



*Training Course:
Method Validation*

*23 - 27 August 2027
Kuala Lumpur (Malaysia)*

Training Course: Method Validation

Training Course code: SC234750 From: 23 - 27 August 2027 Venue: Kuala Lumpur (Malaysia) - Training Course Fees: 6300 € Euro

Introduction

Method validation is the process that provides evidence that a test method is capable of producing results that are suitable for a particular application. It is a requirement of the ISO/IEC 17025 and ISO 15189 laboratory accreditation standards and many other sectoral regulations and directives. Method validation should always be a planned activity. This course introduces the statistics required for interpreting validation data and provides the tools to plan and carry out effective validation studies.

Course Objective

This course will help you:

- Understand method validation and its requirements
- Select and apply the statistics required during method validation
- Select and use the appropriate types of method validation studies
- Appreciate and understand the link between method validation and measurement uncertainty
- Apply statistical principles through laptop-based workshops.

Target Audience

This course is primarily designed for:

- Analysts
- Laboratory managers in the analytical chemistry and related sectors.
- People who are interested to expand their knowledge in method validation.

Course Outlines

Day 1

Introduction to course

- Introduction to statistics
- Population vs sample statistics

- Distributions of data
 - Degrees of freedom
 - Calculating mean, standard deviation, relative standard deviation, standard deviation of the mean
- Introduction to significance testing

Introduction to significance testing

- Probability: level of confidence and significance
- One-tailed vs two-tailed tests
- Hypotheses
- Interpreting results from significance tests

Significance testing: t-tests

- Different t-tests one-sample, two-sample, paired
 - Calculating the t statistic
 - Obtaining critical t-values
 - Assessing the significance of t
- Significance testing: F-test
- Calculating the F statistic
 - Obtaining critical F-values
 - Assessing the significance of F

Day 2

Analysis of variance ANOVA

- What is ANOVA?
- Uses of ANOVA
- Key terms in ANOVA sum of squares, mean square
- ANOVA calculations
- Interpreting the results from ANOVA

Linear regression: Interpretation of parameters and pitfalls

- Uses of regression
- Principles of least squares linear regression
- Assumptions in linear regression
- Interpreting residual plots
- Interpreting regression statistics correlation coefficient, residual standard deviation, etc
- Estimating the uncertainty in predicted values obtained from a linear calibration plot

Day 3

Introduction to method validation

- ISO definition of validation
- Why is validation necessary?
- Who validates a method and when?
- Defining analytical requirements
- Assessing fitness for purpose

Precision

- Definition of precision
- Types of precision estimate repeatability, reproducibility, intermediate precision
- Determining precision
- How many replicates?
- Using ANOVA in precision estimation pooling data
- Exercise on planning precision studies

Bias

- Definition of bias
- Expression of bias
- Using t-tests in bias assessment
- Number of replicates required

- Use of reference materials, spiking studies and reference methods in bias assessment

Day 4

Ruggedness testing

- Definition of ruggedness testing
- The need for ruggedness testing
- Examples of parameters that can be studied
- Planning a ruggedness test: the Plackett-Burman design
- Evaluating results from a Plackett-Burman study

Selectivity

- Definition of selectivity
- Approaches to evaluating selectivity

Capability of detection

- Definitions: critical value, limit of detection, limit of quantitation
- False positives and false negatives
- Typical experiments for establishing LOD
- Statistical basis of limits

Day 5

Linearity and working range

- Definitions of working range and linearity
- Establishing working range and linearity
- Instrument versus whole method linearity
- Prediction analytical linearity
- Measures of linearity
- Tests for non-linearity

Measurement uncertainty and validation studies

- Definition of measurement uncertainty
- ISO approach to evaluating uncertainty
- Basic rule for combining uncertainties
- ISO 17025 requirements
- Using data from validation studies in uncertainty estimates

Registration form on the Training Course: Method Validation

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