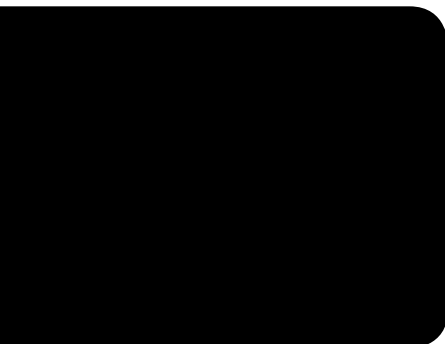




Stability Lab Information Manager



SLIM is a Fully Validated, World-Class Stability LIMS.

SLIM combines the ease of use of browser style user interface and industry standard document technology based reporting with the speed, power, and capacity of a true client/server application. This combination of features will assist in regulatory approval, minimize training requirements and operator errors, and ensure that your drug stability studies are managed with the utmost efficiency.

SLIM includes the following unique combination of functional areas:

- Stability and Formulation databases
- Flexible calendar functions
- Inventory management
- Resource scheduling
- Shelf-life prediction and trend analysis
- 21 CFR Part 11 Compliant features
- Available for Oracle and MS SQL Server

Each SLIM purchase includes on-site installation, training, and support including a year of free maintenance.

The Intuitive, Interactive, Intelligent Way to Manage Your Stability Program.

As you intuitively browse through SLIM, you can tell immediately that user training will be minimal. Just click on a folder to view the contents of that folder (e.g., Clients have Products, which have Formulations, which have Batches, which have Studies, etc.). Property sheets have a comfortable look and feel to them. Data entry (Lab Work Request) forms look the same on the screen as they do when they are printed. Interactive reports have links throughout the database. Just click and go!

SLIM is the state-of-the-art client/server LIMS

(laboratory information management system) for complete management of your drug stability program. From the design of stability study protocols to statistical analysis and presentation of final data for FDA submission, your stability data could not be better managed.

Database Management on Your Desktop, Over a Network, or Around the World.

SLIM is a true client/server application written using Microsoft Visual C++ . The client software runs on modern Windows operating systems such as Windows XP or Windows Vista. The server software is designed for Oracle (version 10g or later) or Microsoft SQL Server (2000 or 2005).

SLIM can easily manage thousands of studies with exceptional speed operating on a standalone PC, on a local area network (LAN), or across the world with different facilities accessing a central SLIM database. SLIM has demonstrated excellent performance over Wide Area Networks, as well as Terminal Server/Citrix and with LDAP Authentication/Active Directory.

We're Proud of Our Quality Validation System.

We work together to maintain compliance with FDA guidelines for software development and validation of our product. By appointment, you are welcome to visit and/or audit our corporate headquarters in Greenville, North Carolina.

SLIM and SLIMStat+ have been validated according to the current GAMP (Good Automated Manufacturing Practices) guidelines. Fundamental points addressed in our Quality System are:

- Production, control, and issue of SOPs and General Documents
- Quality and Project Plans
- Complete functional specifications and design documents
- Configuration management
- Documented software testing
- Change control
- Maintenance plans

Additional on-site validation services are available.

Training and Support to Get You Started and Keep You Going.

With every SLIM purchase, we provide a turn-key implementation that includes installation (including execution of IQ protocols), two days on-site training, and a standard operating procedures template. After installation, we provide telephone and e-mail support from our help desk.

We also offer additional consulting services in the form of data conversions from existing stability systems as well as User Acceptance test documents.

Data Review and Reports

- The extensive report architecture features, such as filtering and sorting of tabular reports, provide powerful tools for customization of reports.
- Interactive forms and reports with links to original data are available.
- Prepares a variety of reports including submission-ready stability reports.
- Out-Of-Spec (OOS) results report is automatically generated, which includes automatic highlighting of OOS results.
- Selected tabular data may be saved to the clipboard for exporting into other applications or data may be exported directly from SLIM into Microsoft Word or Excel.
- Print to PDF is supported.

The screenshot shows the SLIM software interface with a data table. The table has columns for Product, Batch, Lot, and various test results. A 'Details' pop-up window is visible over the table, showing fields for Name, Filter, File Inclusion, and Action.

Product	Batch	Lot	Test	Value	Spec	Unit	Method
Study A	Conform	Conform	Impurity A	0.0	0.0	%	015-D-2
Study A	Conform	Conform	Impurity B	0.0	0.0	%	015-D-2
Study A	Conform	Conform	Impurity C	0.0	0.0	%	015-D-2
Study A	Conform	Conform	Total Impurities	0.0	0.0	%	015-D-2

The screenshot shows the SLIM software interface displaying a 'Specification Alert Report' for Study A. The report includes details about the product, batch, and test results, with a table of results showing values and specifications.

Specification Alert Report

Study: Study A
Product: Product A --- Brown, inactive, solid, sterile tablets. A1C1 segregated on one side and XYZ engraved on the other.
Coordination: John Doe
Batch: Batch A
Purpose: Development
Expiry Date: (not specified)
Formulation: Formulation A
Description: (not specified)
Test Category: Impurities & Degradative Products
Storage Condition: 25°C ± 2°C/60% RH ± 5% RH
Storage Time: 12 month

Test Fields	Specifications	Nominal	Units
Impurity A	n=0.0		%
Impurity B	n=0.2		%
Impurity C	n=0.2		%
Individual Impurities	n=0.2		%
Total Impurities	n=1.0		%

Results

Field: Impurity A	Storage Condition	Storage Time	Value	Spec. Fail	Comment	Method
	(not stored)	Initial	+0.0			015-D-2
	25°C ± 2°C/60% RH ± 5% RH	3 month	+0.0			015-D-2
	25°C ± 2°C/60% RH ± 5% RH	6 month	+0.0			015-D-2
	25°C ± 2°C/60% RH ± 5% RH	9 month	0.4			015-D-2
	25°C ± 2°C/60% RH ± 5% RH	12 month	0.8			015-D-2
					Total Impurities: Refer to OOS	015-D-2
					Investigation TOTAL	015-D-2
					AMPLIMITS: 1234.233.23	015-D-2

Field: Impurity B

Storage Condition	Storage Time	Value	Spec. Fail	Comment	Method
(not stored)	Initial	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	3 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	6 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	9 month	0.1			015-D-2
25°C ± 2°C/60% RH ± 5% RH	12 month	0.2			015-D-2
				Total Impurities: Refer to OOS	015-D-2
				Investigation TOTAL	015-D-2
				AMPLIMITS: 1234.233.23	015-D-2

Field: Impurity C

Storage Condition	Storage Time	Value	Spec. Fail	Comment	Method
(not stored)	Initial	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	3 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	6 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	9 month	0.1			015-D-2
25°C ± 2°C/60% RH ± 5% RH	12 month	0.2			015-D-2
				Total Impurities: Refer to OOS	015-D-2
				Investigation TOTAL	015-D-2
				AMPLIMITS: 1234.233.23	015-D-2

Field: Individual Impurities

Storage Condition	Storage Time	Value	Spec. Fail	Comment	Method
(not stored)	Initial	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	3 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	6 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	9 month	0.1			015-D-2
25°C ± 2°C/60% RH ± 5% RH	12 month	0.2			015-D-2
				Total Impurities: Refer to OOS	015-D-2
				Investigation TOTAL	015-D-2
				AMPLIMITS: 1234.233.23	015-D-2

Field: Total Impurities

Storage Condition	Storage Time	Value	Spec. Fail	Comment	Method
(not stored)	Initial	+1.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	3 month	+0.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	6 month	+1.0			015-D-2
25°C ± 2°C/60% RH ± 5% RH	9 month	0.7			015-D-2
25°C ± 2°C/60% RH ± 5% RH	12 month	1.2	Y		015-D-2
				Total Impurities: Refer to OOS	015-D-2
				Investigation TOTAL	015-D-2
				AMPLIMITS: 1234.233.23	015-D-2

SLIM Report Generator
File Edit View Help

Database: SLIM Server Version 3.4.0 Report generated: Jul 06, 2007 1:34:46 PM

Study A Stability Summary for Generic Pharma

Product / Strength: Mfg. To / From: Batch Size: Purpose of Study: Expiration Date: Active Ingredient (API): API Mfg. / Lot # / Exp: Test Location(s):	Product A: Bulk Drug Manufacturing Site Canada 50,000 tablets Development TSD API Supplier / API 010-12 Chemistry, Microbiology	Batch A / Feb 15, 2005: Packaging / Size: Study Start Date: Study Duration: Container / Supplier: Closure / Supplier:
---	--	---

Batch A / Feb 15, 2005: Location: North Carolina Mar 01, 2005 Mar 18, 2005 40 months C/C Batch ICQPE container / Packaging Supplier Ck/Lot ID: Packaging Supplier
--

Stability Conditions / Orientation: 23°C ± 2°C/90% RH ± 5% RH

Test	Method	Acceptance Criteria	Stability Intervals				
			Initial	3 month	6 month	9 month	12 month
Appearance - Packaging - Visual	Visual	40°C when ICQPE container with Ck/Lot on 02. 2 pieces held overnight. Return with/lot	Conforms	Conforms	Conforms	Conforms	Conforms
Appearance - Tablets - Visual - color	Visual	Discoloration, staining, efflorescence, cracking, etc. All tablets inspected on each side and 100% inspected on the other.	Conforms	Conforms	Conforms	Conforms	Does not conform: 06 = 100%, staining, efflorescence, etc. 06 = 100% tablets (DOE)
Moisture - H ₂ O	H ₂ O, Bar 1	± 0.1% (Average)	0.1	0.7	1.8	0.7	1.7 (DOE) [1]
Active 1 Assay - HPLC-A-9154C-815-A-4	HPLC-A-9154C-815-A-4	99.9 to 100.0%	97.7	99.1	99.3	99.0	99.1
Active 1 Degradation - HPLC-A-1915-815-C-1	HPLC-A-1915-815-C-1	± 0.0%	0.0	0.0	0.0	0.0	0.0 [1]
Active 1 Degradation - HPLC-A-1915-815-B-4	HPLC-A-1915-815-B-4	(N/A) (N/A)	96.10	99.106	99.10	99.10	1.42 (DOE) [1]
Injection B - Degradation Products - Injection A	HPLC-D-2	≤ 0.4%	0.0	0.0	0.0	0.4	0.0 [2]

Page 1 of 2 SLIM Report Generator Version 2.2.0

SLIM Report Generator
File Edit View Help

Database: SLIM Server Version 3.4.0 Report generated: Jul 06, 2007 1:34:46 PM

Study A Stability Summary for Generic Pharma

Stability Conditions / Orientation: 23°C ± 2°C/90% RH ± 5% RH

Test	Method	Acceptance Criteria	Stability Intervals				
			Initial	3 month	6 month	9 month	12 month
Injection B - Degradation Products - Injection B	HPLC-D-2	≤ 0.2%	0.0	0.0	0.0	0.0	0.0 [1]
Injection C - Degradation Products - Injection C	HPLC-D-2	≤ 0.1%	0.0	0.0	0.0	0.0	0.0 [1]
Injection D - Degradation Products - Total Injections	HPLC-D-2	≤ 0.3%	0.0	0.0	0.0	0.0	0.0 [1]
Injection B - Degradation Products - Total Injections	HPLC-D-2	≤ 1.0%	0.0	0.0	0.0	0.7	1.7 (DOE) [1]
Moisture - H ₂ O	H ₂ O, Bar 1	± 0.1%	0.0	0.0	0.0	0.0	0.0

Comments

1	Refer to DOE for instructions: APPEARANCE - TABLETS 06/15/05/12
2	Refer to DOE for instructions: RAREFIED 06/15/05/12
3	HPLC-A-4 Refer to DOE for instructions: ACTIVE 1 (DEGRADATION) 06/15/05/12
4	Total Injections: Refer to DOE for instructions: TOTAL IMPURITIES 06/15/05/12

Report Options

General: Filter: Stability Summary Stability Summary (cont.) Alternate Stability Summary

Options:

Show Approved Only Show Only Active Results Add Signatures Section

Show Shading Show Comments Add Inadequate Potencies

Show Abbreviated Header Show OVR Information Show Scheduled Dates

Exclude Comments Special Instructions Show Shaded Title

Group Packaging Items Add Company Name

Show Full Dates: Show No Full Dates

Show Test Dates: Show 6 Month

Number of Intervals Per Page:

OK Cancel

Page 2 of 2

Result Entry, Verification & Approval

- The Lab Work Request (LWR) data entry forms are interactive forms that allow the user to enter results on screen into forms that look exactly like the printed forms.
- LWR forms are dynamically built, thus if you add a test to a protocol the test immediately appears on the LWR form.
- Data passes through draft, entry, verification, and approval states.
- Optional electronic signatures can be turned on for entry, verification, and approval.

The screenshot displays the SLIM LWR form interface within a web browser window. The browser title is "SLIM - [LWR #100002]". The form is titled "Stability LWR Form - (100002)" and was generated on Jul 06, 2007 at 09:30 AM. The client is CerPharm Inc., and the product is Product A. The LWR status is "Approved Nov 17, 2005 11:09:05 by Amy Lee Hudson".

The form is divided into sections for different tests:

- Appearance - Packaging:**
 - Units: Conforms
 - Failed specifications?
 - Specifications: 40 CC white HDPE container with Clic-Lec II, 2 piece child resistant closure with liner
 - Visual: [Empty text box]
 - Comments: [Empty text box]
 - Performing Analyst: John Doe
 - Method Reference: Visual
 - Verifying Analyst: Peter
 - Notebook Reference: NB01
 - Date Tested: Mar 18, 2005
 - Test Status: Approved
- Appearance - Tablets:**
 - Units: Conforms
 - Failed specifications?
 - Specifications: Brown, marbled, oblong, oval, divisible tablets. ABC engraved on one side and XYZ engraved on the other.
 - Visual/odor: [Empty text box]
 - Comments: [Empty text box]
 - Performing Analyst: John Doe
 - Method Reference: Visual
 - Verifying Analyst: Peter
 - Notebook Reference: NB02
 - Date Tested: Mar 18, 2005
 - Test Status: Approved
- Hardness:**
 - Units: 6.3
 - Failed specifications?
 - Specifications: 10-4.0, n=5.0
 - Visual/odor: [Empty text box]
 - Comments: [Empty text box]

The form is labeled "Page 1 of 3" at the bottom. The browser's taskbar at the bottom shows the Windows XP desktop with various applications open, including Microsoft Office and Microsoft SQL Server.

Flexible Calendar Functions

- Multi-laboratory scheduling of tests
- Generates weekly testing schedules, long term forecasts, and late lists.
- Easily creates product-specific or test-specific schedules.
- Instrument/resource allocations are tracked.
- Highlights scheduled pull dates which are late.
- E-mail notification

SLIM - [Stability Calendar for all accessible labs through Aug 03, 2007]

Product	Test Category	Scheduled	Study	LWR #	Condition	Interval	Study Status
Product A	Appearance - Packaging	Mar 15, 2007	Study F	102932	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Moisture			103102	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Active 1 Assay			102932	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
				103102	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Moisture			102932	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Appearance - Packaging			103102	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Appearance - Tablets	Mar 18, 2007	Study A	102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
				100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Active 1 Dissolution			100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Microbial Limits			100212	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Active 1 Assay			102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Hardness			102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Moisture			100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Appearance - Packaging			102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
				100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Active 1 Dissolution			102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Hardness			100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
	Moisture			102562	30°C ± 2°C/65% RH ± 5% RH	24 month	Active
	Active 1 Assay			100062	25°C ± 2°C/60% RH ± 5% RH	24 month	Active
			Apr 05, 2007	Study D	102762	40°C ± 2°C/75% RH ± 5% RH	6 month
Moisture			102762	40°C ± 2°C/75% RH ± 5% RH	6 month	Active	
Impurities & Degradation Products				102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
				102762	40°C ± 2°C/75% RH ± 5% RH	6 month	Active
	Active 1 Dissolution			102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
	Appearance - Tablets			102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
	Appearance - Packaging			102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
	Active 1 Assay			102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
	Hardness			102762	40°C ± 2°C/75% RH ± 5% RH	6 month	Active
				102712	25°C ± 2°C/60% RH ± 5% RH	6 month	Active
	Appearance - Tablets			102762	40°C ± 2°C/75% RH ± 5% RH	6 month	Active
	Appearance - Packaging	Jul 06, 2007	Study F	102862	(not stored)	Initial	Active
Moisture			102862	(not stored)	Initial	Active	
Active 1 Assay			102862	(not stored)	Initial	Active	

35 of 262 row(s) displayed, 8 column(s)

SLIM Production, Dani...

Protocol Creation & Modification

- Flexible protocol design features
- Capable of assigning multiple storage dates for different storage conditions for a single study.
- Calculates number of units needed for each storage condition.

SLIM - [Protocol Editor - Study A]

	Initial	1 day	1 month	3 month	6 month	9 month	12 month	18 month	24 month	36 month	48 month	60 month
(not stored)	1											
25°C ± 2°C/60% RH ± 5% RH			1	1	1	1	1	1	1	1	1	1
30°C ± 2°C/65% RH ± 5% RH			1	1	1	1	1	1	1	1	1	1
40°C ± 2°C/75% RH ± 5% RH			1	1	1	1	1	1	1	1	1	1

Storage Condition Properties

General

This page displays the general properties for an object.

Type: Storage Condition

Location: Study A

Created: N/A

Condition: 30°C ± 2°C/65% RH ± 5% RH

Instructions: Test at 40°C/75% RH

Initial Date: Mar 18, 2005

Pull Chamber: Chamber 30/65

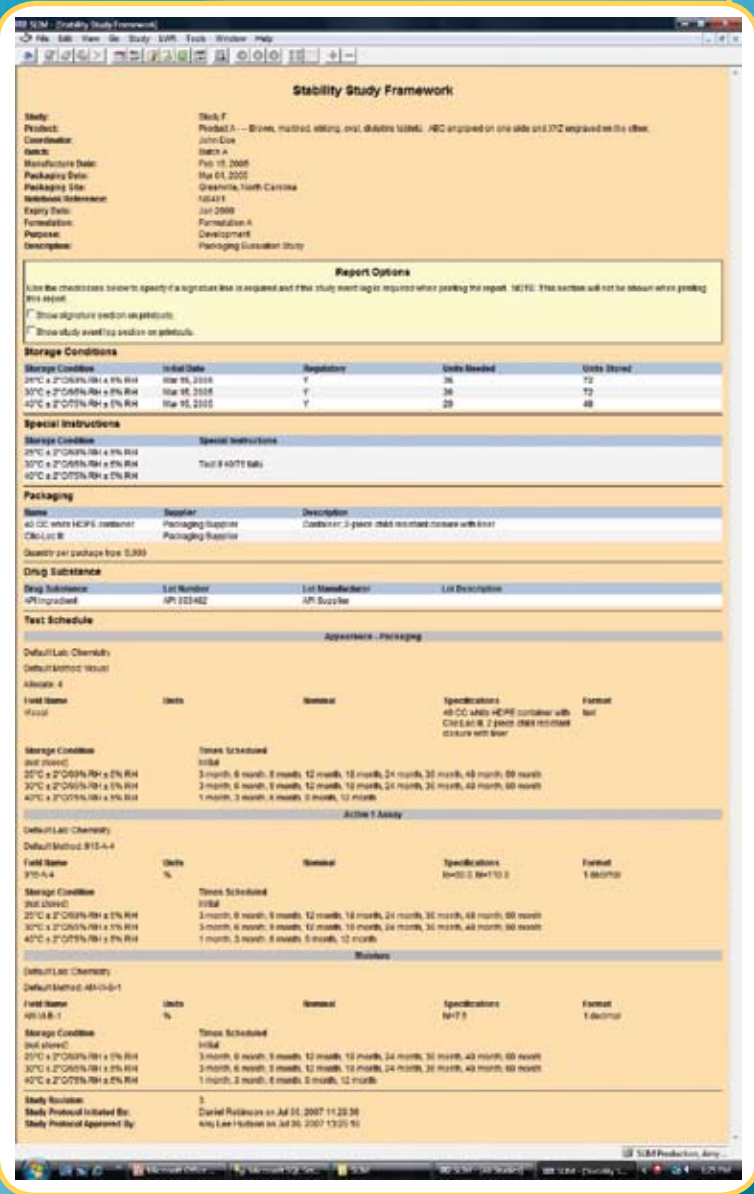
Options

Regulatory

Apply to all existing tests

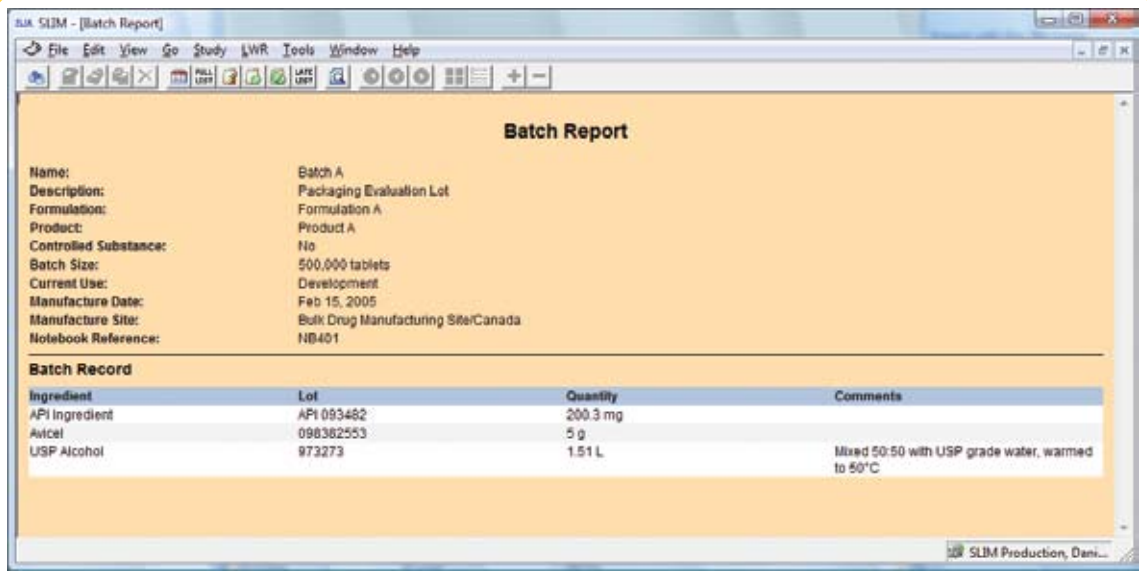
OK Cancel

SLIM Production, Dani...



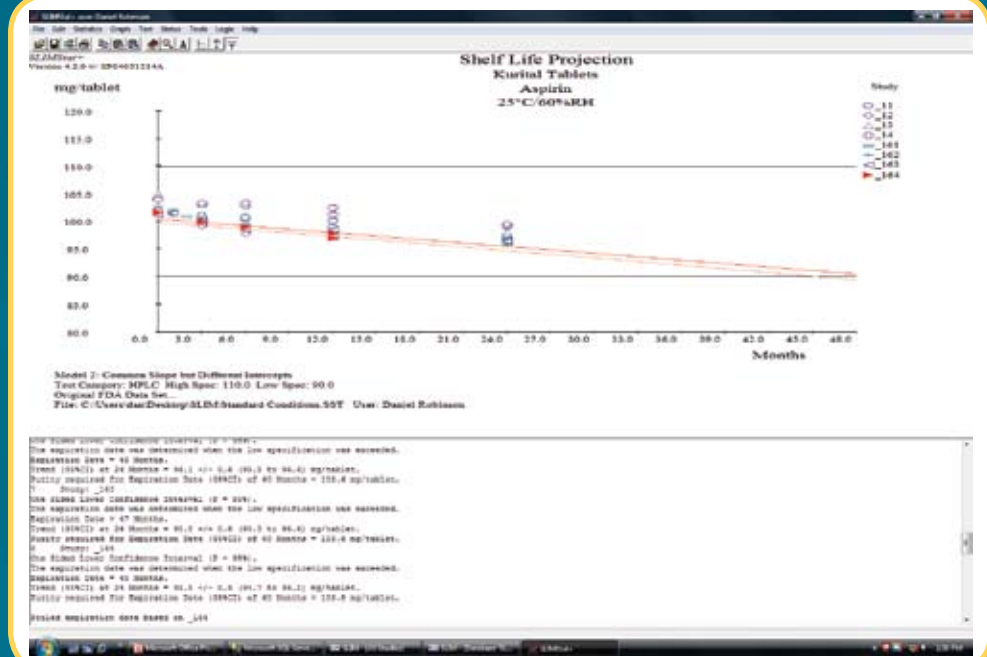
Formulations Database Capability

- Batch records and formulation storage allows batch genealogy tracking.
- Search for studies containing specific lots of drugs, formulations containing a particular ingredient, etc.
- Search for studies containing specific ingredients, packaging components, etc.



Statistical Analysis

- Shelf life projections
- Trend analysis
- Projections based on one-sided or two-sided confidence intervals. Can vary how limit-of-detection values are handled.
- Performs ANCOVA pooling of multiple studies.
- Accelerated temperature shelf life calculations using the Arrhenius equation.
- Graphics can be saved as Windows metafiles for insertion into other documents.



Compliance Features

- Full audit trail includes reference to the date and time of the change, the user making the change, the event type that caused the event to be logged, and description.
- Multiple levels of security
- 21 CFR Part II Compliant Features
- Configurable E-signatures

Date/Time	User	Type	Description	Code	Comments
Nov 17, 2008 13:09:31	Daniel Robinson	LVR Creation	LVR #100132 was inputted		
Nov 17, 2008 13:09:34	Daniel Robinson	LVR Deletion	LVR #100132 was unrequested		
Oct 05, 2008 15:37:15	Daniel Robinson	LVR Promotion	LVR #100042 was requested		
Oct 05, 2008 15:37:27	Daniel Robinson	LVR Promotion	LVR #100042 was pulled		
Oct 05, 2008 16:38:16	Daniel Robinson	LVR Cancellation	LVR #100042 - state removed changed from: Oct 05, 2008 to Dec 16, 2008	Other	Exp Recalculation
Oct 05, 2008 16:48:59	Eric Cash	LVR Promotion	LVR #100042 was unrequested		
Oct 05, 2008 17:47:03	Eric Cash	LVR Promotion	LVR #100042 was requested		
Oct 05, 2008 18:47:27	Eric Cash	LVR Promotion	LVR #100042 was requested		
Oct 05, 2008 18:47:29	Eric Cash	LVR Promotion	LVR #100042 was pulled		
Oct 05, 2008 18:58:00	Daniel Robinson	LVR Promotion	LVR #100042 was unrequested		
Oct 05, 2008 18:58:13	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 3.7 was out of spec "3.8 to 5.8 Rp (average)"		
Oct 05, 2008 18:58:13	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 73-82 was out of spec		
Oct 05, 2008 18:58:13	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 1.2 was out of spec "0.87 to 0.9"		
Oct 05, 2008 18:58:13	Daniel Robinson	Status Change	The status was changed from Inactive to On Hold		
Oct 05, 2008 18:58:13	Daniel Robinson	LVR Promotion	LVR #100042 was unrequested		
Oct 05, 2008 18:58:13	Daniel Robinson	Status Change	The status was changed from On Hold to Active		
Oct 05, 2008 17:03:16	Eric Cash	LVR Promotion	LVR #100102 was requested		
Oct 05, 2008 17:03:17	Eric Cash	LVR Promotion	LVR #100102 was pulled		
Oct 05, 2008 17:04:43	Daniel Robinson	LVR Promotion	LVR #100042 was requested		
Oct 05, 2008 17:04:43	Daniel Robinson	LVR Promotion	LVR #100042 was pulled		
Oct 05, 2008 17:07:16	Daniel Robinson	LVR Cancellation	LVR #100042 - Appearance - Packaging (1) - comments changed from " " to "Test Comments"	Other	Forgot to add comments
Oct 05, 2008 18:18:44	Daniel Robinson	LVR Creation	LVR #100042 was unrequested		
Oct 05, 2008 18:23:17	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 3.7 was out of spec "3.8 to 5.8 Rp (average)"		
Oct 05, 2008 18:23:17	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 73-82 was out of spec		
Oct 05, 2008 18:23:17	Daniel Robinson	Spec Alert	Test 100043 on LVR#100042 value 1.2 was out of spec "0.87 to 0.9"		
Oct 05, 2008 18:23:17	Daniel Robinson	Status Change	The status was changed from Inactive to On Hold		
Oct 05, 2008 18:23:17	Daniel Robinson	LVR Promotion	LVR #100042 was unrequested		
Oct 05, 2008 18:23:15	Daniel Robinson	Name Change	This item was renamed from Study A to W		
Oct 05, 2008 18:23:15	Daniel Robinson	Name Change	This item was renamed from W to Study A		
Jul 08, 2007 08:12:25	Amy Lee Rubin	Status Change	The status was changed from On Hold to Active		
Jul 08, 2007 09:20:27	Daniel Robinson	Status Change	The status was changed from Active to Under Review		
Jul 08, 2007 09:26:53	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 9 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 12 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 18 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 24 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 36 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 48 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 60 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 72 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 84 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 96 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 108 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Protocol Change	Test removed: test category Inquiries & Degradation Products; condition 20°C ± 2°C/65% RH ± 5% RH, Interval 120 month		
Jul 08, 2007 09:26:59	Daniel Robinson	Status Change	The status was changed from Under Review to Pending T		
Jul 08, 2007 09:44:53	Amy Lee Rubin	Status Change	The status was changed from Pending T to Active		

SLIM is the state-of-the-art in stability study management.

H&A Scientific, Inc. is a scientific software development firm specializing in pharmaceutical industry support.



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visit our web sites www.slim-stat.com
or www.hascientific.com, or contact:

Daniel Robinson
Manager of Business Development
PO Box 8133, Greenville, NC 27835
(252) 752-4315 ext. 204; fax (252) 752-9917
E-mail: dan@hascientific.com

