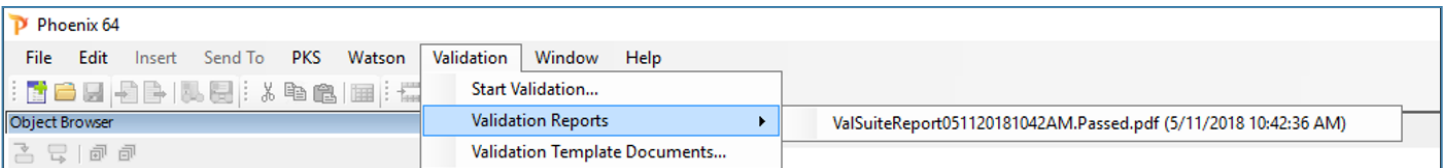# CERTARA

Phoenix NLME Validation Suite
Validation Made Fast and Easy

As required by US FDA's 21 CFR Part 11, International Conference on Harmonization of Technical Requirements (ICH), EudraLex Annex 11, and other regulatory agency guidance documents, computer systems used in the pharmaceutical industry, and output from software used in regulatory submissions, must be validated to assure proper performance. This necessitates companies to invest significant time and resources to manually write and perform the validation steps used in software execution.

The enhanced Phoenix NLME™ Validation Suite is integrated into Phoenix and provides software validation in less than 30 minutes with non-editable PDF reports containing links to saved reference files, user output files, and difference files. Updated validation template documents are aligned with the latest regulatory guidance computer system validation such as ICH E6 Good Clinical Practice (GCP) R2 and can be readily modified to fit individual user/organizational policies and procedures.

Obtain automated NLME validation test results in minutes rather than days

- Automates validation with test results available in less than 30 minutes

- Integration into Phoenix NLME eliminates the need to install a separate application

- Allows other applications to run during execution of the Validation Suite, resulting in minimal down-time

- Automatically executes detailed test scripts, ensuring rapid, consistent, and error-free testing of NLME functionality

- Provides documentation of activities by automatically generating a Validation Report

- Compares output to standard, verified, known results and generates a report of comparisons that is saved in Phoenix and immediately accessible for easy reference

Validation Life Cycle Templates included in Phoenix NLME Validation Suite
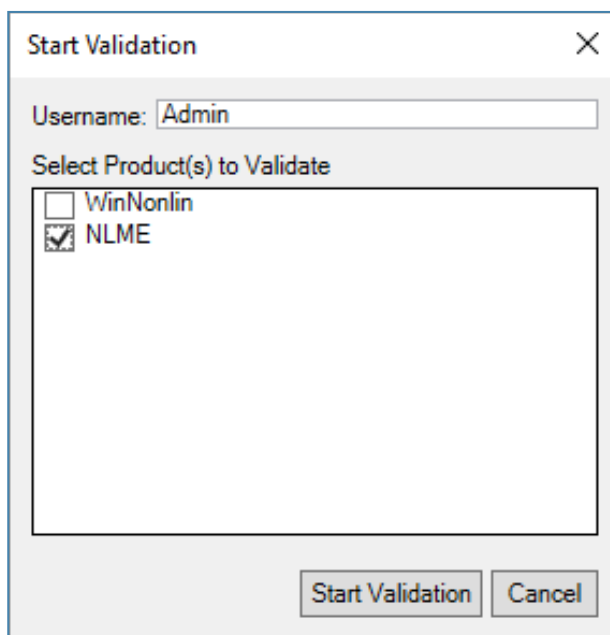
- Validation Plan
- Phoenix NLME Requirements Specification
- Test Plan
- Phoenix NLME Traceability Matrix
- Validation Summary Report

Functions Tested by Phoenix NLME Validation Suite

General Functionality	Phoenix Modeling Engine			
• Installation Qualification (IQ) • Descriptive statistics • Data Wizard calculations • Ratios and Differences calculations	• 14 PK structural models • 4 PD structural models • 2 PK/PD structural models • 6 Indirect Response structural models • 6 Residual Error models • MDV, ADDL, and Steady State	• BLQ censoring • Discrete Observation models (e.g. Count, Logistic, Time-to-Event) • Built-In, Graphical, Textual Model Editors • Model Comparison tool	• 8 Modeling Engines (e.g. FOCE, Laplacian, Naive-Pooled, Nonparametric, QRPEM) • 8 Run Modes (e.g. Simple, Bootstrap, Covariate Search, VPC)	• Continuous, Categorical, & Occasion Covariates • Random effect interactions with Structural Parameters (e.g., additive, exponential, ilogit) • Random effect correlations (Omega matrix)

Automatic execution of NLME Validation Suite scripts

The NLME Validation Suite includes test scripts that efficiently test and document calculations performed by the Phoenix Model object, including all Engines (Naïve-Pooled, FO, FOCE-LB, FOCE-ELS, Laplacian, IT2S-EM, and QRPEM) and Run Modes (Simple, Stepwise Covariate Search, Shotgun Covariate Search, Covariate Search Scenarios, Bootstrap, Profiling, Simulation, and Predictive Check). In addition, the NLME Validation Suite tests Phoenix Framework features such as Descriptive Statistics, Data Wizard Transformations, and the Ratios and Differences tool. Each test script automatically operates Phoenix NLME to generate output, compares the output to verified results, and generates a Validation Report that is saved and available immediately in Phoenix.
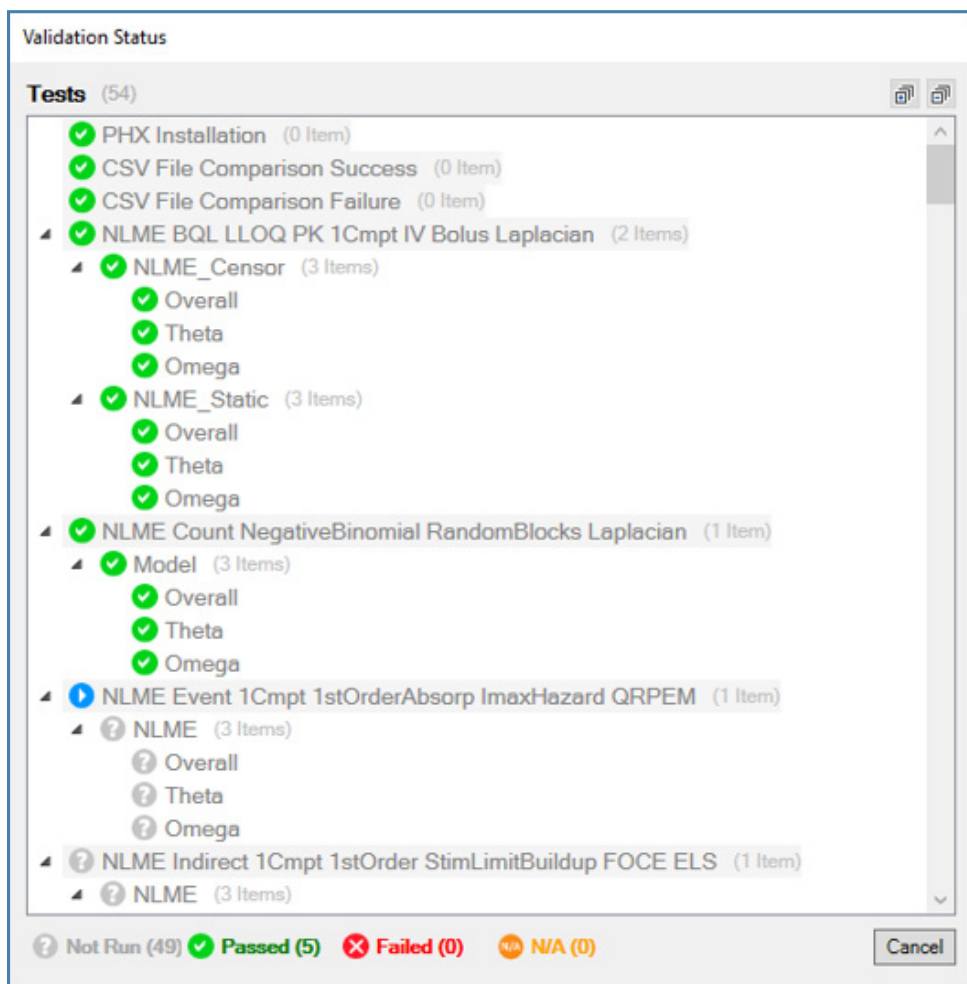

Use Phoenix NLME Validation Suite to ensure compliance under the following conditions:

- Upon a new installation of Phoenix NLME

- After upgrade to Phoenix NLME from a previous version of Phoenix NLME

- Upon re-installation of Phoenix NLME

- If a change to the implemented Phoenix NLME system is determined as part of the internal change control process to impact the validation status of the system

Successful Execution of NLME Validation Suite Scripts

The graphical user interface allows you to easily drill down into the Validation Run Report to assess outcome of all test scripts.

Are you ready to streamline your Phoenix NLME validation testing?

Contact us at sales@certara.com to learn how to automate your validation testing to gain efficiency and productivity.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.