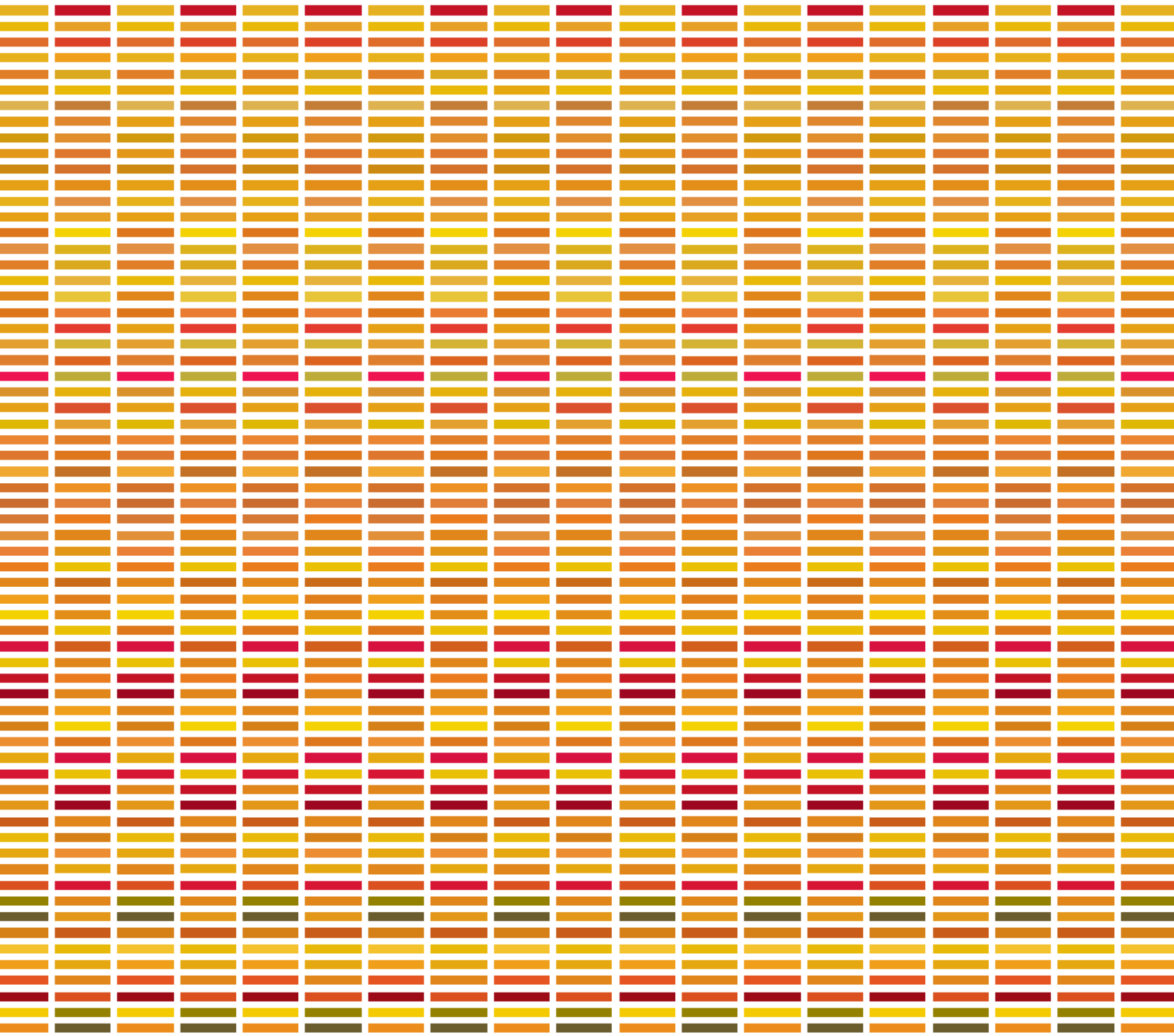
VALIDAT



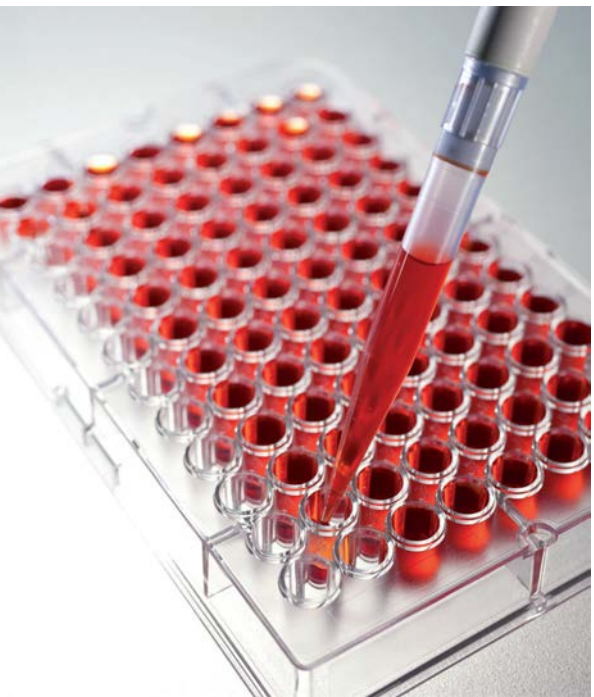
iCD.

The Leading Solution for Method Validation

01 Our Competence for Your Work

VALIDAT Overview

Throughout more than twenty years, VALIDAT established itself as the leading software solution for efficient method validation. Today VALIDAT supports validation documentation according to regulations for our customers in pharmaceutical, chemical, or biotechnical industries, in petrochemistry, materials test, or in car industries: reliable, professional and secure. Gain more profit for your work from our competence. VALIDAT helps you in saving up to 70 percent of time and costs in method validation.



02 Better Overview, Less Costs

Which guidelines are relevant?
Are you compliant to all regulations?

From more than 20 years of practical experience we know:
Method validation is an essential task in every analytical laboratory. The systematic verification of a measurement method's suitability often leads to high expenditures of time and costs – especially where the appropriate analytical tools are missing and the planning, testing and execution of all necessary steps are carried out with standard office applications that must be assured by he use of expensive review processes.

- Which parameters of a method must be considered?
- Which statistics are relevant?
- Do the calculations comply with the regulations and guidelines?
- Operation procedures must be reviewed and approved.
- Measurement values must be transferred via cross-check procedures.

We offer a convincing solution for all these questions: VALIDAT, the leading solution providing certified quality for all types of method validation.

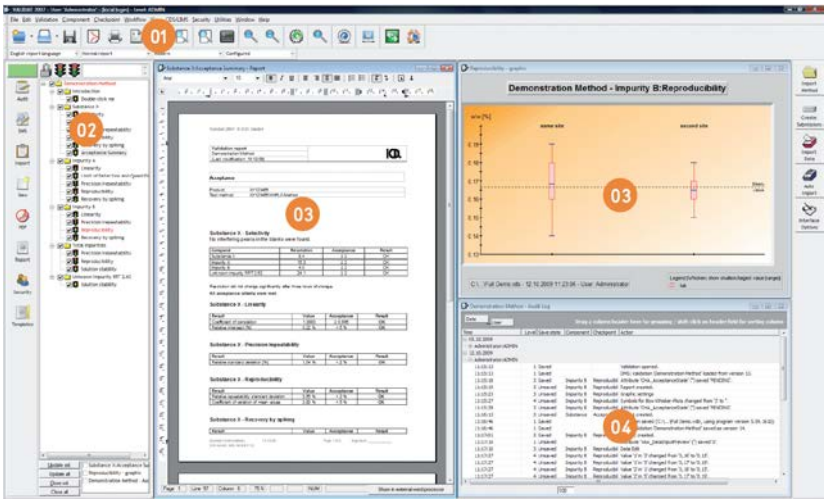
03 Secure Solution in Certified Quality

VALIDAT has been designed according to the strict regulations of DIN EN ISO 001: 2008 and GAMP. In this, two principles have been given priority:

1. High user-orientation that consequently represents the needs of daily laboratory practice.

2. Smartly organized and automated workflows, supporting and considerably simplifying each type of method validation.

Using VALIDAT, your validation projects will be securely stored in local files or on Oracle/ Microsoft SQL servers. Due to the various interfaces to results files, ata systems and our LIMS LABS/Q®, VALIDAT can be integrated effortlessly in your laboratory infrastructure.



01 Standard windows application with easy-to-use user interface

02 Easily navigate the validation project structure

03 Reports and graphics with one click

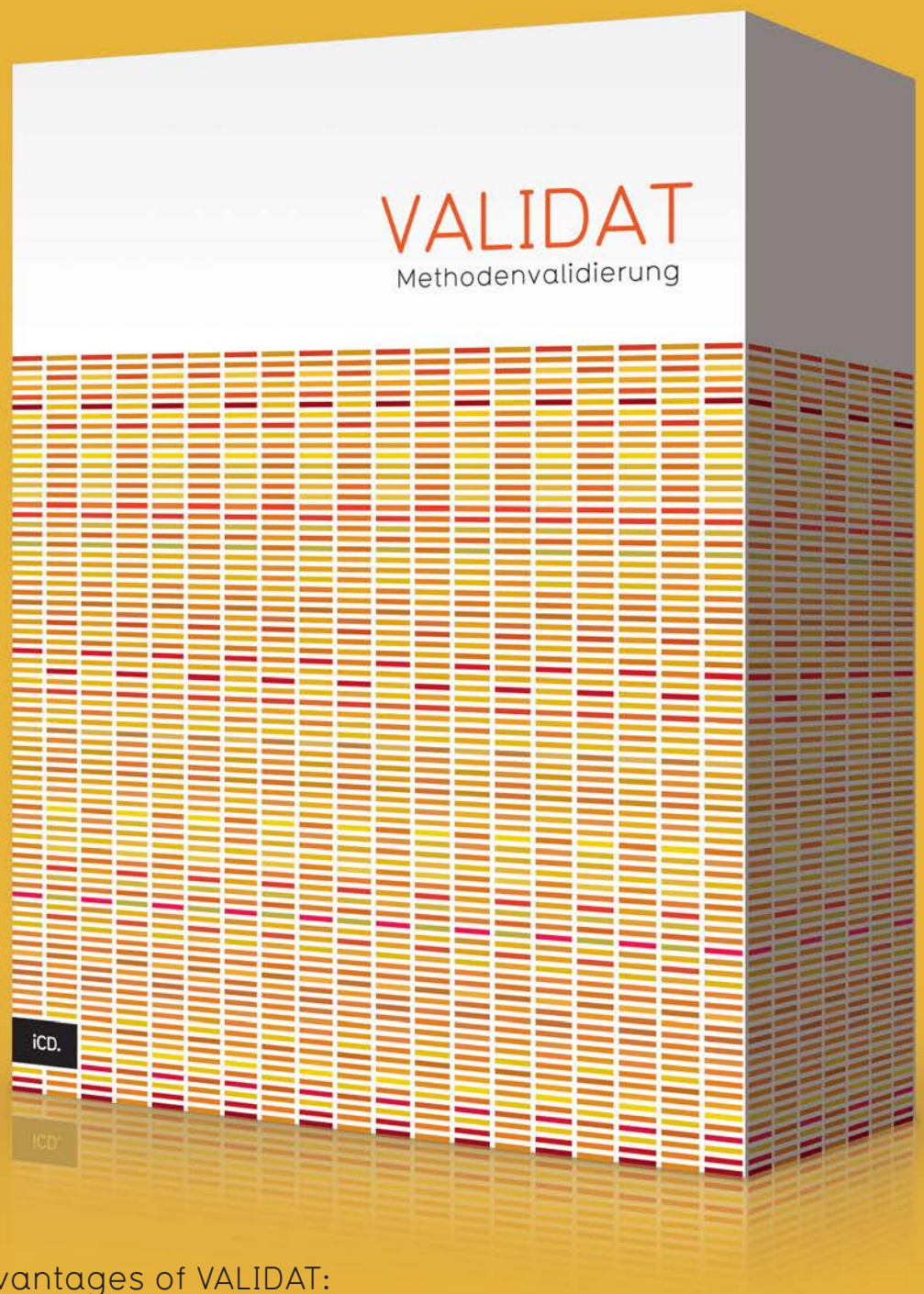
04 Full audit trail

Security and traceability combined within the integrated document management system.

In addition to the full audit trail, VALIDAT saves all versions of your documents in a document management system (DMS) to maintain security and traceability. Thus, you can view each version of your validation report in a DMS viewer or retrieve old sets of your data file versions.

Error of uncertainty according to ISO 17025

With its new easy to use module for error of uncertainty VALIDAT calculates all necessary results based on validation data (e.g. from precision or calibration checkpoints) as well as external multiplicative or additive sources. VALIDAT respects a bias and correction factors and calculates the combined error of uncertainty. The report can be used stand-alone or as part of the overall validation report.



The Advantages of VALIDAT:

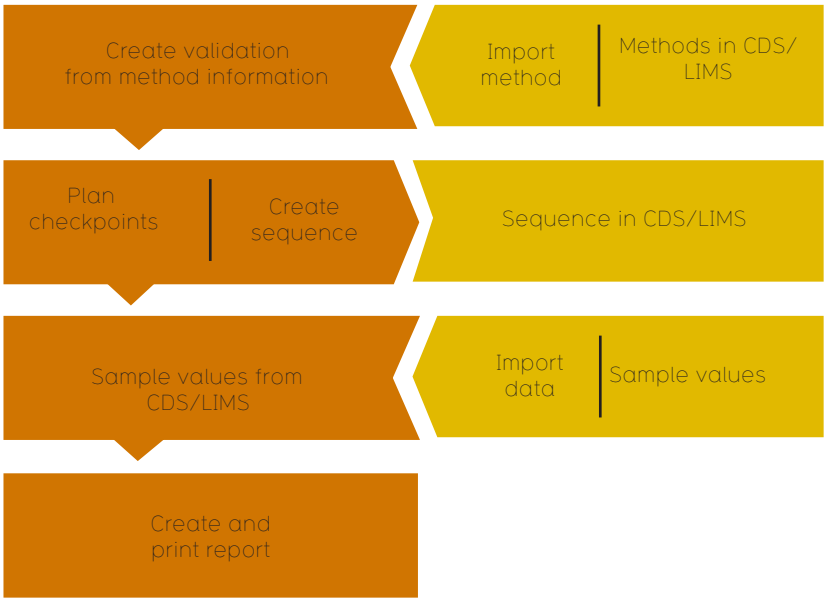
- Completely validated and easy-to-use software designed according to the requirements of GAMP 5 and 21 CFR Part 11
- Validated statistics according to ISO/ICH/FDA
- Report creation with one click
- Easily start new projects using templates
- Interfaces to leading chromatography data systems
- Software-guided workflow

04 Increased Efficiency in Validation Processes

Supported checkpoints

- Precision
- Robustness
- Method capability
- Linearity/Calibration function
- Limit of detection and quantitation
- Interlaboratory tests
- Selectivity/Specificity
- Accuracy
- Stability
- Bioassays
- Uncertainty of results

... and more



Using VALIDATs interfaces to CDS and LIMS establishes a highly automated workflow that is efficient and secure.

Integrated qualification

The fully automated Installation Qualification (IQ) and Operation Qualification (OQ) check installation files (version, size, checksum) and reporting (calculation, report creation) within a few minutes. IQ and OQ reports are saved within the document management system and, thus, are available for documentation purposes.

To carry out your validation projects successfully, VALIDAT provides all mathematical and statistical procedures and full 21 CFR Part 11 compliance. Due to well structured workflows and versatile adjustable templates, VALIDAT organizes your validation processes more easily and efficiently:

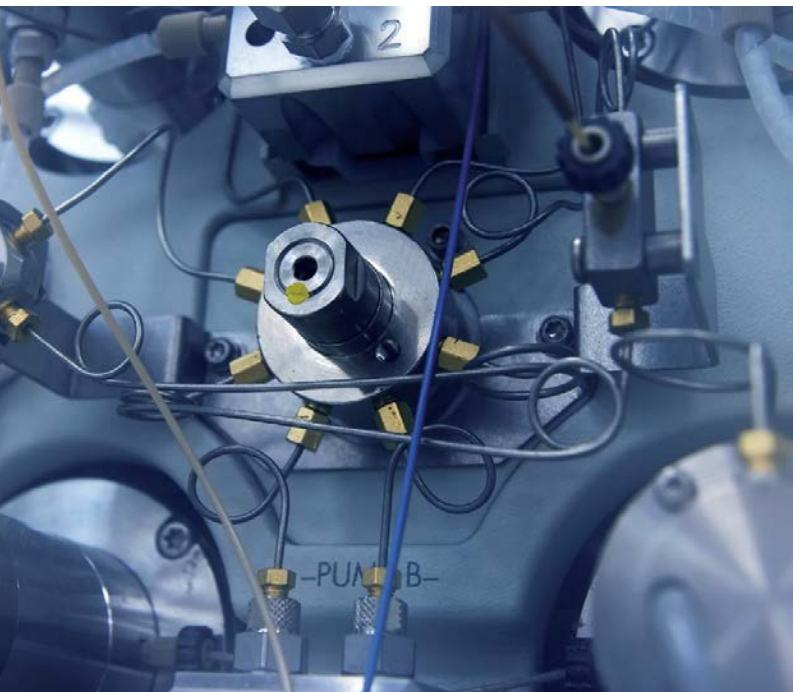
- You can release validation plans electronically and use them as a starting point for sequences in CDS or as inspection orders within LIMS.
- VALIDAT imports measurement data with a click and a complete validation report is created within minutes.
- You simply use successfully completed validation projects to create a template that will serve as a starting point for further projects.
- Alternatively you use the template assistant and merely add the required components to your project.

Generate PDFs with a click

From any report, with a click you generate a secure PDF file that will be saved in the document management system (DMS) automatically. Other file formats as RTF or Microsoft® Word are available just as well. Also graphics can be imported and exported in BMP, JPG, or WMF format.

Security Requirements	VALIDAT
User management	Flexible user security system with five predefined roles
Complete audit trail	Audit trails for validations, program access and presets
Secure data exchange	Oracle and Microsoft SQL-Server supported
Document history	Checksums and encryption for complete security
Tamper-proof data storage	Fully integrated document management system
Electronic signatures	Release reports and authorize important actions

VALIDAT complies with all important requirements regarding security and traceability.

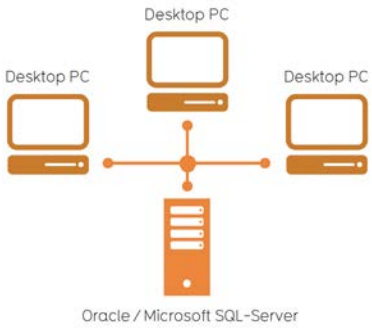


05 Easy Integration in Your Infrastructure

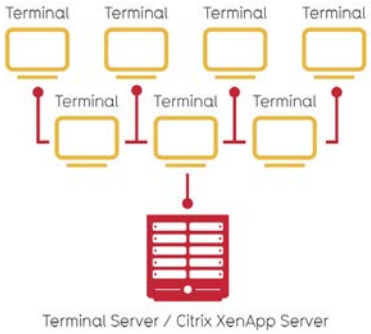
It is quite easy and effortless to adjust VALIDAT to the infrastructure of your company and to your workflows. The following three examples illustrate implementation and configuration for various company sizes of our customers.

Contract laboratory (3 users)	Medium-sized biotechnology company (20 users)	Pharmaceutical or chemical company (150 users, 5 departments, worldwide)
• Installation on single desktop with three users	• Installation on desktops using installation packages	• Installation on Citrix XenApp server
• Validation planning and data is kept in files on local file system	• Validation projects are stored on Oracle database server	• No need to install clients
• Full audit trail and document management system (DMS)	• Central user management and system audit trail	• Validation projects are stored on Oracle database server organized in five separated groups
	• Central document management system	• Central user management for each group and system audit trail
		• Central document management system

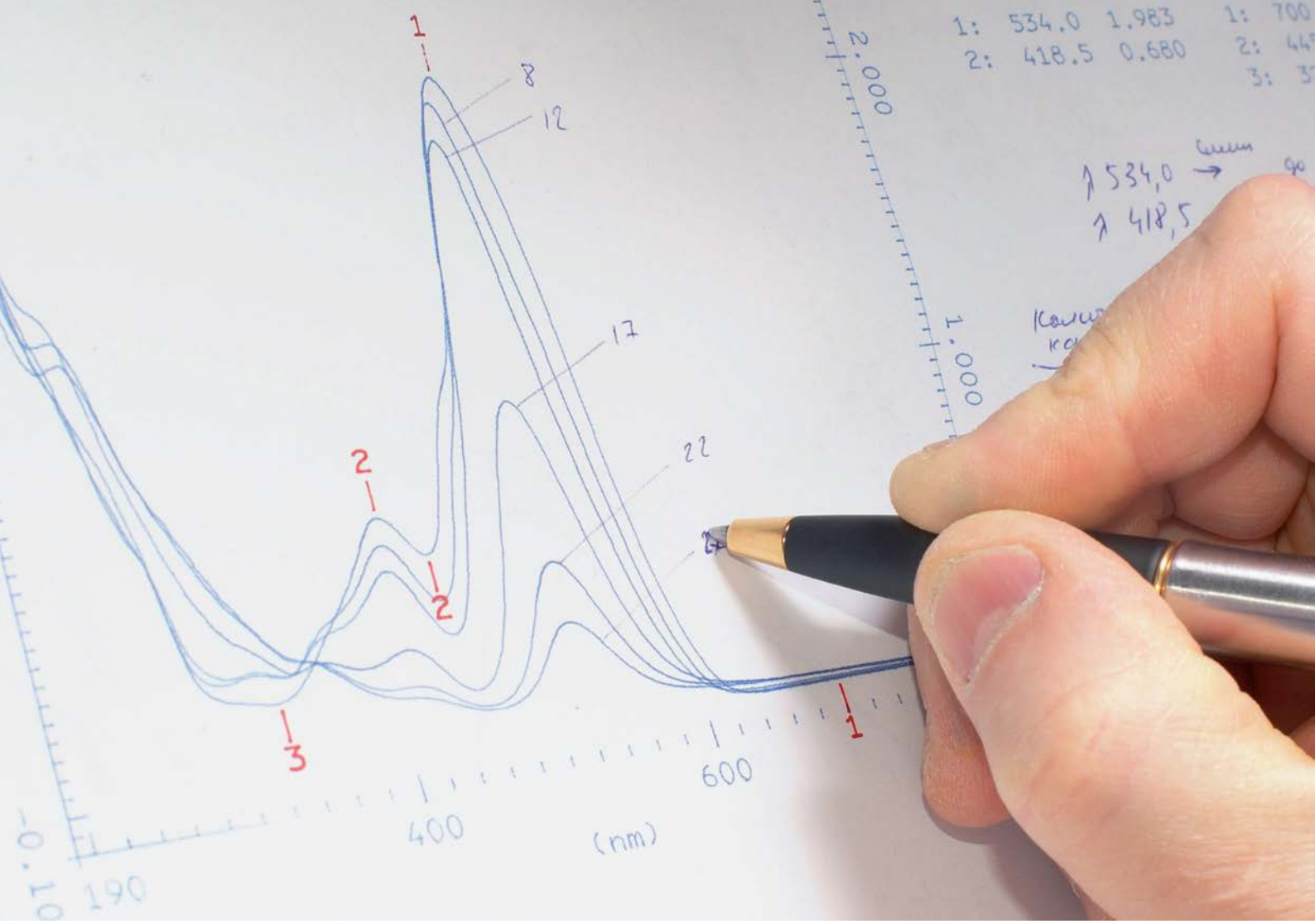
Single desktop installation



Network installation with database server



Installation on terminal server or Citrix XenApp Server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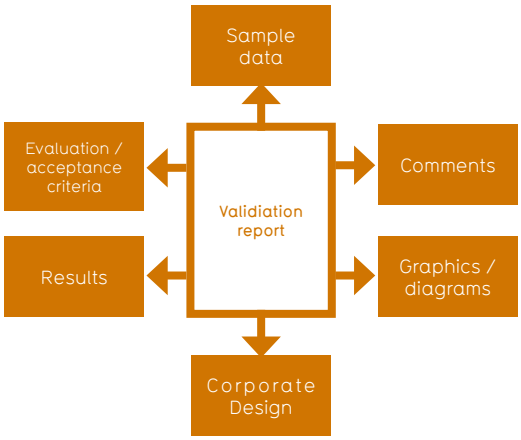
06 For Your Convincing Reporting



Der Report kann leicht an Ihre Anforderungen und an Ihr Corporate Design angepasst werden.

Use any result as an acceptance criterion

By means of text variables you can compare any statistical result with upper and/or lower limits. VALIDAT can output pre-defined texts, indicating whether the criterion is met or not. Thus, you gain great flexible options to specify and evaluate crucial properties of your particular validation project.

Using VALIDAT, your validation reports are created using pre-defined layouts. Furthermore, VALIDAT provides a lot of options to arrange comments and graphics in your report individually. Using text variables and acceptance definitions will assist you with creating result summaries and acceptance tables effortlessly and quickly. You will get a convincing and clearly arranged report.

The integrated text processor component offers a powerful environment for editing your texts:

- Tables
- Graphics
- Compatibility with Excel and Word (clipboard)
- Formatting of paragraphs and characters

Whether you are handling title pages, data system report, list of materials, chromatograms or company logo – by using VALIDAT you can arrange your report according to your corporate design.

Increased flexibility due to automated text variables

You can use text variables at any position within the report. During report creation, the text variables will be replaced with the appropriate contents automatically. Thus, you can add a variety of automatically generated information to your report:

- Name of the validation project
- User name, date or filename
- Number of samples and injections on a given checkpoint
- Header information
- Total number of pages and page numbers
- Results

Each result that has been calculated by VALIDAT can be diplayed at any position within a userdefined text. Thus, for instance, you can output the limits of detection and quantitation within a comment accompanying an analysis of linearity.

- Checkpoint report
- Planning report
- Overall report
- Acceptance overview
- Sample report
- Audit trail report

... and many more

07 Your Advantages

iCD. offers assistance and support at each stage of the project. Beginning with DQ up to the final system qualification we help you on-site with our experienced employees in establishing the very best solution for method validation in your company.

VALIDAT supports you in considerably saving time and costs for method validation:

- Saving time during planning and performing method validation projects
- No validation of calculations is required
- Templates for recurring tasks

Reduce risks by the use of an automated software solution:

- Audit trail and security
- Workflows
- Validated calculations
- Automated transfer of measured values

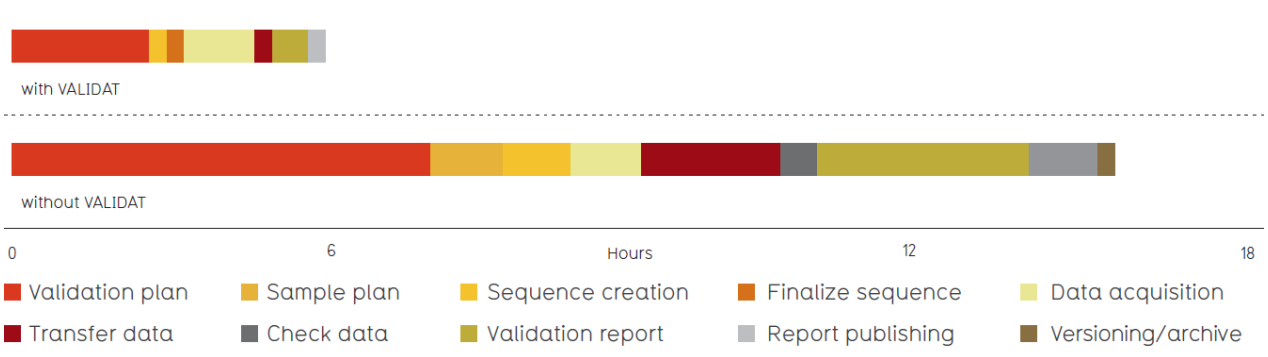
Without a method validation software...

≠ Research guidelines and regulations
≠ Manual planning steps
≠ Validate calculations
≠ Manually transfer and verify sample data
≠ Manually create and verify report
≠ Establish and check workflows

With VALIDAT...

= Fully validated easy-to-use software developed in compliance with FDA 21 CFR Part 11 and GAMP 5 regulations
= Easy validation setup using templates
= Validated statistical functions in compliance to ISO/ICH/FDA
= Use interfaces to leading chromatography data systems
= Create reports with a single click
= Establish workflows fully supported by our software

Your time-savings by using VALIDAT



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