

Solution for **Clinical Laboratories**

Validations Made Easy

"We can trust the results more now, as the process and data traceability is so good!"



Due to increasing regulation especially related to new requirements introduced in ISO 15189 and CE-IVD, validation and verification work of new or modified diagnostic methods have become a tedious task for most clinical laboratories. With **Validation Manager™** software, you have the perfect tool for your laboratory to digitalize, automate and standardize the time-consuming and error sensitive data-handling of validations.

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validationmanager.com

Validation Manager™ makes both validation of in-house developed methods and verification of commercial methods easy and efficient, and helps to ensure that validations are conducted according to the latest regulatory requirements. It helps you to plan, conduct and report validations in a highly automated and standardized way, and eliminates the need for any additional software, such as Excel. **Validation Manager™** can be applied e.g. in molecular diagnostics, clinical chemistry, serology and hematology laboratory disciplines.

Benefits in practice

Improve quality and reduce errors. Electronic transfer of result information from laboratory instruments to **Validation Manager™** eliminates many severe possible errors. Automatic result analysis provides most reliable estimation of the test method performance using latest statistical methods.

Standardize and automate process and working practices. **Validation Manager™** utilizes standardized CLSI protocols that meet or exceed regulations. You conduct validations with the standardized, software-guided process and harmonize working practices across the organization.

Get transparency of validation project progress and results. **Validation Manager™** creates a clear and transparent view on the validation data from reports back to raw experiment data coming from the instruments.

Help accreditations through standardized reports and data formats. **Validation Manager™** provides a centralized data repository and archive, standardized reports and data formats for validations. With an entire view in one source it improves the transparency and quality of the validations. Thus it helps to fulfill accreditations requirements.

Keep up with changing guidelines. We closely monitor changing requirements relevant to validations. **Validation Manager™** is a web-based tool. When new standards emerge and guidelines change, you have access to latest protocols.

Save up to 95 % time. With the help of **Validation Manager™** diagnostics tests can be validated and verified easier, faster and with less costs involved. We have shown up to 95 per cent savings in time required to validate a diagnostic method in a hospital laboratory environment.*

* Improvement of diagnostic method validation processes in a Finnish hospital laboratory using lean methods and a software solution, EMMD 2015, Hirvonen T. et al.