



SLIM

STABILITY LAB DATABASE MANAGEMENT



## H&A Scientific. Stable. Simple. Reliable.

Since 1992, H&A Scientific has developed programs for the laboratory with one directive in mind: Better software equals better science. Leveraging decades of experience, our product line is designed to help streamline and improve compliance with the latest U.S. Food and Drug Administration requirements and Good Automated Manufacturing Practice guidelines.

H&A Scientific's goal is to provide stability professionals with the most stable, simple, and reliable software on the market. Our products' reliability is backed up by best-in-class customer service for our partners, with an in-house team of experienced expert scientists known for its rapid response times and superior technical support. This ensures agency-friendly solutions that produce accurate results, improving your company's success rate in regulatory submissions.

H&A Scientific understands the complexity normally associated with implementing laboratory software in order to get a product successfully to market. Our products are therefore designed to be complete turn-key solutions that simplify installation, validation, training, maintenance, and day-to-day use.

### WE'RE PROUD TO DEVELOP AND VALIDATE OUR PRODUCTS FOR COMPLIANCE WITH AGENCY GUIDELINES AND REQUIREMENTS. FUNDAMENTAL AREAS OF OUR QUALITY SYSTEM INCLUDE:

- |                               |                         |
|-------------------------------|-------------------------|
| STANDARD OPERATING PROCEDURES | VALIDATION MASTER PLANS |
| QUALITY & PROJECT PLANS       | CAPA & DEVIATION SYSTEM |
| FUNCTIONAL & DESIGN DOCUMENTS | CHANGE CONTROL          |
| CONFIGURATION MANAGEMENT      | MAINTENANCE PLANS       |

## SLIM Commercial Off-the-Shelf Solution for Complete Management of Your Drug Stability Program

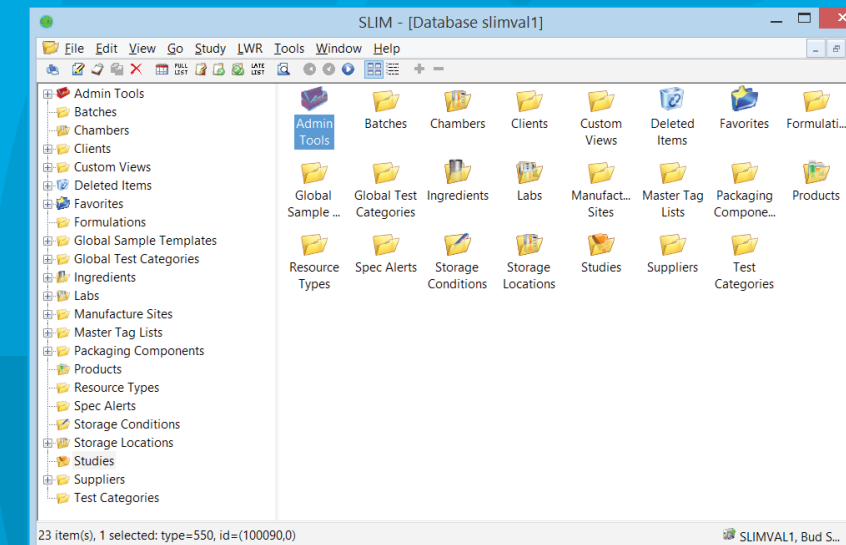
A Laboratory Information Management System (LIMS) should make your job easier, not harder. Enter H&A Scientific's SLIM (Stability Lab Information Manager). SLIM has the rich feature set required to meet the challenges today's Lab Supervisors and Stability Managers face on a daily basis. SLIM's fast, intuitive user interface and exceptional reliability provides simple, seamless operation, allowing it to manage your company's drug stability program with optimal efficiency.

Operating under the principle that better software equals better science, H&A's experienced chemists and scientists have spent over 20 years perfecting

SLIM. Fine-tuned with extensive customer feedback and backed by world-class partner support, the SLIM Software Suite is the simple, yet powerful solution your company needs.

SLIM includes SLIMStat for statistical shelf life analysis and Report Generator, which simplifies presentation of final data for regulatory submission. SLIM's off-the-shelf scalability allows it to remain affordable for businesses of all sizes, with installation, validation, training, and support provided by H&A Scientific. SLIMStat can also be purchased as a stand-alone application.

### INTUITIVE BROWSER INTERFACE



SLIM is a fully validated software system designed to be compliant with FDA guidelines for software development and validation. It includes functionality for electronic records, audit trails, and electronic signatures rules of 21 CFR Part 11 as they relate to "closed" systems.

SLIM also features a GAMP 5 Risk-based validation methodology that allows for a streamlined-yet-comprehensive, ready-to-execute IQ/OQ validation package – no need for complex testing of endless configurations.

### SYSTEM REQUIREMENTS

SLIM is a client/server application designed to utilize either an Oracle or Microsoft® SQL Server database. Operating on Windows environments such as Microsoft® Windows 7, 8, Server 2008, or Server 2012, the SLIM software suite can be implemented on a standalone PC, local area network (LAN), or across the world using Terminal Server, Citrix, or the Cloud.



## More Features. Less Complexity. The SLIM Solution from H&A Scientific.

### KEY FEATURES AND BENEFITS

- » Study Matrix Editor for intuitive study/protocol creation and matrix design
- » Automatic time point scheduling, sample pull management, and resource scheduling
- » Complete stability database with extensive formulation capabilities
- » Secure data entry, verification, and approval with easy-to-use Form or Spreadsheet modes
- » Workload calendar functions and e-mail notifications
- » Stability chamber inventory management from setup to discard
- » Batch Analysis, Batch Summary and Turnaround Times Reports
- » Multi-level attachments allow documents and links to be attached to associated data
- » Global Sample Templates allows the grouping of tests to be dragged-and-dropped in the Protocol Matrix Editor
- » Custom Views filtering to focus only on your work area
- » Configurable product and study inventory labels and bar codes
- » Sub-Study and Non-Pull Event capabilities

### STUDY PROTOCOL CREATION & MODIFICATION

- » Easy to use Matrix Editor for simple and flexible protocol set-up
- » Reduce study creation time with global grouping of like-testing, reusable templates and study copy-paste features
- » Capable of assigning multiple storage dates for different storage conditions for a single study
- » Automatic calculation of the number of units needed for each storage condition
- » Adhoc like-testing and study revision

### DATA ENTRY, REVIEW, AND APPROVAL

- » Lab Work Request (LWR) data entry that passes through entry, verification, and approval status
- » Alternate Specs, Alert Limits, email notifications, and electronic signatures
- » 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.
- » Import/Export data to a third party software with our Systems Interface Toolkit

### CALENDAR FUNCTIONS AND REPORTS

- » Generates weekly testing schedules, long-term forecasts and late lists
- » Easily create product-specific or test-specific schedules
- » Supports multi-laboratory scheduling of tests
- » Workload calendar allows users to view and adjust the upcoming work schedule
- » Pull Calendars that allow one-click grouping of upcoming work
- » Out-of-the-box systems reports include Stability Study Framework Report, Detailed Study Results Report, Inventory Report, and Out-of-Spec (OOS) Result Report, just to name a few

### LAB WORK REQUEST (LWR) FORM

SLIM - [LWR #102326]

Server Version 5.0.0      Stability LWR Form - [102326]      Report generated: Oct 12, 2015 04:55 PM

Client: Client 38A      Responsible Lab: Raw Material Lab

Product: Product 38A      LWR Status: Requested Oct 12, 2015 by Bud Smith

Formulation: Formulation 38A      Storage Time: 1 month (Sep 15, 2015 to Oct 15, 2015)

Batch: Batch 38A      Sub Storage Time: (not specified)

Study: Study 38A      Units Needed: 11

Storage Condition: 5°C      Units Removed: 11

Sub Condition: (not specified)      Date Removed: Oct 12, 2015

**Assay**

98.9      % I.c.      Precision: 1 decimal      Specifications: lo=90.0, hi=110.0

Salicylic Acid (# of Results: 1)

Comments:

Performing Analyst: Bud Smith      Notebook Reference: NB1-10

Method Reference: TMKT-001      Date Tested: Oct 12, 2015

Test Status: Entered

**pH**

7.0      Units      Precision: 1 decimal      Specifications: lo=6.6, hi=9.0

New Test Field #0055

Comments:

Performing Analyst: Bud Smith      Notebook Reference: NB1-10

Method Reference: Method 1      Date Tested: Oct 12, 2015

Test Status: Entered

### PROTOCOL MATRIX EDITOR

SLIM - [Protocol Editor - Study 38A]

Sample templates:

	Initial	1 day	2 day	7 day	1 month	3 month	6 month	12 month
(not stored)	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A							
5°C (SEP 15, 2015)		Global Sample Template 38A, Global Sample Template 38A	Global Sample Template 38A, Global Sample Template 38A	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A	Assay pH Sample Template, Global Sample Template 38A, Global Sample Template 38A
25°C/60%RH (MAY 26, 2015)		Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A	Test Category 38A (Lab 38B), Test Category 38A
30°C/60%RH (SEP 30, 2014)		Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay	Global Sample Template 38A, Global Sample Template 38A, Assay pH Sample Template, Assay

Condition    Time Point    Sample Template    Test / Event    Lab    Sub Condition    Sub Time Point

5°C    1 month    Assay pH Sample Template    Assay    Raw Material Lab    (not specified)    (not specified)

5°C    1 month    Assay pH Sample Template    pH    Raw Material Lab    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Physical Appearance    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Moisture    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Moisture    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Physical Appearance    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Moisture    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Moisture    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Assay    Lab 38A    (not specified)    (not specified)

5°C    1 month    Sample Rotation/NonPull    Lab 38A    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Global Test Category 38A    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Global Test Category 38A    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Global Test Category 38A    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Global Test Category 38A    HPLC    (not specified)    (not specified)

5°C    1 month    Global Sample Template 38A    Assay    Lab 38A    (not specified)    (not specified)

### WORKLOAD BALANCE CALENDAR

SLIM

October 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
2 LWRs	8 LWRs	2 LWRs	2 LWRs	7 LWRs 1 NonPull	2 LWRs	2 LWRs
18	19	20	21	22	23	24
1 LWR	1 LWR	1 LWR	1 LWR	1 LWR	1 LWR	1 LWR
25	26	27	28	29	30	31

Product	Event Type	Study	Sample Template	LWR # / NonPull #	LWR / NonPull Status	Scheduled	Collection	Condition	Interval	Lab	Unit Allocation	Location
Add-In Product	RPG Status Study 12			102065	Scheduled	Oct 15, 2015	(not specified)	Add-In Storage Condition	5 day	Add-In Lab	15	Add-In Chamber ()
Add-In Product	RPG Status Study 12			102077	Scheduled	Oct 15, 2015	(not specified)	Add-In Storage Condition	5 day	LAB305-01	20	Add-In Chamber ()
Product 38A	NonPull: Sample Rotation	Study 38A		102093	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	Lab 38A		
Product 38A		Study 38A	Assay pH Sample Template	102326	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	Raw Material Lab	11	
Product 38A		Study 38A	Global Sample Template 38A	102341	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	HPLC	30	
Product 38A		Study 38A	Global Sample Template 38A	102342	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	HPLC	30	
Product 38A		Study 38A		102405	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	Lab 38A	1	
Product 38A		Study 38A		102406	Scheduled	Oct 15, 2015	(not specified)	5°C	1 month	Lab 38A	1	



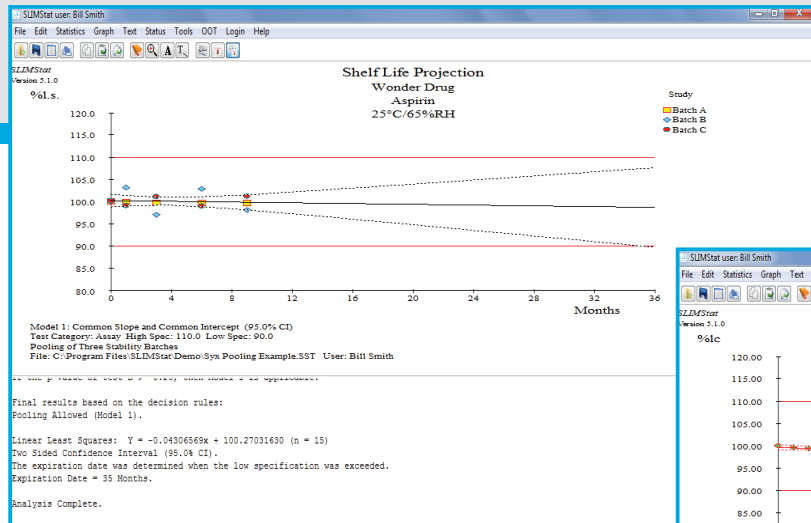


**INCLUDED IN THE SLIM SOFTWARE SUITE OR AVAILABLE AS A STAND-ALONE SOLUTION...**

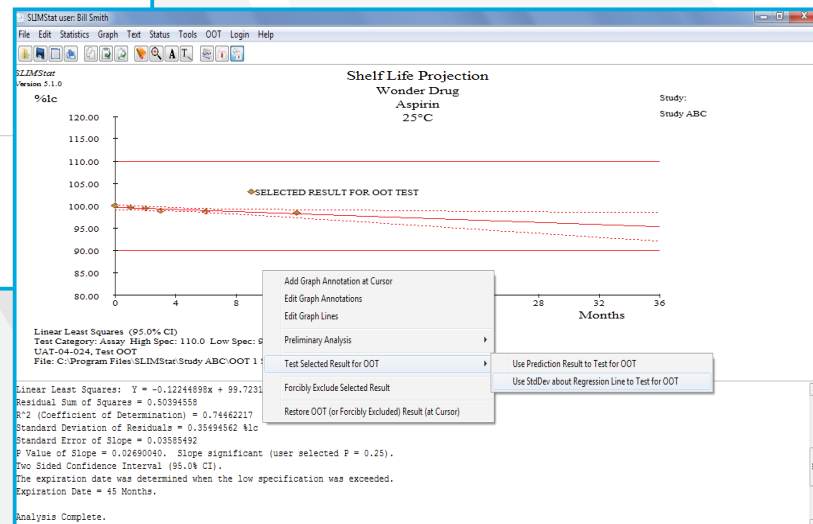
SLIMStat is extremely easy-to-use software developed specifically to determine the shelf life of drug products that have been placed on stability. This interactive and intuitive tool empowers non-statisticians the ability to generate statistical analyses with complete confidence.

Fully validated and 21 CFR Part 11 compliant, SLIMStat accepts data directly from the SLIM database, keyboard, clipboard, or any suitably-formatted text/Excel file. The product's shelf life for single or pooled studies are then automatically calculated. It's that easy!

**POOLED BATCHES**



**OOT DETERMINATION**



**KEY FEATURES AND BENEFITS**

- » Determines shelf life using one-sided or two-sided 95% confidence intervals
- » Quickly and easily calculates shelf life, trend analysis, out-of-trend (OOT) determinations, ICH Q1E batch pooling, back-purity, and kinetic analyses (Arrhenius Equation)
- » Graphical visualization of the data can be saved as Windows Metafiles or PDFs for easy insertion into other documents
- » ANACOVA calculations yield the same industry recognized results as the program used by the FDA
- » Configure reports for international acceptance with user configurable decimal separator and date formats, UNICODE compliance, and display of non-localized date-time audit logs
- » User-selected treatment of Limit-of-Detection values
- » A tool to save R&D formulators time and money utilizing kinetic analysis (Arrhenius Calculation)



**INCLUDED IN THE SLIM SOFTWARE SUITE...**

SLIM Report Generator (SRG) is an extremely configurable reporting tool included with every purchase of the SLIM software suite. The built-in Report Generator allows users to produce validated, submission-ready stability summary reports. While utilizing SLIM's security/database features, SRG provides an abundant amount of formatting options to display your stability data tables. From Stability Summary Reports, to Certificates of Analysis, to Global and User defined report templates, the configurations of SRG ensures you have the layout required to meet your regulatory department's requirements. SRG will be an essential part of your drug stability program with its functional time-saving reports. Simply select a study and generate the report...leave the formatting to us!

**KEY FEATURES AND BENEFITS**

- » Submission-ready reporting made easy with pre-designed industry recommended data table formats.
- » Select a study and see a final submission-ready summary report at any time.
- » Easy to format Global and User defined Report Templates ensures company-wide format compliance.
- » Traditional Certificate of Analysis Report and the display of a given time point (storage condition and interval combination).
- » A specification events table can be displayed to show the specification changes for a given study over time.
- » The addition of signature lines and a free-text GMP statement enhances report approvals.

**STABILITY SUMMARY REPORT**

Database: SLIM Server Version 4.0.0 Report generated: Oct 13, 2015 2:47:36 PM by Administrator

**KureitAll Study 38A Stability Summary for H&A Scientific, Inc.**

<b>Product / Strength:</b>	KureitAllB / 100 mg	<b>Lot # / Mfg. Date:</b>	Lot 12973 / Nov 04, 2005
<b>Mfg. By / Site:</b>	Acme Gesellschaft, GmbH	<b>Package / Site:</b>	Acme Gesellschaft, GmbH
<b>Batch Size:</b>	1,000,000 vials	<b>Package Date:</b>	Nov 07, 2005
<b>Project Number:</b>	34DS32	<b>Package Quantity:</b>	100,000 cases
<b>Purpose of Study:</b>	Japanese Study	<b>Study Start Date:</b>	Nov 22, 2005
<b>Expiration Date:</b>	Apr 2008	<b>Study Duration:</b>	40 month
<b>Active Ingredient (API):</b>	AKEnzyme	<b>Package Item(s) / Supplier:</b>	50 cc clear vial (Container) / Fisher Scientific Aluminum Crimp top seal / Fisher Scientific Grey Rubber Induction Seal / Fisher Scientific
<b>API Mfg. / Lot# (s):</b>	Sigma - Aldrich / Lot 12872A		
<b>Test Location(s):</b>	BenTakt QC Lab, Northeastern Labs, QC Lab, R&D Lab		
<b>Study Description:</b>	SLIM Study for Demo		

<b>Drug Substance:</b>	AKEnzyme	<b>Lot:</b>	Lot 12872A	<b>Lot Manufacture Site:</b>	Sigma - Aldrich	<b>Lot Description:</b>	Triple Distilled
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**Stability Condition / Orientation:** 25°C ± 2°C/60% RH ± 5% RH (Row H, Shelf 3)

Test	Method	Acceptance Criteria	Stability Intervals			
			Initial	1 month	3 month	6 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms
Moisture	TM003	8.0 to 10.0 %	0.9	1.1	1.2	1.3
pH	TM004	6.6 to 8.6	7.0	7.1	7.1	9.0 (OOS)
Assay - Program	TM002	92.0 to 110.0 % I.e.	100.0	99.9	99.1	98.7
Particulate Testing - 10 µm	USP 788	= 6000 Counts per container	259	499	475	399
Particulate Testing µm						78

Report Properties dialog box is open, showing options for report formatting such as 'Show Approved Only', 'Show Shading', 'Show Abbreviated Header', etc.



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**H&A Scientific**

Better Software. Better Science.

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