



Method validation On-line programme

Session timings

Standard session times are:

Session 1: 09:30-12:00 GMT

Session 2: 13:30-16:00 GMT

Some courses are scheduled with afternoon and evening sessions to allow participation from other time zones. Please see the website for details.

Sessions will include a mixture of presentations, interactive exercises and practice calculations.

Each session is scheduled for 2.5 hours but it is expected that most sessions will last for approx. 2 hours.

You will also be scheduled for a 30 min pre-course connectivity test to allow you to check your audio and access to the Webex platform.

Session 1	Session 2
Module 0.1 – Pre-course work – familiarisation with Excel and basic statistical tools	
Module 1 Introduction to statistics Introduction to significance testing	Module 2 Significance testing: <i>t</i> - and <i>F</i> -tests
Module 3 Analysis of variance (ANOVA) Linear regression	Module 4 Introduction to method validation Evaluating precision
Module 5 Evaluating bias Planning precision and bias studies	Module 6 Ruggedness testing Selectivity
Module 7 Capability of detection Linearity and working range	Module 8 Measurement uncertainty and validation studies



Module	Topics
<u>Module 1</u>	<p>Introduction to course</p> <p>Introduction to statistics</p> <ul style="list-style-type: none">• Population vs sample statistics• Distributions of data• Degrees of freedom• Calculating mean, standard deviation, relative standard deviation, standard deviation of the mean <p>Introduction to significance testing</p> <ul style="list-style-type: none">• Introduction to significance testing• Probability: level of confidence and significance• One-tailed vs two-tailed tests• Hypotheses• Interpreting results from significance tests
<u>Module 2</u>	<p>Significance testing: <i>t</i>-tests</p> <ul style="list-style-type: none">• Different <i>t</i>-tests (one-sample, two-sample, paired)• Calculating the <i>t</i> statistic• Obtaining critical <i>t</i>-values• Assessing the significance of <i>t</i> <p>Significance testing: <i>F</i>-test</p> <ul style="list-style-type: none">• Calculating the <i>F</i> statistic• Obtaining critical <i>F</i>-values• Assessing the significance of <i>F</i>
<u>Module 3</u>	<p>Analysis of variance (ANOVA)</p> <ul style="list-style-type: none">• What is ANOVA?• Uses of ANOVA• Key terms in ANOVA (sum of squares, mean square)• ANOVA calculations• Interpreting the results from ANOVA <p>Linear regression: Interpretation of parameters and pitfalls</p> <ul style="list-style-type: none">• 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



Module 4

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

Module 5

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

Module 6

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

Module 7

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

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
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Module 8

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

Course wrap up
