# NeoLiCy®

Analytical Methods' LifeCycle Assessment

- **Take part in NeoLiCy® project.**

When operating according to quality management systems (e.g., according to GxP, ISO 17025 or ISO 15189 guidelines), statistical assessment of the analytical procedures used is of the utmost importance.

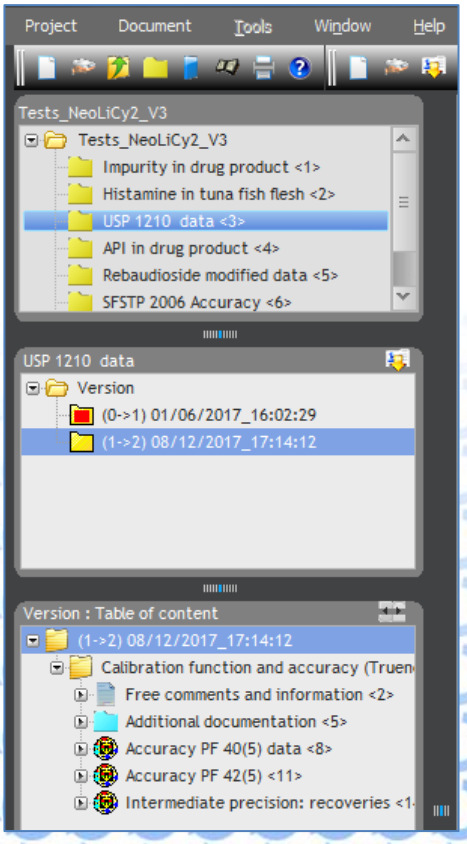
This includes for instance analytical methods robustness and validation, analytical stability studies, uncertainty of measurement estimation, on-going performance assessment, method transfer and many others assessment steps during the analytical method life cycle.

**NeoLiCy®** software project is designed to fulfill these steps requirements according to proven and established recommendations and regulations. Each new release of **NeoLiCy®** shall address one or several more aspects of analytical method's life cycle statistical assessment. Release 4 of **NeoLiCy®** specifically addresses analytical methods robustness, analytical methods validation, uncertainty of measurements, analytical stability, on-going performance assessment and methods comparison assessment.

- **Universally accepted.**

**NeoLiCy®** is developed considering international recommendations and regulations on analytical methods performance assessment. It is based on the ICH recommendations (ICH Q14 on method development, ICH Q2 on method validation, ICH M10 on bioanalytical methods validation…), EMA, FDA, USP (e.g., <1210>, <1220>), EP guidelines and ISO standards related to the subject.

A constant technological monitoring of these guidelines and recommendations is the core of **NeoLiCy®** development specifications.



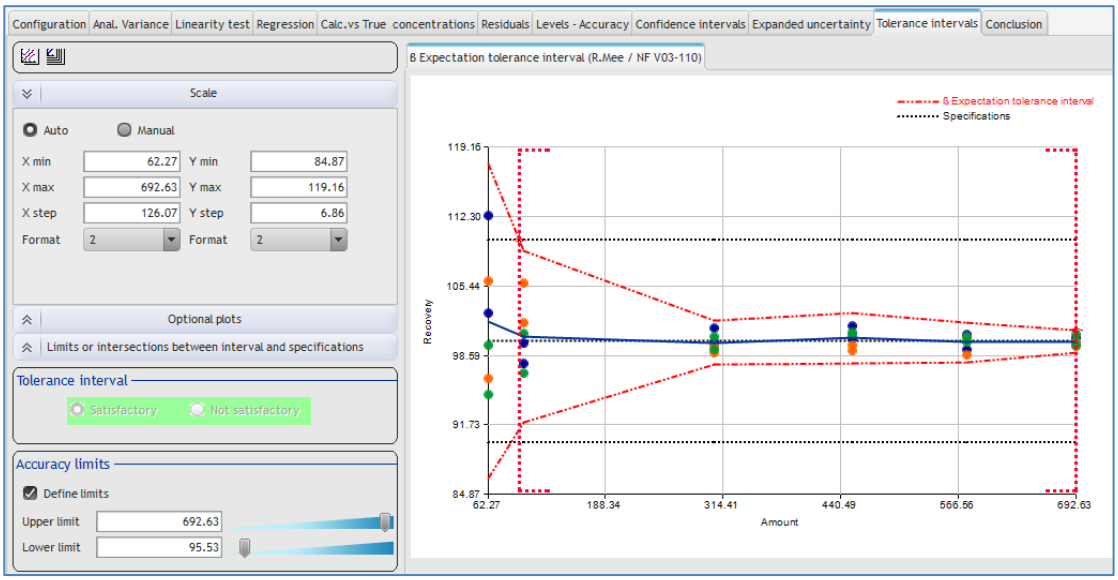

- **Versatile configuration.**

**NeoLiCy®** is a configurable software designed for statistical assessment of any kind of analytical method. It contains ready to use templates related to the configuration of the statistical tests, associated calculations and experimental designs. These templates comply with the guidelines and recommendations for pharmaceutical, biopharmaceutical, clinical, cosmetics, agro-foodstuff, environmental and chemical industry. For ease of use these templates are pre-configured and additionally the user may create and save new templates. This high degree of versatility enables **NeoLiCy®** to be used for the validation of all analytical procedures in any kind of industrial activity.

- **Powerful project management.**

**NeoLiCy®** database management allows creation of up to five classification levels. The project level is the main classification level;

it contains all the data and revisions of the different files, documents and chapters related to the products or compounds in the products contained in the project. The characteristic level is the final statistical assessment level, dedicated to the evaluation of a single characteristic (e.g., method validation characteristic).



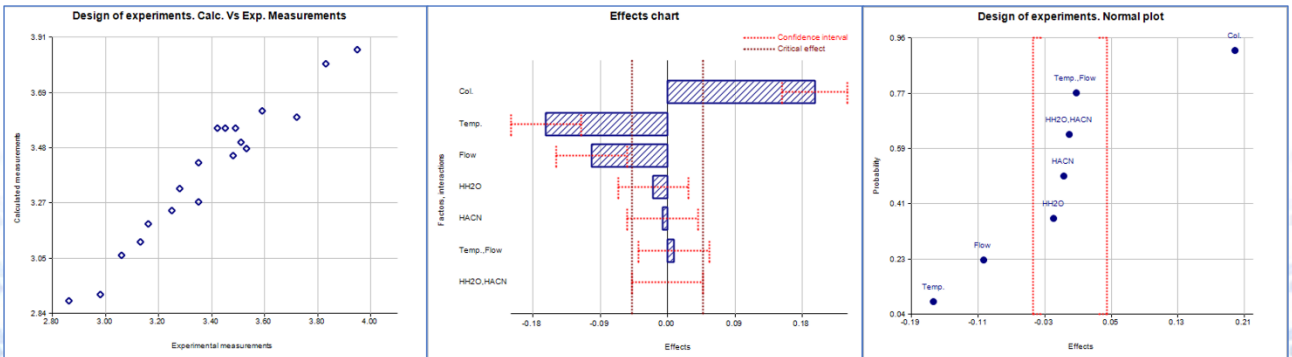

As some of these classification levels are optional, **NeoLiCy®** provides a high level of flexibility in the projects content management, allowing study of several compounds in a single product or several products, study of analytical methods related to several matrices and so on.

Even the list of characteristics to be assessed for a specific analytical method may be user defined, manually or by use of chapter or document templates.

Of course, **NeoLiCy®** user management provides tools to adapt the rights given to each user in the project management tasks.

- **Easy projects and documents creation.**

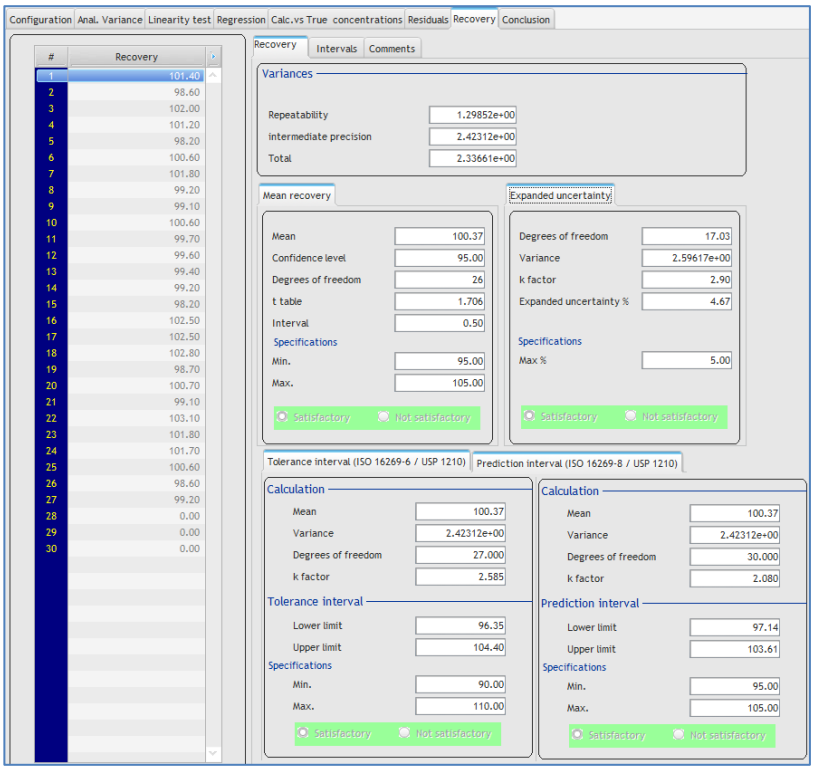
Once a project has been created, the user may apply ready to use document templates containing a set of characteristics to be assessed. Wizards are provided to help the user in building his project and tables of content may be adapted or modified in order to comply with specific regulations or to your own company statistical assessment procedures and design of experiments.




| Factor name | Effect | Effect (%) | Std. deviation | Conf. Interval | F value | Stat F | p value (%) | t value | Stat t | p value (%) | Critical effect value (abs) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Col. | 0.20 | 5.92 | 0.02 | 0.04 | 96.515 | ( 4.84) | ***( 0.00) | 9.824 | ( 2.20) | ***( 0.00) | 0.04 |
| Temp. | -0.16 | -4.90 | 0.02 | 0.05 | 56.982 | ( 4.84) | ***( 0.00) | 7.549 | ( 2.20) | ***( 0.00) | 0.05 |
| Flow | -0.10 | -3.07 | 0.02 | 0.05 | 22.428 | ( 4.84) | ***( 0.06) | 4.736 | ( 2.20) | ***( 0.06) | 0.05 |
| HH2O | -0.02 | -0.58 | 0.02 | 0.05 | 0.792 | n.s.( 4.84) | n.s.( 39.26) | 0.890 | n.s.( 2.20) | n.s.( 39.26) | 0.05 |
| HACN | -0.01 | -0.20 | 0.02 | 0.05 | 0.100 | n.s.( 4.84) | n.s.( 75.81) | 0.316 | n.s.( 2.20) | n.s.( 75.81) | 0.05 |
| Temp.,Flow | 0.01 | 0.242 | 0.02 | 0.05 | 0.139 | n.s.( 4.84) | n.s.( 71.61) | 0.373 | n.s.( 2.20) | n.s.( 71.61) | 0.05 |
| HH2O,HACN | -0.00 | -0.019 | 0.02 | 0.05 | 0.001 | n.s.( 4.84) | n.s.( 97.76) | 0.029 | n.s.( 2.20) | n.s.( 97.76) | 0.05 |

- **Easy data input.**

Data input in **NeoLiCy®** may of course be done manually, for security purpose this right is part of the user administration configuration. Moreover, any data can be copied from data tables (e.g., Microsoft® Excel™ spreadsheets).




- **Automatic calculation.**

After method characteristics assessment configuration, including specifications (acceptance criteria) on results, according to the company procedure or any regulation to be applied, calculations are carried out by a simple click and statistically checked with regards to the applied procedure. The conclusion on each of the assessed characteristic is proposed to the user by **NeoLiCy®**, providing large spaces for any comment or user decision depending on the calculated results. According to the user rights, the final conclusion on each characteristic can be modified and justified separately.

- **Automatic report compilation.**

After input of the comments and decision, the statistical assessment report is created with only a mouse click. The report may content from a single characteristic up to a full project results, including a detailed description of the statistical procedures used.

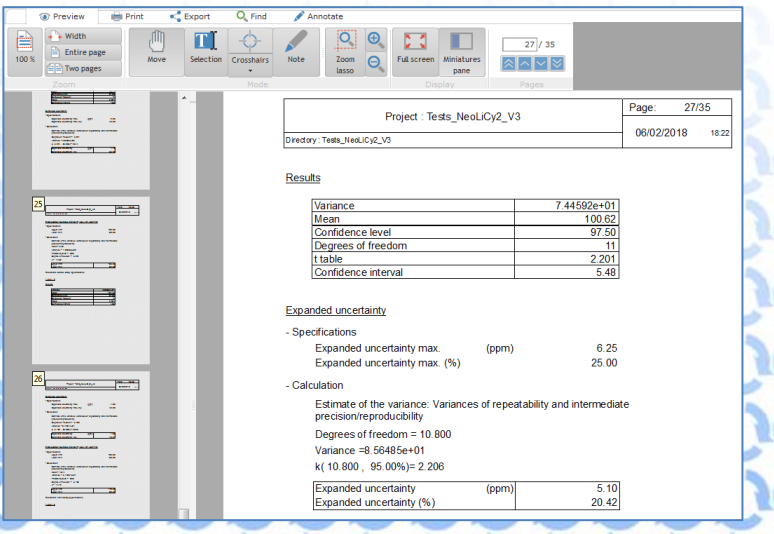
**NeoLiCy®** provides the user with different options to create the report:

- As a write protected standard **NeoLiCy®** report,
- As a rtf format file, compatible with Microsoft Word,
- As a Adobe® Acrobat™ pdf file, protected or not.

- **Compliant with international standards.**

Whatever is the characteristic to be assessed, **NeoLiCy®** has been designed for full compliance with international standards and industry recommendations and regulations. Release 4 of **NeoLiCy®** provides statistical assessment of the following characteristics:

-Robustness, by means of Design of Experiments (Plackett-Burman screening designs, Full factorial designs, fractional factorial designs)
-Specificity, selectivity.
-Precision, including repeatability, intermediate precision and/or reproducibility.



-LOD and LOQ estimation, by means of the S/N ratio or calibration curve data.
-Response Function assessment: linear, linearized, quadratic, power, Michaelis-Menten or weighted linear/quadratic models, by means of back calculated concentrations residuals and/or ANOVA.
-Linearity of standard and/or method.
-Accuracy by means of accuracy (bias) and precision assessment or use of the total error concept (prediction and tolerance intervals, accuracy profiles).
-On-going performance assessment by means of control charts.
-Methods comparison by means of correlation or regression tools and Bland-Altman graphs.

- **Validated and fully FDA 21CFR part 11 / EU GMP Annex 11 compliant.**

**NeoLiCy®** is, of course, validated. Its validation certificate is included in the software package. In addition to the operating system security layer, **NeoLiCy®** provides all necessary functions for full FDA 21CFR part 11 or EU GMP Annex 11 compliance:

-IQ and OQ procedures, installed together with the software.
-User administration, based on defined user profiles (user rights).
-Audit trails.
-Projects management by revision.
-Electronic signature.
-Archiving.
-Write protection of the software functions, calculations algorithms and validation report.

- **Flexible installation.**

**NeoLiCy®** has been designed to operate in standalone or network environment. It supports single desktop/laptop installations, network installations with a data server or full network installation using Windows Terminal Server / Remote Desktop Services or Citrix Terminal Session server environment.

- **Substantially time saving.**

As a comprehensive tool for analytical methods' life cycle statistical assessment, **NeoLiCy®** supports the user in the different steps of the corresponding processes. Substantial time savings can be realized during calculations and compilation of the report.

## NeoLiCy® - the time and costs saving tool for statistical assessment of analytical methods can save days of work.