

GENERAL DESCRIPTION

Only the statistics you need and the decision you expect.

The objective of your analytical procedure is to quantify accurately. The objective of the validation is to provide laboratories as well as regulatory bodies guarantees that your method can achieve its goal. The objective of **e-nova/Seelva** is to join both objectives adequately by estimating and displaying the performance of your analytical procedure.

That's the most efficient way to reliably provide quantified evidence that your analytical procedure is likely to quantify tomorrow's samples with the accuracy you wish.

There is one objective for your analytical procedure; **e-nova/Seelva** gives you only one related decision.

An application easy to use.

e-nova/Seelva is an internet based service (<https://>) that requires you to only have a browser, an analytical procedure and your data.

The latest technology makes **e-nova/Seelva** easy to install, to maintain and to disseminate throughout your organization. Optimally designed graphical display and interactive information make its use natural, its interpretation obvious and so requires limited trainings.

A solution fully validated in compliance with regulatory documents; a validation report ready to use.

e-nova/Seelva is not just another statistical software, nor another friendly website.

e-nova/Seelva is a true industrial solution for your laboratory that has been developed, validated and documented following the strongest standards and is compliant to 21CFR-Part 11. Those outstanding standards in quality were achieved by partnering closely with Qualilab (www.qualilab.com), a company well established in laboratory quality and software validation.

The final output itself, a PDF non-editable report you can tailor to your needs, constitutes the definitive document you release for demonstrating the validity of your analytical procedure.

In a couple of minutes you get a report that is clear, intelligible, self-explicit and validated!

Extracts of pages from the report generated by **e-nova** >>>



Page 1 (Top): Header with Arlenda logo and company information. Section 4: Precision. Text: "Precision is the closeness of agreement among measurements from multiple sampling of a homogeneous sample under the recommended conditions..." Table VI: Analytical Performance Parameters and Acceptability. Table VII: Absolute Precision, Precision and Generality.

Concentration level (µg/mL)	Mean (observed) (µg/mL)	Standard Deviation (SD) (µg/mL)	Intermediate Precision (IP) (%)	Intermediate Precision (IP) (µg/mL)
400	400	10	2.5	10
200	200	5	2.5	5
100	100	2.5	2.5	2.5

Page 2 (Middle): Section 2: Regression Statistics. Text: "The response function of an analytical method is, within the range, the existing relationship between the response (Signal) and the concentration (Quantity) of the analyte sample..." Table III: Summary of the calibration model. Table IV: Regression parameters.

Model	Summary Index	Linear and/or other forms of regression (1-100, 1000)	Deviation Range (index)	Residual Index	Residual Index
Linear Regression	0.999	100, 1000	1.000	0.000	0.000

Parameter	Value	SE	Residual SE
Intercept	0.000	0.000	0.000
Slope	1.000	0.000	0.000

Page 3 (Bottom): Section 4: Accuracy. Text: "Accuracy refers to the closeness of agreement between the test result and the accepted reference value, namely the conventionally true value..." Figure 2: Accuracy Profile. A graph showing Accuracy Profile with Y-axis 'Accuracy (%)' and X-axis 'Concentration (µg/mL)'. It includes a solid line for the regression, a dotted line for the acceptance limit (20%), and green dots for relative back-calculated concentrations.

Make your procedure compliant with regulatory documents; be confident in your procedure.

Too often the analyst has to make trade-offs between being compliant with most regulatory documents and releasing a procedure that provide reliable results. The concepts and approaches implemented by **e-nova/Seelva** will make you confident in your method while being in accordance with all regulatory bodies.

e-nova/Seelva is the ultimate scientific achievement in the area resulting from more than 8 years of in depth brainstorming and scientific development between experts from academia and industry specialized in analysis and statistics.

With **e-nova/Seelva** you will be able to fulfil regulatory requirements without pain while being able to control and minimize the risk of use of your analytical procedure.

A wide variety of calibration models to achieve accurate results.

As pointed recently in a FDA guide, the simplest model describing the relationship between the quantity and the response must be used as a calibration model. **e-nova/Seelva** goes well beyond!

e-nova/Seelva will automatically suggest the simplest model that maximizes the accuracy of your method. You have developed a method to quantify accurately, not to fit simple models. That's obvious, isn't it?

Find the most extreme and reliable limits of quantitation.

The objective of most analytical procedures is to be able to quantify accurately over a large range of values and in particular to remain accurate for extremely low quantities.

New algorithms built into **e-nova/Seelva** will help you to find the lowest (and largest) limits of quantitation you can rely on blindly.

How will you benefit from e-nova/Seelva?

- **e-nova/Seelva** meet ICH, FDA, Washington Conference and ISO requirements in Validation of Analytical methods.
- **e-nova/Seelva** adequately analyze the data of the validation phase of your analytical methods to ensure perfect conformity to requirements such as for example linearity, precision, trueness, accuracy, limits of quantitation and detection, quality of fit, residuals,...
- **e-nova/Seelva** have been developed and validated in strict accordance with requirement in software validation such as 21CFRpart11, GxP, ISO.
- **e-nova/Seelva** is not only a statistical tool but also a report generator. In **20 minutes**, you will have not only the statistical calculation of your data but also a fully stand alone pdf report which will contain all the information you have to report for the validation of your method.
- Computations and delivery are performed using **SAS** system, the definitive reference of quality in number processing.
- **Risk Management:** through β -expectation Tolerance interval, you are able to predict the results your method will produce in routine analysis.

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