



Laboratory Information Management



QLIMS

**Laboratory Information Management System –
Stability Module**

www.onqsoft.com.au

OnQ
software

Acknowledgments

This document includes information about QLIMS

© 1992-2015 OnQ Software Pty Ltd. All rights reserved.

The information in this document is subject to change without notice.

jQuery is a registered trademark of the jQuery Foundation

SQL Server is a registered trademark of the Microsoft Corporation.

Windows, Windows Server are registered trademarks of the Microsoft Corporation.

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT OWNER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

QLIMS Overview

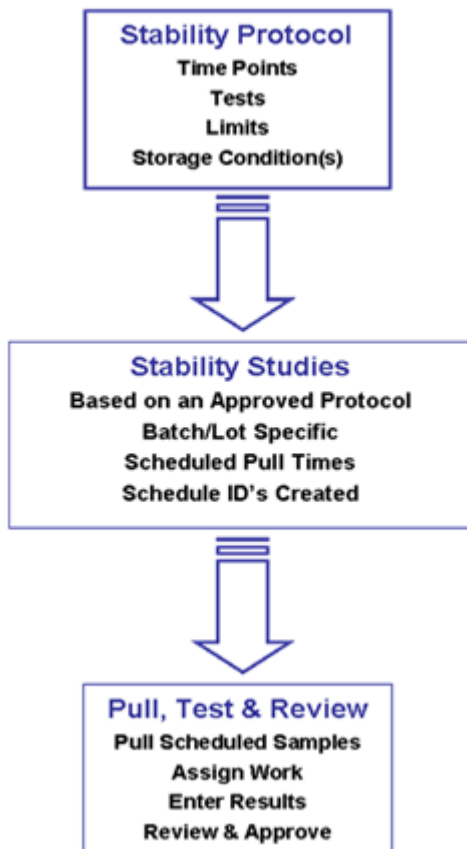
Do you monitor the shelf life stability of your products? If so, take a close look at the power of the **QLIMS** Stability Module, from **OnQ**. The Stability Module has been redesigned to provide maximum efficiency to the user through the use of an intuitive, user-friendly interface.

The Stability Module permits qualified users to create stability protocols and studies, initiate stability submissions, view status and summaries of stability samples and provide advanced scheduling by using a combination of reports and interactive screens. The Stability Module is fully integrated with the core **QLIMS** Package.

Pre-defined tests and limits are automatically pulled in from the standard **QLIMS** Sample Type Manager. By using a single source of defined tests and limits, the user can ensure consistency for all types of product testing.

If needed, the user can modify the tests that should be conducted at each of the time points. This is accommodated through a simple point-and-click interface that allows for maximum flexibility.

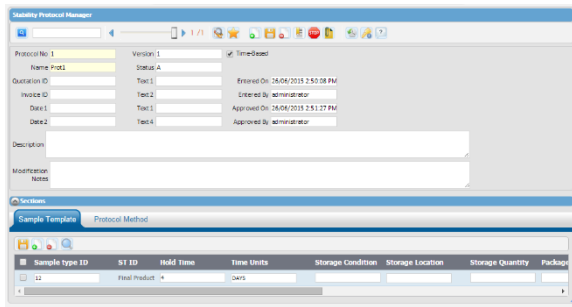
Combine the power of the Stability Module with the mobility of the **QLIMS** via use of your browser and **OnQ** allows you to have your...



Protocol Definition

Users can create a Stability Protocol that describes how samples are stored, when they are scheduled for testing, and exactly what testing is to be conducted. Most laboratories that require stability testing are subject to governmental regulations (e.g. FDA), an audit trail is automatically kept; recording who designed the protocol (and when), who approved the protocol (and when) along with the status (New, Approved, Obsolete) of the protocol.

Through the use of the newly designed point-and-click user interface, users can easily add time points and adjust the tests and limits associated with each station.



Within the protocol setup, users can fully describe the template, including Dosage, Container/Closure, Department and Purpose. When necessary, **OnQ** can customise the Stability Module to allow the user to track additional information.

All Stability Protocols are version and status controlled. Once a study has been created, it is given a Status of "N". This allows a supervisor or colleague to review the protocol prior to its use in creating a lot-based submission.

Once the Stability Protocol has been approved, the Status is changed to "A", indicating that it has been approved and is now ready for use in creating stability submissions.

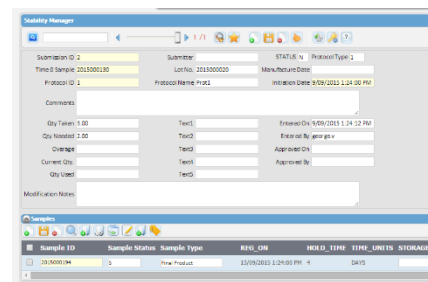
Should there be a need to change the protocol...perhaps due to a comment letter from the FDA, the user can simply create a new version of the Stability Protocol with the change(s). If a user wishes to add a new time point the user would simply duplicate one of the rows and update the Hold Time to reflect the additional requirement.

Once all of the changes have been made, the Protocol would be reviewed and approved by the appropriately authorised users. The previous version of the Protocol would be changed to "O" upon the approval of the now current version; this ensures full audit trail capabilities that are normally required by FDA.

When combined with the **Electronic Signature** option from **OnQ**, your organisation can be 21 CFR 11 compliant.

Stability Submission

After a Protocol has been approved, the user can begin creating lot-based Stability Submissions. When the user creates a Stability Submission, **QLIMS** uses the selected Stability Protocol (only approved ones are available) to generate the Sample ID's. The information associated with the Time Zero (T0) sample are automatically copied to each of the scheduled samples to ensure consistency of information throughout the study.



Just as with the Stability Protocol setup, Stability Submissions can also be approved by a supervisor or colleague. If desired, the status of the individual samples can be kept in a “Hold” status until the submission has been approved by an authorised individual. Changes made to Stability Submissions are local; in other words, the Stability Protocol is not affected, thereby giving the user ultimate flexibility.

When combined with the Electronic Signature option from **OnQ**, your organisation can be 21 CFR 11 compliant.

The Database and Reporting

QLIMS is a fully functional system that takes advantage of the latest Relational Database Management System (RDBMS) technology. By centralising information in the database, **QLIMS** provides an easy to implement and easy to use Stability Module.

Some of the database tables that are used by the Stability Module include:

- Protocol
- Study
- Submission
- Sample Type
- Sample
- Lookups

The Stability Module from **OnQ** is fully integrated with the standard Core Package.

Information regarding stability samples may be viewed in a wide variety of ways which is determined by the end user during the configuration process.

Contact Us

Australia

OnQ Software Pty Ltd

ABN 77 143 983 788

Omnico Business Centre Monash
Suite 4, Building 4
270 Ferntree Gully Road
NOTTING HILL, VIC 3168

PO Box 549 Brentford Square
FOREST HILL, VIC 3131

Telephone: +61 3 9501 9595
Fax: +61 3 9501 9585
Web: www.onqsoft.com.au
Sales: sales@onqsoft.com.au
Support: support@onqsoft.com.au

Singapore

OnQ Software

Level 30
6 Battery Road
Singapore 049909

Telephone: +65 6320 8595
Email: info@onqsoft.com.au

