

METHOD VALIDATION (ANALYTICAL LABORATORIES)



Aim of Course

The Method Validation (Analytical) course aims to provide attendees with a fundamental understanding of the importance of Quality Control and Quality Assurance in a laboratory, as well as the reasons for conducting Method Validation.

It furthermore provides the tools for conducting Method Validation and the methodology for approaching this often vexing requirement. Attendees are afforded ample opportunity to reinforce the theoretical aspects with practical and hands-on assignments on a daily basis.

Pre-Requisites for attending this course

- Introduction to Measurement (strongly recommended)
- Grade 12 Mathematics (strongly recommended)

Course Overview

- Define the meaning of Validation and be able to highlight the essential processes within it. These processes include an understanding of testing, calibration, verification and qualification.
- Understand the importance and be able to explain the use of statistics as a tool in quality control and the validation process.
- Draw a sample from the larger population and to be able to compare the mean of the sample with the mean of the population.
- Basic statistical methods (mean, weighted mean, median, variance, standard deviation).
- Distributions.
- Coefficient of variance (%CV). Coverage Factor
- Tests
 - Outliers (Dixon & Grubbs)
 - F, t pooled t, Pooled t with multiple samples, Horwitz, Horrat
 - % Error, Z-score
 - ANOVA
- LOD, LOQ, Regression Analysis and Linearity
- Ruggedness, robustness, precision, bias, Trueness repeatability and reproducibility
- Introduction to uncertainty with many laboratory examples
- Correct rounding of digits

Course requirements

A scientific calculator (such as a Sharp EL 531 or similar) must be brought by each student. (Pens, Paper, Course notes, Tea/Coffee and Lunch will be provided). Arrangements can normally be made for special dietary requirements but please advise the NLA-SA at least a week before the course is due to start.

Who should attend

Scientists, laboratory technicians, quality control staff, researchers

Course Duration

5 Days

Evaluation

Students are evaluated on attendance, daily tests and the passing of a final examination. The daily tests account for 30% of the final marks and the examination accounts for 70% of the final marks.

The examination will be written approximately two weeks after the completion of the course.

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