Why investing in Validation Manager makes perfect sense!

Following the ISO 15189 standard, laboratories are required to verify the performance of all new instruments and tests. Verifications are also required every time something changes, as for example: lot changes, instrument calibrations, instrument maintenance, minor or large instrument relocations and so on. In addition, as part of the ISO standards, it is imperative that measurement uncertainty is estimated and regularly updated for each method run in the laboratory. Furthermore, laboratories need to demonstrate the comparability of examination results between methods, instruments and locations. All these requirements serve one purpose: to monitor the operation of the laboratory and to improve the quality of the running diagnostics. After all, accuracy of the diagnostics is essential for patient safety and efficient operation of the entire healthcare system.

The financial aspect - gains and savings through increased efficiency:

- Time and competences are the most valuable and expensive resources we have. Laboratory professionals are difficult to recruit, so it is much more desirable to increase our laboratory throughput by making all our operations leaner and more efficient. As the ever-increasing quality requirements take up a major part of laboratory professionals' time, it is crucial to automatize the quality processes as much as we can. Validation Manager provides your laboratory with top of the range competences while saving a huge amount of time through automation - time that is today spent on tasks that are completely unnecessary.

- With Validation Manager the many verification and quality assurance processes for all the laboratory's instruments and tests can be automatized and standardized, which means:

    - **Much less staff resources are required to perform the verification and quality assurance work.**
    - **Less time and money spent on verification and statistical trainings and upgrading courses for staff.**
    - **More staff resources can be used in the laboratory's routine work such as the production or in research.**
    - **Instead of time being wasted on unnecessary manual and trivial tasks, staff can instead be further educated. Their competences can be enhanced in other areas securing the lab's ability to meet future demands and challenges.**
    - **Some labs might, instead of investing in upgrading staff competences or leaner operations, reduce their workforce relative to the time savings.**

Where do these savings and gains come from?

✓ **No time spent investigating and collecting updated information from guidelines / articles / other validation and verification projects**
With Validation Manager you will always use the latest internationally approved methods and can trust the results and calculations to be correct. Future staff will need only very little training to work with verifications in Validation Manager.

✓ **No time spent on lengthy processes planning your projects**
Create standardized project templates in Validation Manager once and keep applying them across your organization – saving your lab hours of work every time you have to start a new project.

✓ **No time wasted on manually typing data into spreadsheets**
Avoid typos and many other errors - Validation Manager can import the raw data from instruments, middleware and LIS directly - saving your lab days of work per project.

✓ **No time wasted making calculations, equations, creating graphics and statistics**
Validation Manager handles all complex statistics automatically, according to the latest standards – saving hours of work and allowing you to focus on the results.

✓ **Minimal time required for report writing**
Results can be analyzed and commented in real-time by multiple people, and everything is automatically collected in a formal project – saving hours or days of work.

✓ **Save hours of work with accreditation audits**
Everything is stored in one place; everything is standardized, traceable and easy to understand.

✓ **Save hours sharing data among colleagues**
Everything is available in one place.

✓ **Save money on small and limited spreadsheet add-ons**
Validation Manager is the only solution needed for complete verification project support.

✓ **Save money on buying guidelines**
Save hundreds of pounds buying guidelines already implemented in Validation Manager.

✓ **Save your lab from spending time on redoing faulty and erroneous calculations, conclusions and whole projects**

The quality aspect – increase diagnostic quality with less effort:

- The ISO 15189 and ISO 17025 standards require that laboratories have a working quality system in place: encompassing means to improve the overall and individual quality of processes, instruments and tests.

- Among these important measures are the periodic verifications and investigations into the lab performance - such as precision and accuracy studies, instrument and assay comparisons, lot-to-lot variations, IQC performance tracking and monitoring and calculating the measurement uncertainty of all the laboratory's instruments and tests. It is in everybody's best interest – from patient to clinician, management and society - that laboratories provide trustworthy, precise and objective results.

- It is generally accepted that around 80% of all diagnoses given by doctors in hospitals around Europe are based on lab generated results. Therefore, providing accurate and precise results are of paramount importance, just like the consequences of poor analytics can be paramount.

- As lab instruments and tests have such a profound and decisive impact on the treatment of patients, it is not uncommon to see laboratories are performing, as a minimum, monthly or quarterly check-ups on current performance through verification studies of all their instruments and assays, while also monitoring quality performance over time – As it might save lives.

- Validation Manager takes away the manual work done today in spreadsheets, data transfers, calculations, graphic representations and report writing, while increasing lab quality and verification transparency from raw data to the final conclusion.

- Validation Manager secures that you use correct protocols and statistics when making conclusions about your quality. We have seen in many laboratories that wrong choice of statistics, e.g. regression models and precision statistics, or missing knowledge on how to evaluate confidence, has caused poor or even failed end results to be mistakenly accepted, and the faulty test being taken into routine use.

- Validation Manager enables your laboratory to fulfill all these requirements with much less effort than today and with improved quality, performance and understanding as a result. Many Validation Manager user-labs have started to follow their IQC, measurement uncertainty, lot-to-lot variation, inter-laboratory comparisons and parallel instrument performance regularly using Validation Manager. Even with a much-increased focus on performance studies, timesaving's through automation and standardization are remarkably large. These new practices have helped in many cases in finding faulty instruments, bias between reagent lots and poor performance with some methods.

- Easily get both an overview and a detailed understanding of your lab's quality performance
- Manage and initiate required actions in a timely and proactive manner
- Remove expensive and time-consuming manual, error-prone tasks and significantly lower the risk factors of wrong conclusions
- Use correct statistics to make correct conclusions
- Ensure fluent accreditation
- Make objective, rather than subjective, analyses based on relevant statistics
- Ensure and increase the reliability and relevance of your lab's results
- Maintain completely transparent projects with full traceability with nearly no effort
- Set relevant, important and meaningful performance goals for all your laboratory verification projects
- Standardize all processes and practices in these verification and quality assurance projects
- Easily read and understand both peers' reports as well as older reports and calculations in Validation Manager
- Easy access to valuable functions not readily available in spreadsheets. For example, automatic calculations of:
  - All results, including the 95% confidence interval – key to your statistical significance
  - Measurement uncertainty of all your assays and instruments
  - Comparisons of all your parallel instruments and assays
  - Cross laboratory, location or peer lab comparisons

- If your lab is conducting verification projects and quality performance checks as stated in the ISO 15189 standards such as precision and accuracy studies, periodic instrument and assay comparisons, lot-to-lot variations, IQC performance tracking and monitoring and calculating the measurement uncertainty of all your laboratory's methods and managing it in excel sheets and inherited templates and word documents maybe with some add-on spreadsheet tools? Then we're 100% convinced that you very quickly will find and realize the quality improvement, financial gains and timesaving that are easily attainable from your current verification processes.