Validation Manager

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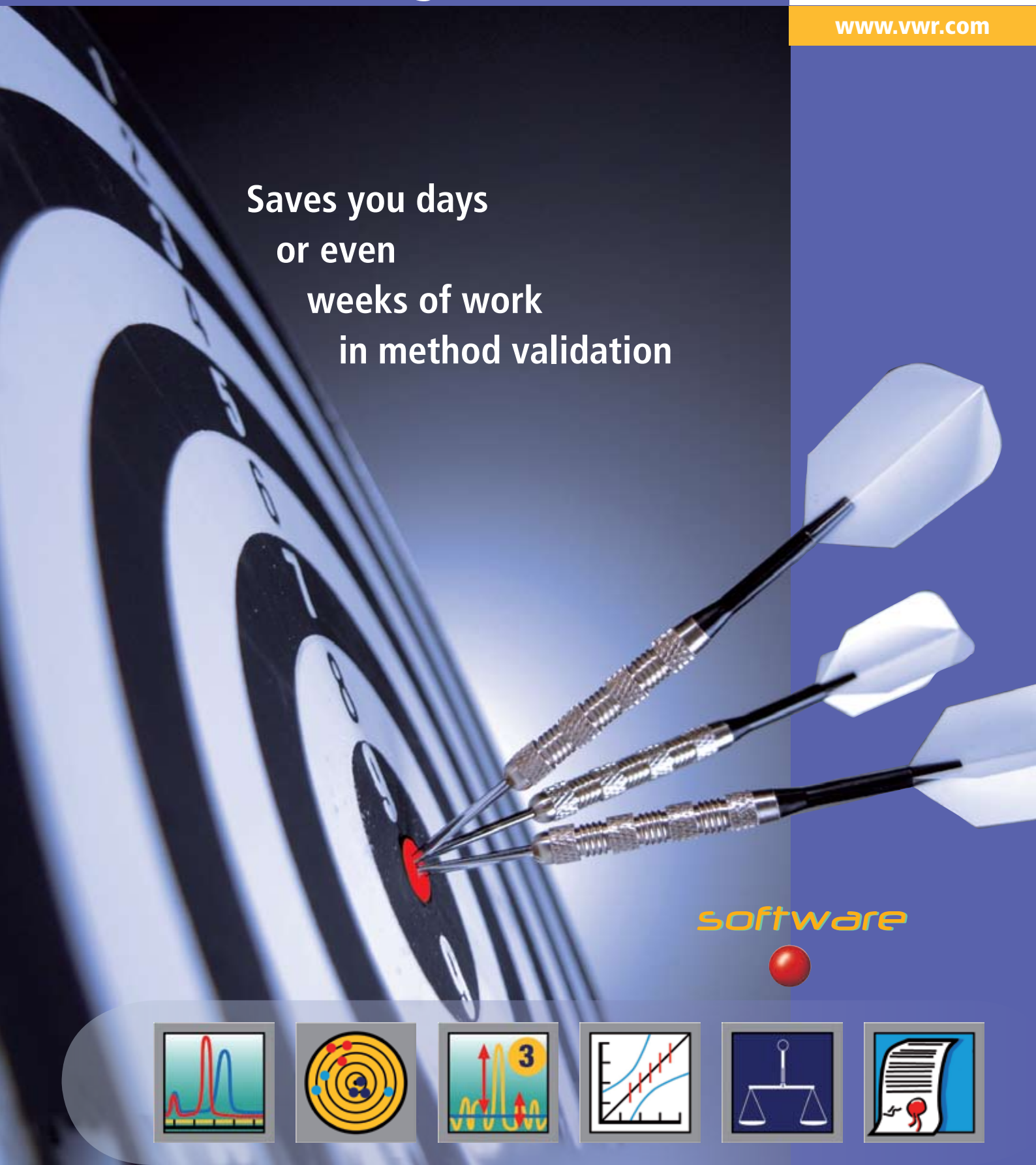
Saves you days
or even
weeks of work
in method validation



software

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Validation Manager 3.0

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 utmost importance. However, this process including compilation of the Validation Report is often tedious and time-consuming. The Validation Manager is a valuable, time-saving aid that checks whether your analytical methods are suitable for the intended use and automatically produces the Validation Report you need.

Following method characteristics can be evaluated by Validation Manager:

- Specificity
- Precision
- Linearity
- Limit of detection and limit of quantitation: estimation
- Limit of quantitation: validation
- Accuracy - at target concentration and over linear range
- Robustness
- Working range

Universally accepted

Validation Manager is based on the international guidelines for the validation of analytical methods as established by EP, USP, FDA, ICH and ISO (ISO-5725, ISO-11095, ISO-8466, ISO-11843, ISO-16269).

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 Validation Manager to be used for the validation of practically any analytical procedure.

Ease of operation

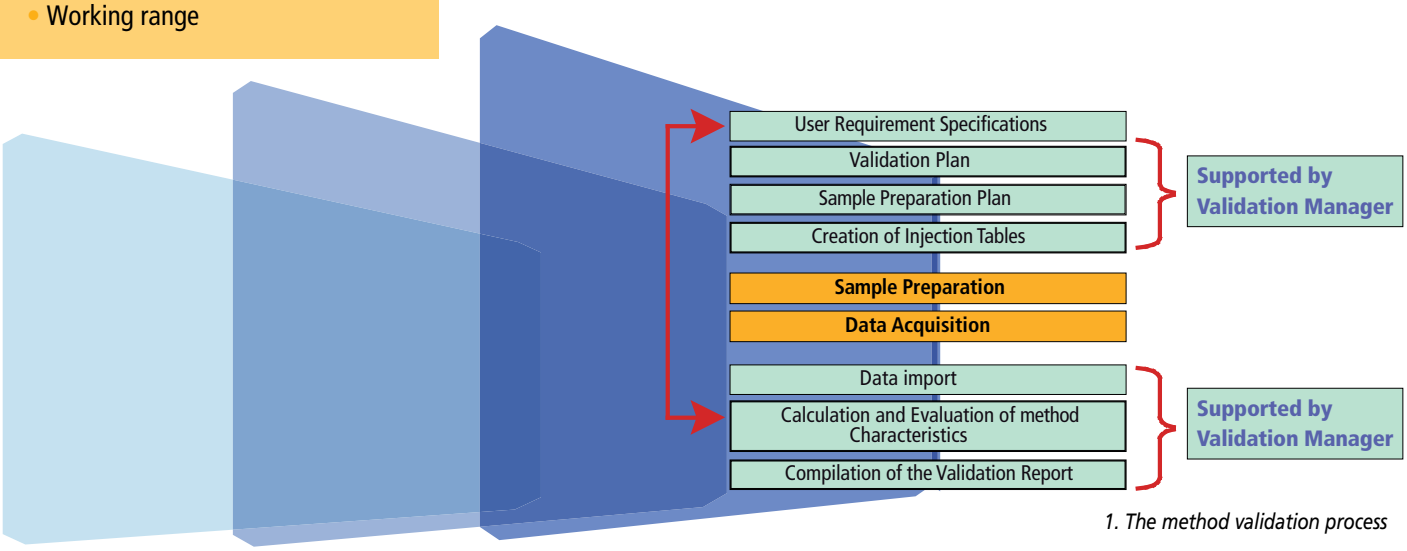
Validation Manager is extremely simple to use. Only a few questions must be answered in a wizard dialogue, then the validation project and document is created with a push of a button.

Easy creation of sample preparation worksheets and injection tables

A Programming Assistant helps to create sample preparation worksheets for the different method characteristics to be assessed. Even injection tables for the EZChrom Elite™ Chromatography Data System can be created automatically.

Easy data entry

Chromatography data can be imported from the chromatography data systems EZChrom Elite™, D-7000 HPLC System Manager and ChemStation™. Moreover, any data can be copied from EXCEL tables or input manually.



1. The method validation process

Automatic calculation

After data entry, the required method characteristics are automatically calculated and statistically checked according to the configured procedures.

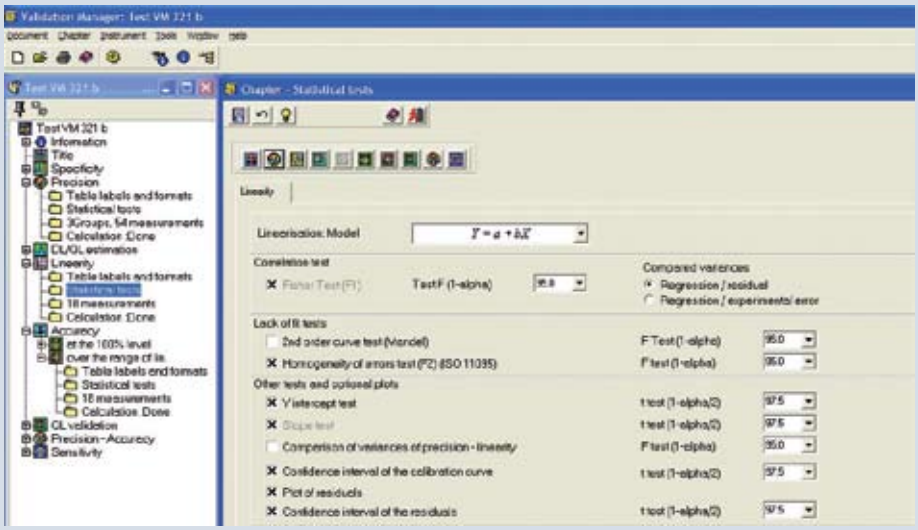
Automatic report compilation

After entering your comments and decisions, the entire Validation Report is created – at the click of the mouse. It can be printed as a write-protected standard Validation Manager Report and stored as a pdf file. Moreover, the report can also be created in WORD format to enable additional information, documents and figures to be inserted.

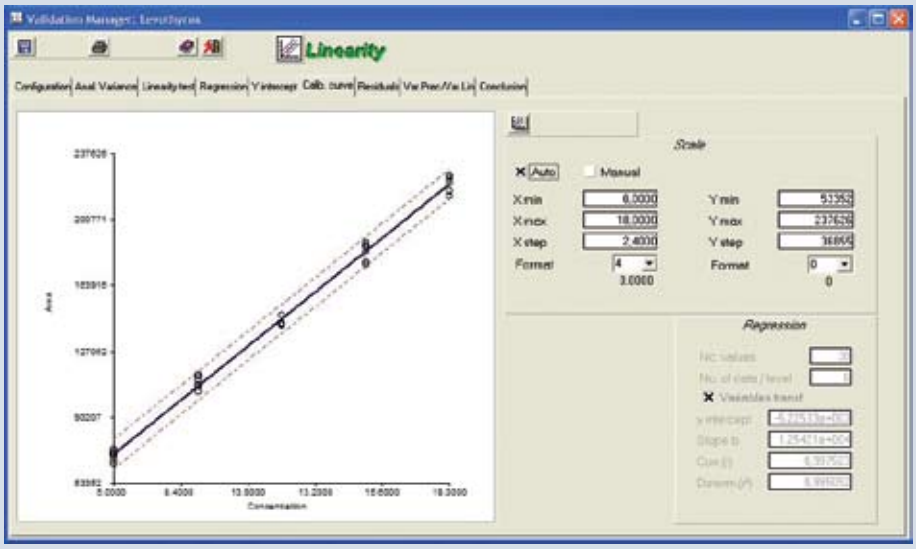
Validated and fully FDA-compliant

Validation Manager Software is validated and the validation certificate is included in the software package. It contains all functions to make it fully FDA 21CFR part 11 compliant as:

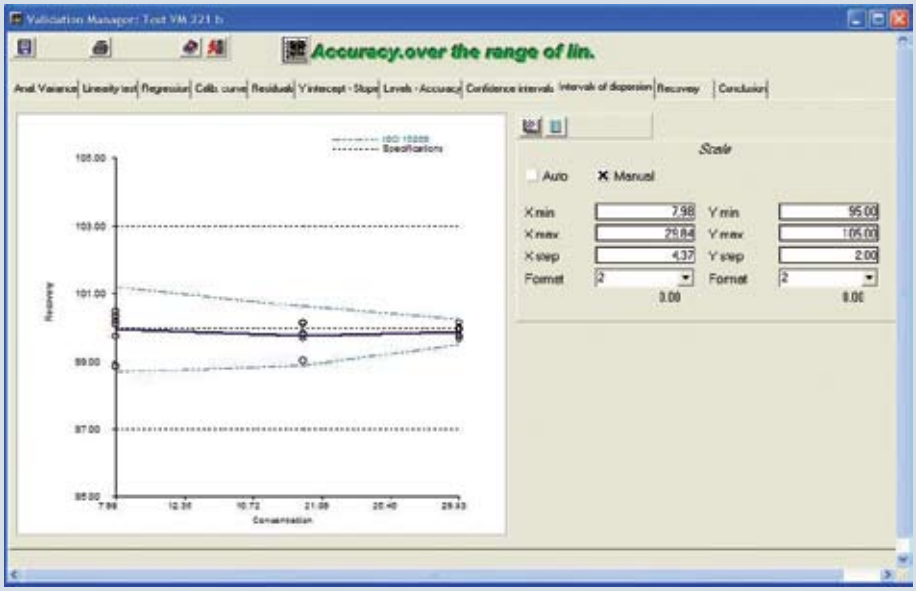
- User administration
- Audit trails
- Storage of all versions of the validation document
- Electronic signature
- Archiving
- Write-protection of the software functions and algorithms
- Write-protection of the report file



2. The navigation screen has been designed to provide easy and comfortable navigation between the data, configuration (statistical tests and formats) and calculation results screens for each characteristic.



3. Linearity: Calibration curve with confidence band and curve parameters



4. Tolerance intervals : Estimation of the total error (trueness and precision) in the accuracy study. According to the recommendations of the ISO standards, these are the intervals in which you have a reasonable chance (i.e. confidence level 95%) to find more than, for example 90% of the results of a population of results, calculated from a sample of n individual results. This is the most important new feature in Validation Manager version 3.0.

Time-saving with Validation Manager

As a comprehensive tool for computer-assisted method validation, Validation Manager supports the user in the different steps of the validation procedure.
Substantial time savings can be realised especially by the automatic compilation of the validation report.

Minimum PC configuration required:
Windows 2000™, XP Pro™ or Vista™
CPU Intel Pentium® III or higher, 500 MHz or higher,
256 Mb RAM, 8 Mb Graphic Adapter

Ordering information

Description	Cat. No.
Validation Manager 3.0	908-0036
Validation Manager 3.0 multi-user license / network version	908-0037
Upgrade to Validation Manager 3.0	908-0040
EZChrom Elite™ Automation Toolbox connection between EZChrom Elite and Validation Manager	906-0092
Software maintenance agreement	908-0038
Training	on request

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