



### the quick and reliable way to validate analytical methods

When operating according to quality management systems (e.g. GMP, GLP or ISO guidelines), validation of the procedures used is of the great importance. This process, including the compilation of the validation report, is often tedious and time-consuming. The VM is a valuable, easy to use, time-saving tool, that checks whether your analytical methods are suitable for the intended use and automatically produces the validation report you need.

### versatile configuration for all analytical techniques

The validation procedure can be configured with regard to formats, used terms and language as well as with regard to calculation methods and statistical tests to be applied. Several pre-configured templates can be selected. New templates can be created and stored. This high degree of versatility enables the VM to be used for the validation of practically any analytical procedure.

### easy operation

The VM is extremely simple to use. Only a few questions must be answered in a wizard dialogue, then the validation project and document are created with a push of a button

### versatile

Depending on the application and the analytical method used, the validation of different method characteristics is required. The VM enables such characteristics to be flexibly selected, calculated, validated and reported. The validation report can be exported to Microsoft® WORD™ 97 and subsequently edited in the desired format and language. Table and column headings can be adapted to the requirements of the various analytical techniques. There is sufficient space for comments. Different statistical calculation methods and applied confidence levels can be selected as well. The high degree of versatility thus enables the Validation Manager to be used for the validation of practically all analytical procedures.

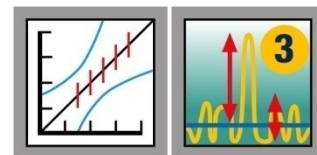
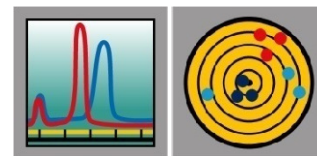
### fully FDA 21CFR Part 11 compliant

All calculation functions of the VM have been validated by extensive procedures, which are documented in the validation certificate. For revalidation in your laboratory a data set is supplied together with the software. The VM is a write protected software dedicated to only method validation, which prohibits alteration of any of the applied algorithms. For data security, the software possesses its own user administration and logbook. It contains functions that make it fully FDA 21CFR part 11 compliant: **user administration, audit trails, storage of all versions of the validation document, electronic signature, archiving functions, write-protection of the software functions and algorithms, write-protection of the report file.** You can have full confidence in the results from the validation manager.

Save days or even weeks of work in method validation with

...

## Validation Manager® Software



**Universally accepted**  
**Based on the international**  
**guidelines for validation**  
**of analytical methods**  
**as established by**  
**EP, USP, ICH and ISO.**



## reliable validation results – statistically proven

Each of the required method characteristics is calculated and statistically checked according to reliable and acknowledged procedures. You can therefore have complete confidence in the quality of the results and the validation report.

### specificity

The specificity of the analytical method can be assessed visually; subsequent to graphical super-imposition of the analytical results obtained (e.g. chromatograms). Data can be entered as graphic files.

### precision

The precision of a method is determined by calculating the coefficient of variation for each set of data and by calculating the repeatability, the intermediate precision and/or reproducibility. The set of values can be checked for outliers by using either the Dixon or Grubbs test. The homogeneity of variances can be assessed using the Cochran or Bartlett test.

### detection limit and quantitation limit

The Validation Manager provides three different methods for estimation of these characteristics. Two of these are based on the determination of signal-to-noise whilst the third uses the calibration curve and the calculated residual variance. In addition, the Validation Manager provides an extra calculation function for validation of quantitation limit.

### linearity

The calibration curve is compiled using linear regression in conjunction with the least square fit method. Subsequently, the linearity is statistically verified by establishing the presence of a significant slope and by testing the validity of the calibration curve. A plot of the residuals provides additional information on the quality of data for assessment of this method characteristic.

### accuracy

Accuracy of the method is verified by its determination either at the target concentration or over the entire working range. Using the Student Test, the distribution of recovery rates, as calculated from the theoretical and measured concentrations, is checked as to whether it includes the 100% value.

### robustness: inter-laboratory trials

The robustness of a method is assessed by establishing the effect of defined alterations to the method on precision and accuracy of the analytical results obtained. On the other hand, the reproducibility of a method is determined by inter-laboratory trials, whereby the precision and accuracy of the data obtained from several laboratories is calculated.

## dramatic time-savings in compiling the validation report

After entering data and performing calculations for the method characteristics selected, the Validation Manager automatically prints a validation report. Its contents are selectable. In the most comprehensive form it contains:

- A description of the calculation methods applied, including mathematical formulae
- Documentation of the input data
- Documentation of the calculated data
- Comments
- Validation results and their evaluation.

Input data, calculations and results can be supplemented by the analyst's own comments. Form and language of the report can be adapted by exporting it as a WORD™ 97 document. This validation report can be submitted directly to the authorities as a final method validation document.

**Compared to the manual preparation of a validation report, the completely automatic report compilation by the Validation manager saves you days or even weeks of time.**

**further information from  
The ChromSword® Group  
[www.chromsword.net](http://www.chromsword.net)**

### North America

**IRIS Technologies International, Ltd.  
1615 Branch Valley Drive  
Roswell, GA 30076, USA**

- **Tel: +1 404-348-4130**
- **Fax: +1 404-806-9525**
- **[www.iristech.net](http://www.iristech.net)**
- **E-Mail: [info@iristech.net](mailto:info@iristech.net)**