



NOVA-STABILITY

Stability Management Software

Determining the shelf-life of a pharmaceutical product is critical for the long-term safety of the patient. Managing a stability study is a complex and time-consuming process. Studies can last three to five years and mistakes along the way can bring unwanted regulatory citations requiring you to repeat an entire study causing product delays to market and potential recalls for your company.

Stability studies are highly scrutinized by regulatory agencies and companies must prove the validity of their data. To reduce the risk of a failed study, you must use a compliant software solution that manages your stability operations and performs an accurate shelf-life analysis. Gone are the days of using complicated and cumbersome spreadsheets for pulling, reviewing and analyzing data. Avoid missed pulls, late pulls, non-compliance and unacceptable calculation errors by implementing a dedicated stability software system.

THE POWER OF NOVA-STABILITY

Nova-Stability is an industry proven standard solution with over 20 years of managing stability programs in hundreds of pharmaceutical and biotech companies worldwide. Scalable from one to thousands of studies, Nova-Stability will manage your entire stability process from R&D to QC. Nova-Stability accommodates any type of study from any phase including production, pre-clinical/clinical as well as post production commitment studies. The Nova-Stability solution can be used as either a standalone application or integrated into your existing Nova-LIMS, LIMS or ERP/MES system (SAP). Nova-Stability provides paperless automation that saves you time and reduces costs. Built-in compliance with the latest ICH/FDA Stability guidelines, 21 CFR Part 11, and data integrity guidelines, Nova-Stability ensures your organization will reduce or eliminate all regulatory risks.



PERFORM ALL TYPES OF STABILITY STUDIES IN A SINGLE SYSTEM WITH NOVA-STABILITY:

ACCELERATED
LONG TERM

INTERMEDIATE
STRESS TESTING ON API'S

PHOTO STABILITY
FORCED DEGRADATION

TRANSPORTATION STUDIES
STORAGE STUDIES

MANAGING YOUR RISKS



SECURE YOUR SAMPLES

COMPLETE SAMPLE TRACKING:

Missed samples are a regulatory risk that can force you to repeat entire studies and delay product to market.

Reduce the risk of missed samples with Nova-Stability's time point scheduling and sample pull reports that assures users are pulling the correct samples on time all the time.

Reduce the risk of citations with automated email notifications including escalation emails for missed samples.

Reduce the risk of human error with barcoding capabilities that track and scan samples for a wide variety of operations including: pull out, put back, discard, navigate and search within the entire Nova-Stability application. Dozens of samples can be pulled at once with barcode scanning.

INVENTORY CONTROL:

Track inventory "set down": label and designate stability inventory at study start.

Full sample pull history: view user date and time for every pull time. Know the who, what, where, when, and why of your study.

Real time inventory of your chamber: virtually see what is in your chambers at any given time.

Chain of custody on samples: track pulling, shipping, receiving, discard, and sample status.



THE COMBINATION OF NOVA-STABILITY'S FORMULA BUILDER TOOL AND POWERFUL STATISTICAL PACKAGE LEAD TO AN **ACCURATE** AND **RELIABLE** DETERMINATION OF SHELF-LIFE WHILE MAINTAINING COMPLIANCY.



SERIOUS STATISTICS

EMBEDDED STATISTICAL PACKAGE:

Performing your statistical analysis manually or outside a software system can lead to compromising calculation errors and non-compliance with 21 CFR Part 11 and FDA's Data Integrity guidelines. All of which make it difficult to validate and justify results of your studies.

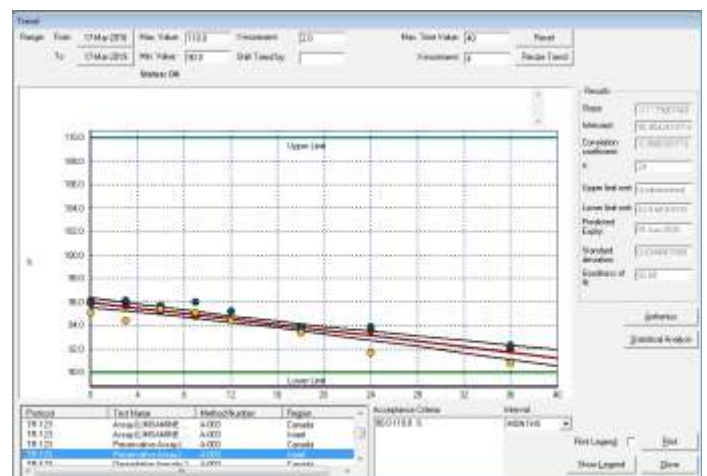
Reduce your risk with the industry's most comprehensive, embedded, and validated statistical package that comes standard with the following models:

- ✓ **Regression analysis**
- ✓ **Analysis of variance (ANOVA tables)**
- ✓ **Analysis of covariance (ANCOVA tables)**
- ✓ **Data pooling (p-value)**
- ✓ **Arrhenius equations (regression & estimation models)**

FORMULA BUILDER:

Create and validate your own formulas in the system, with Nova-Stability's powerful **Formula Builder Tool**.

Reduce or eliminate the need to export your results to an external application and maintain data integrity.



No need to manually trend data in a non-validated system compromising data integrity guidelines. Nova-Stability will accurately execute calculations you need with its powerful embedded statistical package.

LESS WORK | FASTER RESULTS



NOVA-STABILITY FEATURES & BENEFITS

Take advantage of these stability specific features that provide convenience & accelerate your productivity:

COMPLIANT REPORTING PACKAGE	Generate regulatory submission reports, study reports and user configured reports.
GLOBAL REGULATORY COMPLIANCE	Built in global specifications and best practices allow for quick and easy reporting based on individual market requirements.
OOS OOT INVESTIGATION EMAIL NOTIFICATIONS	Link investigations to your Quality Management System and perform root cause analysis to react and identify problems sooner.
AUTOMATED APPROVALS	Email notifications allows for rapid review and approval for multiple studies.
STUDY/PROCESSED BASED SYSTEM	Follows full testing process not just individual samples giving users a complete view of their study.
FEATURE RICH DESIGN FOR COMPLIANT TESTING	Built-in functionality and calculations for industry specific tests such as dissolution, content uniformity, impurity testing and weight loss.
ENTERPRISE SYSTEM	Centralizes data for multiple sites. Authorized users may view data from one or more sites.
HARDWARE & INSTRUMENT CONNECTIVITY	Save time and reduce data entry with a variety of laboratory instrumentation interfaces.
USE OF ATTACHMENTS	Attach or upload of any type of supporting file to the summary for any given study.
ACCESS SYSTEM ANYWHERE	Choose from cloud or on-premise deployment options.

A SYSTEM THAT YOU CAN COUNT ON

WE TAKE A PARTNERSHIP STRATEGY APPROACH TO IMPLEMENTING YOUR SOFTWARE SOLUTION



IMPLEMENTATION



INTEGRATION



VALIDATION



CONSULTING



TRAINING & SUPPORT

Nova-Stability is an out of the box fully validated software system with built-in company specific options to make the system your own. All Novatek solutions are delivered as a turnkey package that includes on-site installation, integration options, a validation package and hands on training. The benefits for Nova-Stability extend far beyond the product itself. We provide the support that you need every step of the way with global technical assistance in your local language that is available 24/7.

Why trust your stability management to any other system? Reduce your risks, save time and get your products to market sooner with the leading solution: Nova-Stability.

NOVATEK

EUROPE

THE LEADING PROVIDER OF REGULATORY COMPLIANT SOFTWARE

The Novatek approach provides the building blocks for a complete quality management solution that can be tailored to any client's needs. Our software can be used as standalone modules or integrated with other modules to form large-scale comprehensive solutions. With 20+ years of successful installations globally, Novatek has developed an extensive base of regulatory knowledge ensuring compliance and peace of mind during audits.

SOLUTIONS

Our comprehensive business-ready portfolio of easy-to-use regulatory compliant software

CONTAMINATION CONTROL

Water & Utility
Monitoring

Environmental
Monitoring

Cleaning
Validation

Disease Control &
Hygiene Monitoring

QUALITY EXECUTION LIMS

Raw Material
Analyzer

In-Process & Finished
Product Analyzer

Stability
Management

QUALITY PROCESS

Quality Management System

Training

Deviations

Audit

Investigations

CAPA

Complaint Reporting

Document

Change Control

Calibration
& Preventive
Maintenance

ADDITIONAL SOLUTIONS

Automated
Proofreader

Column
Organizer

Consumable
Inventory

Innovation
Management

Screen
Capture Tool



Build **your solution** with the flexibility to grow
with **your needs** and implement at **your pace**

NOVATEK
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Contact us for more information on
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