

METHOD VALIDATION

SAVANT TECHNOLOGIES

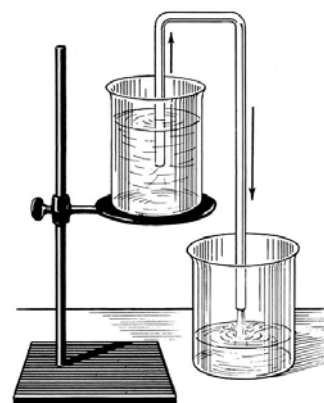
ISO 17025 requires that laboratories must demonstrate that they can properly operate standard methods and that they must validate any non-standard or in-house methods they use. Validation is the confirmation by provision of objective evidence that the requirements for a specific intended use are fulfilled.

This one or two day workshop considers first how customer requirements for uncertainty, regulatory limits etc. should influence planning of the validation. It then covers performance aspect such as limit of detection, working range, precision, trueness. It considers also how the ruggedness of methods to variable conditions can be estimated. Some guidance is given on the sort of materials that can be used and how experiments should be statistically designed. Finally the information to be provided in a validation report is discussed.

The instruction given is based on materials drawn from guidance documents such as 'The Fitness for Purpose of Analytical Methods' from Eurachem. Guidance from sector-specific documents such as DWI, MCerts or food contaminants regulations can also be included. This is explained and illustrated in contexts and applications that will be understood by laboratory staff.

This workshop is complimented by others offered by **Savant Technologies** on Statistical Tools and Measurement Uncertainty.

The workshop is structured into short presentations and example exercises. Materials are available for use in Microsoft Excel where delegates have access to computers. Workbooks are provided that contain notes on the presentations, example exercises and answers and references to useful books and resources.



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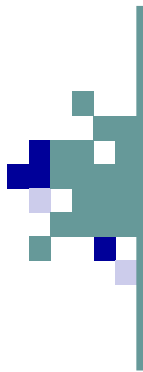
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matter. Benefits
that count**



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Course Content

Planning

- ◇ Customer requirements
- ◇ Expectation of samples to be analysed
- ◇ Product specifications and regulations
- ◇ Sector specific guidance

Tools and Resources

- ◇ Blanks
- ◇ Routine samples
- ◇ Spiked samples and CRMs
- ◇ Collaborative trials
- ◇ Statistical design and evaluation

Working Range

- ◇ Instrument working range
- ◇ Testing requirements
- ◇ Analytical range

Detection Capability

- ◇ Limits of detection and quantification
- ◇ Detection capability for qualitative tests

Trueness

- ◇ How to estimate trueness
- ◇ Interpreting bias

Precision

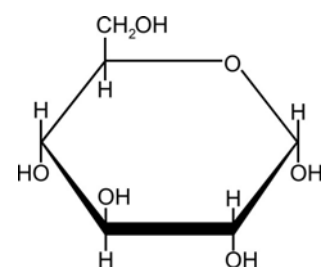
- ◇ Estimating repeatability and reproducibility
- ◇ Defining limits for replicate analyses
- ◇ Using Analysis of Variance

Ruggedness

- ◇ Ruggedness and reliability
- ◇ Identifying critical factors
- ◇ Ruggedness experiments

Reports

- ◇ Contents
- ◇ Conclusions on fitness for purpose
- ◇ Review



PUBLIC COURSE TRAINING

CLOSED COURSE AND ON-SITE CLASSROOM TRAINING

SIDE BY SIDE TUITION

SPREADSHEET BASED TRAINING

DESIGN OF QUALITY ASSURANCE SYSTEMS

COMPUTER BASED SOLUTIONS

STATISTICAL CONSULTANCY & TRAINING

ESTIMATION OF MEASUREMENT UNCERTAINTY

LABORATORY ACCREDITATION

UNDERSTANDING ISO 17025

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