in a matter of seconds. When creating time-based studies, the desired initiation date is assigned and this date is used to calculate the actual pull dates and

times for the associated samples by adding the nominal times to the initiation date (and time if applicable). Labels, with barcodes, can be printed upon initiation and affixed to the individual samples for easy retrieval from storage.

Once the study has begun, dashboard web parts, reports and automated notifications can be used to let you know when samples are due for testing to eliminate the possibility of missing any testing events.

## Results Entry and Data Review

Samples that have been created for a study are treated like any other WinLIMS sample so special training is not required for managing shelf life samples. The only real difference between shelf life samples and other WinLIMS samples is the additional information that is assigned to its record to identify the study, storage condition and pull time.

This means that all WinLIMS results entry tools can be used to record the measured results.

WinLIMS allows you to enter results:

- by Sample
- by Test Method
- by Worklist
- by Instrument Interface
- by Excel
- by Mobile App

The variety of data entry tools allows you to acquire data the most convenient means possible to further improve the efficiency of your laboratory.

Once the data has been entered it can undergo multiple levels of peer and supervisory review to ensure the integrity of the data prior to reporting. Once data has been reviewed it can be locked from further editing.

*Automated data entry into WinLIMS via direct instrument interface or through frequently used tools such as Microsoft Excel or hand-held applications add great efficiency to the laboratory. These tools are embraced by the laboratory staff by the elimination of mundane data entry tasks.*

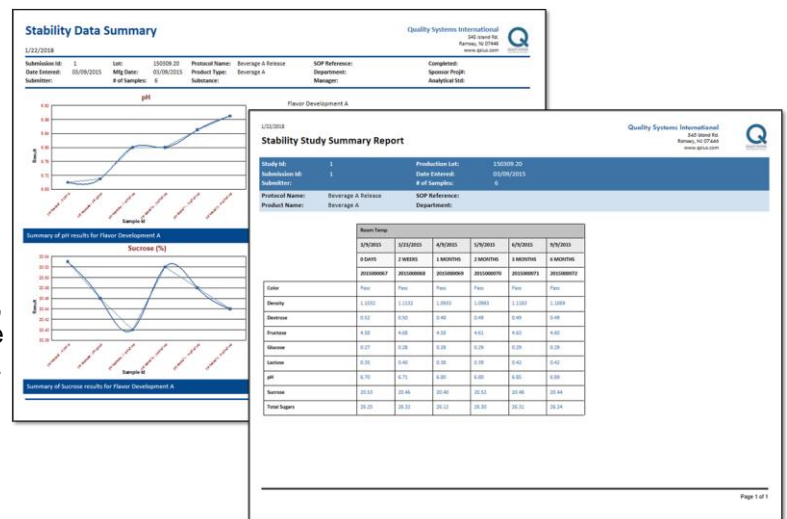
## Reporting

WinLIMS integrates the popular and powerful Crystal Reports software from SAP. QSI provides a variety of reports that you can use 'as is' or you can easily edit them to present the data in a format of your liking.

If you need a new report design, you can use the QSI Help Desk Service to have your WinLIMS project manager design them or you can design

them yourself. QSI provides training during system implementation to enable you to design your own reports.

If you have your own internal report design tool, you can use that too since WinLIMS uses either SQL Server or Oracle as its underlying database.



## Automated Email and Reports

An essential tool for time-based studies is the ability to be notified via email, text message, electronic or hard-copy reports when a significant time or event has occurred. The LIMS Event and Scheduler tools ensure that information is transmitted to the right

people at the right time. LIMS Events is a configurable tool that allows you to send notifications whenever user-defined conditions exist. For example, you may wish to send an email or text message to the

quality manager when a result exceeds testing limits or send an incremental study report as a PDF or Excel spreadsheet to a product manager whenever testing has been completed for each testing period.

*Automatic delivery of messages that provide warnings, general workflow information and reports enhance the quality of products by allowing informed decisions to be made on a timely basis.*

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## Automated Email and Reports (continued)

The LIMS Scheduler is used to send notifications (via email, text message or report) on a timed basis. For example, an email can be sent to inform users of the samples that need to be pulled for testing using a specified time period (e.g. daily, weekly, monthly, etc.) in order to simplify the scheduling of employees, equipment, lab supplies. Management reports that summarize the current status of each study can be automatically sent each week so they're waiting for you in your inbox at the start of each day or week.

Notifications on-demand is another feature that is included within WinLIMS. On demand notifications allow you to send reports or emails using a single click of a button to all of the people who are associated with a specific study.

This is a confirmation that the following sample has been approved:

Sample ID: 2016000064  
Lot/Batch#: 150309.20  
Seq#: 012  
Product Code: Beverage A  
Sample Description: Flavor Development A

Here's the link to the Sample record:  
<https://shafta.qsius.com/winlims/ahama/pages/sampleUpdate>

See more about noreply@qsius.com.

**Certificate of Conformance**  
Quality Systems International  
545 Island Rd  
Ramsey, NJ 07446

22-Jan-18

Item#: Beverage A  
Lot#: 150309.20  
Description: Flavor Development A  
Mfg#: 012  
Product Name: General Sweetened Beverage

Spec Status: PASS  
Logged: 8/10/2016  
Unit#: Tank 100

Parameter	Result	Unit	Specification Limit
pH	6.89		6.50 to 7.10
Density	1.1470	g/cc	1.0000 to 1.2000
Glucose	0.41	%	Max 0.70
Sucrose	19.68	%	18.00 to 22.00
Fructose	5.15	%	Max 6.00
Lactose	0.22	%	Max 0.70
Dextrose	0.40	%	Max 0.70
Total Sugars	25.89	%	24.00 to 28.00
Color	Pass		Pass

## About QSI Corporation

Quality Systems International is the world's leading innovator in LIMS (Laboratory Information Management System) software. Our WinLIMS software is used in over 800 organizations throughout the world to add productivity and savings by optimizing the flow of information to and through the laboratory. WinLIMS.NET provides the tools required to operate within fully comply with regulations such as FDA, GLP/GMP and EN 17025 or GLP / GMP while ensuring a productive laboratory

environment through the optimization of work processes.

The flexibility of WinLIMS allows it to be used in laboratories of all types (QC, R&D, Analytical Service, Commercial Testing, etc.) and in a variety of industries (Chemical, Pharma, Food & Beverage, Physical Testing, Petrochemical, etc.).

QSI's experienced employees have an understanding of both laboratory operations and software development. This combination of talents ensures our

customers that their needs can be translated into a successful and effective implementation. Personalized support and training ensure long-term payback for your investment.

By following the Agile approach to development and implementation, QSI has implemented hundreds of LIMS projects with great success on time and within budget. This demonstrable success clearly differentiates QSI from any other LIMS vendor!