Solution for Diagnostic Companies

Validations Made Easy

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

Bringing new diagnostics tests to the market is a tedious task for most diagnostics companies. This is even more challenging now with ever tightening regulatory requirements posed by e.g. the new CE-IVD and FDA. With Validation Manager™ you have the perfect solution to shorten your time to global market.

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validationmanager.com

1. Validation Manager™ helps you in your internal validations by digitalizing, automating and standardizing the time-consuming and error sensitive data-handling of preclinical validation studies.

2. Validation Manager™ is an ideal solution for external performance evaluations, where collection, analysis and real-time monitoring of data from external laboratories require often tremendous efforts.

3. By offering Validation Manager™ to your laboratory customers during product evaluations, you can drastically facilitate their burden on evaluating your assay and increase the chance to get it in use.

Benefits in practice

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

You can be sure that you product fulfills the regulatory requirements. Validation Manager™ provides standardized, transparent and fully traceable way of managing diagnostics test validations. Systematic validation process helps to conform to new regulatory requirements set by e.g. the new CE-IVD and FDA, and results are based on CLSI guidelines.

Harmonized working practices. All data handling previously done in Excel, statistical tools or with paper notes is digitalized and highly automatized in Validation Manager™. This enables organization to harmonize and standardize the working practices between people, and enables having a clear and transparent view of the validation progress for any relevant stakeholders.

Ease-of-use and flexibility to adapt to your needs. Validation Manager™ is easy and intuitive to use and can be trained and taken into use by the organization even in a day. Introducing the solution requires minimum level of efforts, as it doesn´t require any installations.

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