



Seelva is a software dedicated to the validation of bioassays such as ELISA, RIA, parallel line, parallel curve, slope-ratio and microbiological assays, qPCR, ...

Seelva allows you to assess the trueness, the precision and the accuracy of your analytical method. **Seelva** generates Accuracy Profiles that are the keys to take a decision on one hand about the way for calibrating (which regression model) and about the validity of your method.

- **Seelva** is the validation software for your laboratory that guarantees that your methods will be compliant to regulatory documents such as ICH Q2, FDA, ISO, EMA, MHLW, USP 1210, USP 1225, USP 1033 and EDQM.
- **Seelva** is suited for the qualification or validation of bioassays which provide results expressed in concentration or quantity.
- **Seelva** is suited for the qualification or validation of relative potencies assays for which analytical results are assumed following a lognormal distribution.
- **Seelva** generates an e-CTD compliant report within minutes, in full compliance with authority expectations.
- **Seelva** is based on the Total Error approach.
- **Seelva** is a decision tool: one graph = one decision.
- **Seelva** makes the statistic easy to understand and to interpret; Accuracy Profile is summarising all the information you need to know.
- **Seelva** proposes you 10 statistical models to compute your calibration data. A ranking will be proposed to help you in the decision (Accuracy Index).
- **Seelva** will help you to manage your RISK. Through the β -expectation Tolerance Interval, you simulate how your method will behave in routine.
- **Seelva** is validated according to the GAMP5 guidelines and is 21 CFR part 11.
- **Seelva** is a Software as a Service (SaaS) application. No installation: no need to validate the software on site. No maintenance costs. Always the latest version available.

Calibration Models available:

- *Unweighted Four Parameter Logistic Regression*
- *Weighted (POM) Four Parameter Logistic Regression*
- *Unweighted Five Parameter Logistic Regression*
- *Weighted (POM) Five Parameter Logistic Regression*
- *Unweighted Log-Log Regression*
- *Unweighted Quadratic Regression*
- *Weighted (1/X) Quadratic Regression*
- *Weighted (1/X²) Quadratic Regression*
- *Unweighted Power Regression*
- *Weighted (POM) Power Regression*





Validation design

Before starting the validation phase it is possible - and recommended - to determine the optimal number of experiments to perform (number of series and number of replicates by series). Those optimal numbers will be based on the results - Precision and accuracy - obtained in the prevalidation phase. Indeed, performing too few experiments could lead to rejection of an acceptable analytical method. Conversely, too much experiments, leading to an excessive power, will make the prevalidation phase longer than necessary. Between these two extremes, exists an optimal number of experiments that can be found in table here below.

The following tables give you the minimal Recommended Sample to achieve the success in 95% of the case in the validation stage using the Total Error or β -Expectation Tolerance Interval with less than 5% risk that future measurements will fall outside the acceptance Limits:

Please select your parameters :

Acceptance limit: 5
Expected Bias: 0

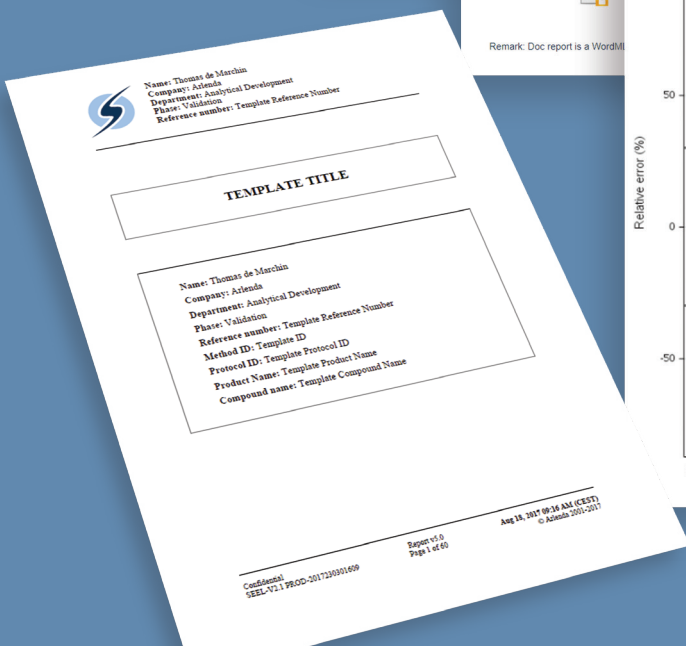
Validation form (using responses) - Model selection (3/4)

Model	Accuracy Index	Dosing Range Index	Precision Index	Trueness Index	Limits of Quantitation	Included in Report	Selected Model
Weighted (POM) Four Parameter Logistic Regression	0.6765	0.9524	0.3561	0.9129	[24.74 , 450.0]	<input type="checkbox"/>	<input type="radio"/>
Four Parameter Logistic Regression	0.6758	0.9455	0.3414	0.9564	[27.84 , 450.0]	<input type="checkbox"/>	<input type="radio"/>
Quadratic Regression	0.6414	0.8279	0.3630	0.8779	[18.53 , 388.2]	<input type="checkbox"/>	<input type="radio"/>
Five Parameter Logistic Regression	0.6363	0.9372	0.3253	0.8452	[18.29 , 436.8]	<input type="checkbox"/>	<input type="radio"/>
Weighted (POM) Five Parameter Logistic Regression	0.6281	0.9340	0.3249	0.8165	[18.03 , 435.1]	<input type="checkbox"/>	<input type="radio"/>
Weighted (1/X) Quadratic Regression	0.6070	0.8224	0.3590	0.7576	[13.30 , 380.5]	<input type="checkbox"/>	<input type="radio"/>
Weighted (POM) Power Regression	0.3679	0.3880	0.2429	0.5286	[276.8 , 450.0]	<input type="checkbox"/>	<input type="radio"/>
Weighted (1/X) Quadratic Regression	0.2866	0.3837	0.07780	0.7890	[138.1 , 309.5]	<input type="checkbox"/>	<input type="radio"/>
Log-Log Regression	0.0000	0.0000	0.0000	0.0000	[0.00 , 0.00]	<input type="checkbox"/>	<input type="radio"/>
Power Regression	0.0000	0.0000	0.0000	0.0000	[0.00 , 0.00]	<input type="checkbox"/>	<input type="radio"/>

Potency form - Get report (4/4)

Get your report by clicking on the icon corresponding to the format you want:

WordML: 
Non-secured PDF (eCTD): 
Secured PDF: 
Remark: Doc report is a WordML

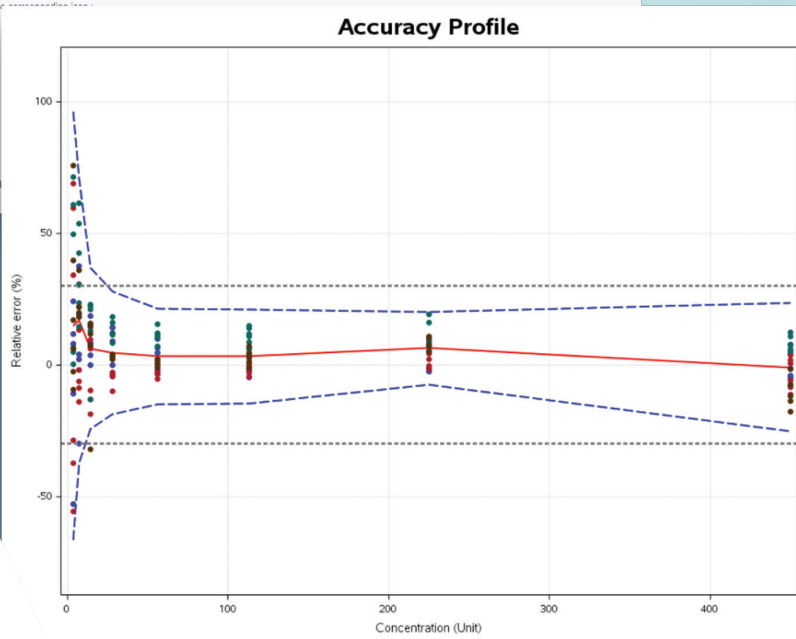


TEMPLATE TITLE

Name: Thomas de Marchin
Company: Arlenda
Department: Analytical Development
Phase: Validation
Reference number: Template Reference Number
Method ID: Template ID
Protocol ID: Template Protocol ID
Product Name: Template Product Name
Compound name: Template Compound Name

Report v1.0
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← Example of screenshots from **seelva**