ChemLMS
Add-On Module

IIM
Integrated Information Management

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HP ChemStudy Windows NT® Client Stability Shelf-Life Application

The HP ChemStudy NT client stability shelf-life application, developed for HP ChemLMS laboratory information management systems (LIMS), lets you automate the stability shelf-life process from the definition of the study protocol through product testing and data archival. HP has taken Chem Study, a proven application since 1994, and has combined the best of both worlds by offering HP ChemStudy with an NT client. Customers can now take advantage of increased productivity by leveraging the familiarity and ease of use of the Windows graphical user interface.

HP ChemStudy makes it easy to draft and review study protocols, initiate studies, conduct study sample testing, report findings, query study and sample information, handle approvals, and archive results.

A comprehensive approach to stability shelf-life study planning and study execution

While other systems can help you manage sample testing and data treatment, HP ChemStudy lets you plan your study from the start. This means you can structure your entire stability study process to match your protocol. You also can check your data against your plan at any point in the cycle.

HP ChemStudy is so flexible that you can adapt your study design and execution to comply with virtually any kind of regulatory guidelines. This is particularly valuable to companies that are doing business in various countries and are governed by evolving and even competing regulations.

Audit Trail and Secure Data Repository Enhance Compliance

To ensure legal and regulatory requirements associated with stability shelf-life studies are met, HP ChemStudy and an Oracle® database provide a secure, audited repository for study data that can be shared throughout the laboratory. In addition to serving as the single source of information for all aspects of the study plan and execution, HP ChemStudy offers two approaches to auditing.

The first is a value-based audit trail that automatically records any changes, notes who made them and when. The other is a time-slice revision audit trail that stores every revision of the study protocol continuously. This means you can substantiate the status of the protocol at any point in time and include all pertinent data regarding alterations during the entire life of the study. The net result is an automated plan that's secured, consistent, reliable, and clearly documented under audit trail control.

Improve Consistency by Defining Protocols Automatically

What would be impossible using a manual or paper-based system can be accomplished with a few keystrokes using HP ChemStudy. A Windows® graphical user interface (GUI) lets you create and manage your protocol quickly and easily. You can load a pre-defined study structure or build your own. Screens pop up in logical succession to prompt you through the process of filling in attributes, definitions, events, and reviewers.

Figure 1.
Four Phases of the Stability Study.

There's even a section to record all the regulations that apply to your protocol. These user-defined templates accelerate study protocol development dramatically. You also can copy existing studies, both format and content, to create a new study protocol. Either approach enables you to maintain consistency from study to study.

Link Test Material, Study, and Sample Information

Maintaining a relationship between the study test protocol and the test materials is vital to the integrity of any stability study. After you set up your study protocol plan, the software steps you through a series of screens that let you tie your data and your plan to the materials under test. You assign study lot(s), define products and packaging, and create information for each new batch. Even complex composite products and batches, consisting of multiple components, can be fully defined and tracked within the ChemStudy stability database. And, because the database maintains ChemLMS LIMS sample information it serves as a common reporting and query environment that lets you combine study information, test materials information, and sample test results.

Manage Test Materials Throughout the Study

Test materials management is handled automatically from the moment you initiate the study until its completion years later. Once you have defined your production batches and manufacturing lots, the software helps you plan test material storage and track test material inventories. You simply associate the materials with each study condition within your various storage chambers.

The software calculates the minimum amount of test materials required to complete the study for each storage condition. By tracking the materials removed at each pull interval, HP ChemStudy lets you maintain an accurate estimate of study materials in storage.

Working in a Logical Progression

HP ChemStudy enables you to create your study protocol and construct a secure record of all the information you accumulate during the four phases of the stability study cycle. The software is designed to match the way the cycle progresses beginning with the initial drafting of the protocol through final approval and archival.

Phase 1: Draft and Review Protocol

Study Definition

Using templates or copying existing studies, you can create your protocol quickly and easily. The software lets you define the following essential protocol elements:

- study title
- product under test
- protocol access permission
- four pages of study text
- study name alias
- project name for study

Study Regulations

Next, you can record regulations in effect for the duration of the study. By including references to regulations, standard operating procedures (SOPs), and corporate

specifications within the application, you can access them at any time for reporting or query.

Reviewers, Validators, and Approvers

Those responsible for reviewing and endorsing the study can also be included in the process. Lists of personnel authorized to review or amend a protocol or final approve a completed study are maintained by the system. You have the option of specifying mandatory and optional participants in the review, validation, and approval processes.

Study Attributes

Study attributes are descriptive fields of information assigned to the study for reporting or query purposes. The software accepts both numeric and textual attributions. HP ChemStudy lets you assign any number of attributes you wish to create many different study protocol formats.

Protocol Events

Protocol events enable you to define future activities within the protocol definition. The software allows for an unlimited number of study events to be defined. Experienced users create event macros that can be triggered by study protocol status transitions or changes in attribute values.

Phase Two: Initiate Study

Assign Study Lots

Once you have defined the protocol, you may assign one or more product manufacturing lots to establish a relationship between the protocol and the test materials. Specific sampling schedules, storage chamber load plans, inventory pull plans, and schedule events can be set up for each lot. You also can amend your protocol and add more study lots whenever necessary.

Study Scheduling

Using a convenient two-dimensional matrix panel, you can define storage condition and time point interval schedules for each study lot. The software automatically links the HP ChemLMS LIMS test procedures to each interval you assign. Each condition/time point interval represents one study sample to be logged into ChemLMS LIMS. Another plus within HP ChemStudy is the ability to tailor LIMS study sample login activity for each study schedule.

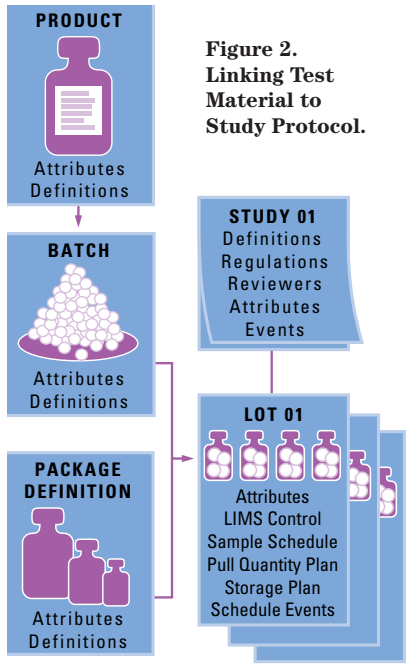

Figure 2. Linking Test Material to Study Protocol.

Schedule Storage and Inventory Plans

As you move through the scheduling process, the software lets you define both a storage and an inventory plan for your test materials. You can associate storage chambers and locations with each study schedule storage condition. The minimum storage amounts required to complete the study are automatically computed and displayed. The software even provides a storage multiplier that increases the amount of test material stored for the study by a fixed factor.

Likewise, you can define the amount of test material to pull from all your storage chambers at each time interval. Here, too, the software computes and displays the quantity of test material required by the procedures conducted at that interval. You can either accept a default minimum or increase the quantity.

Schedule Events

You also can define schedule events to establish future activities that are to take place during the study. The software lets you specify any interval, not just those times that correspond to condition/timepoints established in the sampling plan.

Phase Three: Sample Testing and Data Management

Study protocol creation, amendment and review are managed centrally through the Study Home screen. Although the protocol can be amended by any user who has

write access without calling up the audit trail function during the "draft submitted" stage, any amendment that takes place after the protocol has been reviewed will automatically invoke audit trail. If changes are extensive, the software may generate a new protocol revision. A complete record of all revisions is maintained including the user name, date, time, and a mandatory audit comment.

The software's Pull Sheet report links all study samples and their associated intervals within a specific window of time. In addition to identifying the study, the report calls up the storage location and pull quantity for each qualifying study time interval and condition. The report can trigger automatic study sample login to HP ChemLMS, or defer that activity until samples have been pulled. Study test procedures are scheduled during login and the LIMS automatically updates HP ChemStudy protocols with key information concerning each study's LIMS samples.

Phase Four: Study Approval and Archival

The software manages each study through a progression of study states. Once all scheduled samples have been analyzed and approved or canceled in HP ChemLMS, HP ChemStudy promotes the study to completed status where the list of approvers can review the study plan and data.

After the study has been approved, the protocol and related LIMS sample data can be archived to off-line media for secure long-term storage.

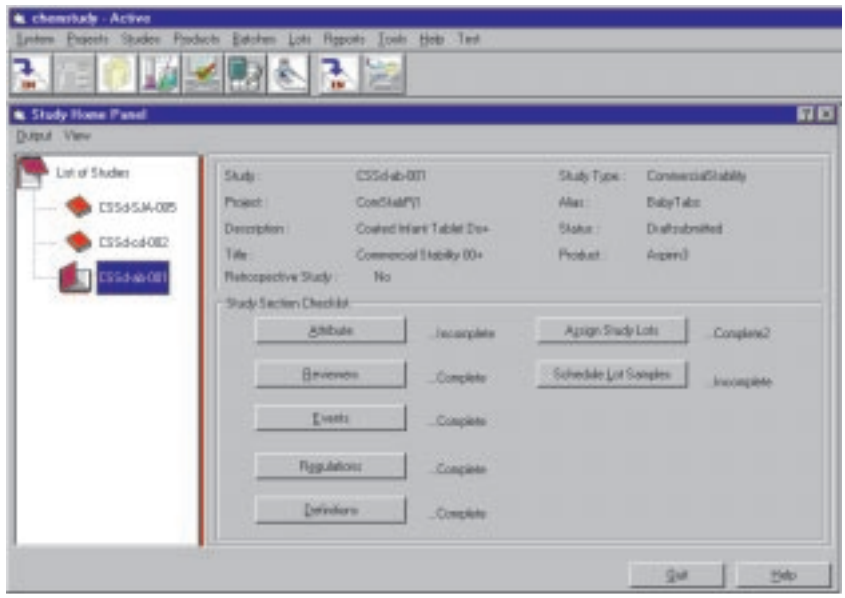

Figure 3. Study Home Screen.

A Single Source for Comprehensive Reporting

Because HP ChemStudy provides a single source of information about the study plan, the status, and sample information, you can develop com-prehensive reports for corporate management, regulatory agencies, and other interested parties. Popular data treatment tools such as SPSS, SAS and RS/1 provide SQL-compliant access to read study information and store statistical results to HP ChemStudy and HP ChemLMS. Industry-standard report generators such as Platinum InfoReports and Oracle Reports™ can be used to further enhance report writing capabilities.

HP's Strong Support Services Keep You on Track

HP ChemStudy and HP ChemLMS are backed by HP's dedication to quality and support. An experienced team of systems integration professionals are available worldwide to take care of any needs you may have. As a leading manufacturer of analytical instruments and laboratory data systems, HP has a deep understanding of what it takes to succeed in your business.

For more information on HP ChemStudy, contact your local HP office and ask for a chemical analysis sales representative or visit www.hp.com/go/chem

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