

SQL*Stability™ Software: The LIMS Solution for Product Shelf-life Testing and Stability Studies

- Efficiently manage and easily execute sophisticated stability studies for research and development
- Speed up your time to market by streamlining your testing and regulatory compliance programs
- Seamlessly integrate with the SQL*QA™ and SQL*LIMS® software systems
- Maximize your return on products in development

The Leader for LIMS

Continuing as the leading global provider of laboratory information management solutions for the pharmaceutical, chemical, petrochemical, agriculture and food industries, Applied Biosystems offers SQL*Stability™ software.

Used to determine the expiration date of products that are released to market or used as ingredients to make a product, SQL*Stability™ software allows efficient management and easy execution of sophisticated stability studies for research and development.

The software can increase your productivity by helping you to develop your products faster, providing you with better regulatory compliance, and allowing you to introduce your products to the market faster.

To support new product development, SQL*Stability™ software provides project management, lot or batch product tracking, and stability testing on unlimited combinations of product packaging materials under a variety of



storage conditions. These features provide measurable R&D information on the resources used to manufacture your product. This information is invaluable in determining pricing and return on investment and in evaluating product efficiency support.

Seamless Integration with SQL*QA™ and SQL*LIMS® Software

Because SQL*Stability™ software is part of the SQL*LIMS® product offering, you get the added benefit of seamless integration to the SQL*QA™ application, as well as to the SQL*LIMS® software.

Since 1981, SQL*LIMS® software has been designed and implemented using Oracle's market leading RDBMS. SQL*LIMS® 4 software has been designed using the latest in Object Relational Database Design, Oracle8i™. Oracle8i™ is the foundation for delivering the highest level of RDBMS technology in the market today and is the platform for deliver-

ing web-enabled applications into the future.

At the touch of a button in the SQL*Stability™ application, you can view the time zero data or product genealogy data (ingredients) stored in the SQL*QA™ software. This integration is very valuable when using SQL*Stability™ software for your products.

To maintain regulatory compliance, products in production must be periodically placed on a stability study. SQL*Stability™ software enables the SQL*QA™ application to place active lots onto stability studies or to allow the SQL*Stability™ software user to select from a list of available SQL*QA™ application products.

This traceability allows you to completely control, gain access to, and interpret all the information necessary to release products.

Proven technology since 1991, SQL*Stability™ software was developed in collaboration with our informatics customers and is currently used in the pharmaceutical, agriculture, and food industries. It is a productivity tool that maximizes your return on products in development.

21 CFR Part 11 Compliance

In addition, we designed SQL*Stability™ software to meet the demanding challenges of the U.S. Department of Health and Human Services Food and Drug Administration (FDA) electronic records rule, 21 CFR 11.

SQL*Stability™ software and SQL*LIMS® software both provide a complete audit trail and electronic signature for data. In addition, you can implement full method version control and genealogy with approval and electronic signature.

Track the Life Cycle of your Stability Studies

Stability testing usually involves monitoring a product's stability over a period of many years. Any project of this duration is difficult to manage effectively, as personnel, procedures, regulations, and priorities change. The combination of business rules and audit trail in SQL*Stability™ software gives you the control you need to manage long-term and follow-up studies of established products.

SQL*Stability™ software includes functions that control the study life cycle in a simple and logical fashion. You can perform surveillance testing, converging studies, R&D studies, cycling testing, and marketed product conformance testing (see figure 1).

Project managers use SQL*Stability™ software to create, approve, and initiate a study. These automated management functions help document

and manage validation plans while providing consistency, change control, and automation throughout the entire life cycle of the study.

During the course of a study, you can replace or change a product's packaging or storage condition — a necessity for cycling testing or exception handling.

All Your Stability Information at Your Fingertips

SQL*Stability™ software provides a tab-folder interface that enables you to build a stability study to mirror your

standard operating procedures and meet your needs in product shelf-life testing. The hierarchical relationship of the stability study objects includes:

- Project tracking
- Study description
- Lots or products to test
- Packaging types (containers)
- Storage conditions
- Time points (testing schedule)
- Work groups of users/laboratories
- Testing profiles

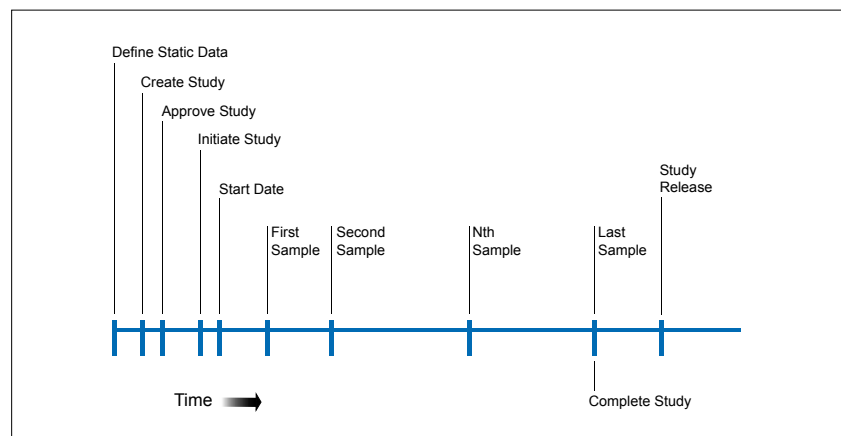


Figure 1. The life cycle of a stability study.

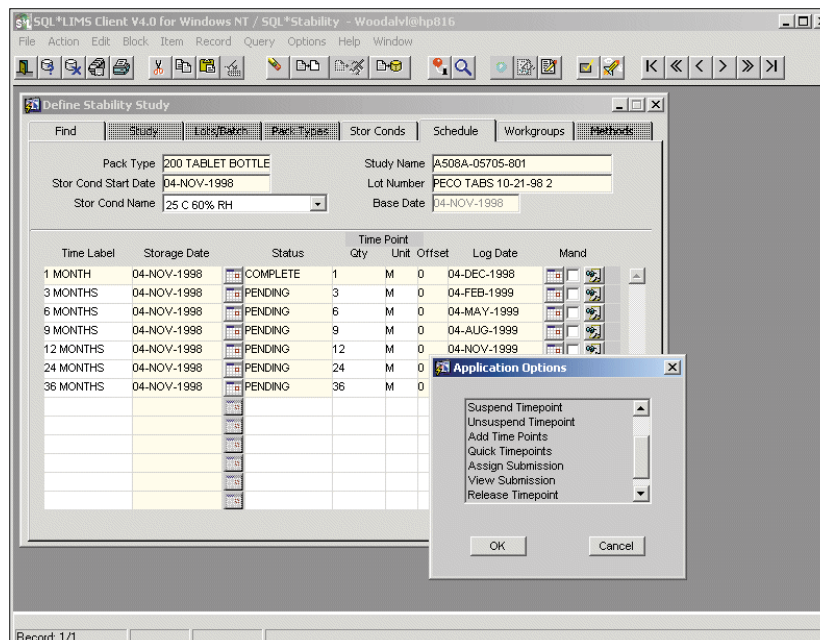


Figure 2. SQL*Stability™ software provides a tab-folder interface that enables you to build a stability study to mirror your standard operating procedures and meet your needs in product shelf-life testing.

You can pre-define packaging materials, storage conditions, sampling time schemes, and projects to provide consistent and correct configuration of your studies.

You can also define stability start dates and end dates at various object levels. Integration with SQL*LIMS® software allows you to utilize work-groups (groups of users), certified testing profiles, multiple specification handling, and other features.

You can create template stability studies that can be used as models for creating studies for routine or similar product testing. Template studies provide a rapid study definition mechanism for configuring both simple and complex tests. After a stability study is approved, you can determine the degree of change control and auditing for a given study.

Controlling a SQL*Stability Study

A spreadsheet window provides an overall view of your stability study where you can see the samples pulled and the associated tests and results. You can view all the time points by storage condition, starting at the date of your stability study. This allows you to drill down on the actual results or scroll to previous or future time points.

The Control Study window enables the stability manager to enter, approve, modify, and view all the information associated with a time point.

Dynamically Create Reports Anywhere Within the Application

The application offers complete secured access to all information stored in the Oracle® database. SQL*Stability™ software is provided with Oracle Reports™ software and a number of example reports. Dynamic reports allow you to execute a report

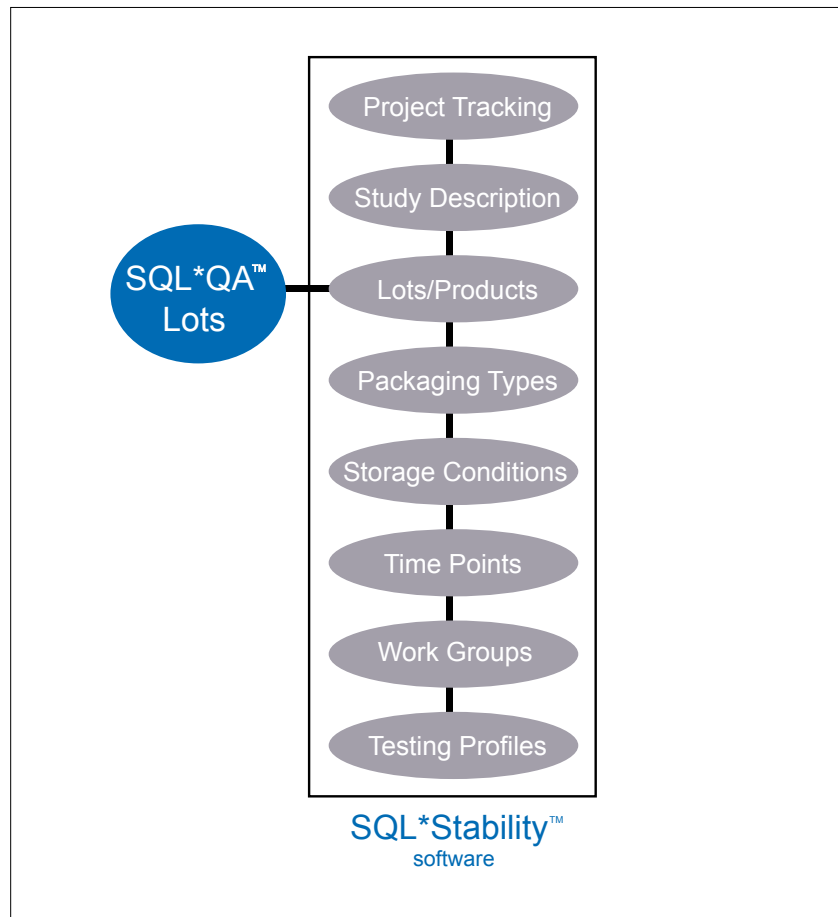


Figure 3. SQL*QA™ and SQL*Stability™ provide a seamless integrated solution for QA needs within a stability environment.

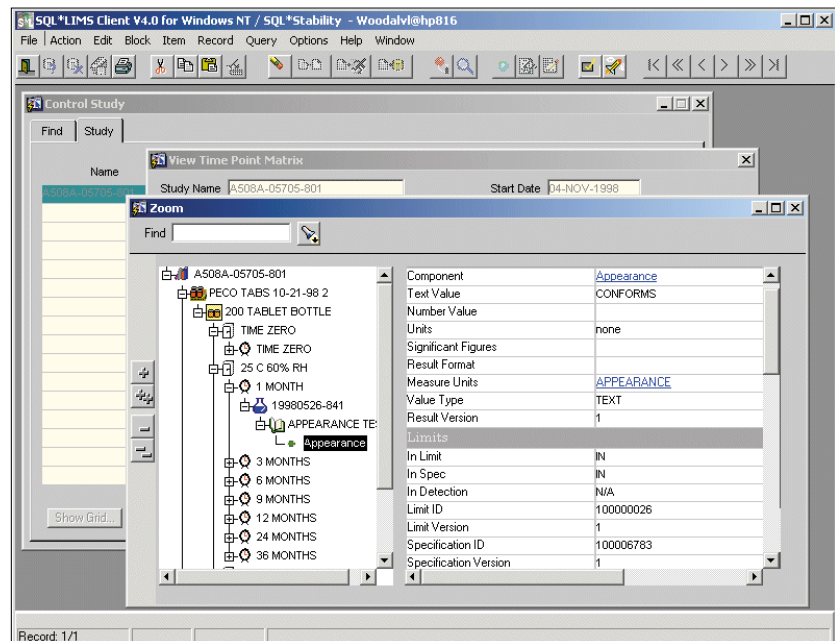


Figure 4. The Control Study window enables the stability manager to enter, approve, modify, and view all the information associated with a time point.

