LIBERTY PRO (PTY) Ltd.

achieving excellence together

Statistical Method Validation & Uncertainty of Measurements

Course Description

ISO 17025:2017 was developed with the objective of promoting confidence in the operation of laboratories. The standard contains requirements for laboratories to enable them to demonstrate their competency to generate valid results.

Method validation is a key requirement of ISO17025 and ISO 15189 accreditation standards and other regulations and directives. Method validation is the process that provides evidence that a test method is capable of producing results that are suitable for a particular application.

The course aims to provide attendees with a fundamental understanding of the importance of method validation, the methodology for conducting method validation and the evaluation of method performance characteristics including measurement uncertainty using appropriate statistical tools.

Course Objectives

- Provide a deep understanding of the importance of method validation in testing laboratories.
- Provide the tools and methodology for conducting method validation.
- Expose delegates to practical examples of method validation reinforcing the theoretical concepts delivered during the course.
- Provide delegates with the skills and knowledge to perform their own validations.
- Enable participants to meet the accreditation requirements of their testing laboratories.

COURSE OUTLINE

Module 1: Introduction to method validation

Definitions
Validation versus verification
When to validate analytical methods
Importance of method validation

Module 2: Introduction to statistics-description statics
Module 3: Significance testing-the T-Test
Module 4: Significance testing–the F-test
Module 5: Analysis of variance
Module 6: Validation protocol
Module 7: Performance parameters and their estimation

- 7.1 Precision-different precision parameters
- 7.2 Bias
- 7.3 Ruggedness
- 7.4 Selectivity, LOD, LOQ
- 7.5 Linearity and working range.

Module 8: Introduction to measurement uncertainty

- 8.1 Measurement uncertainty principles
- 8.2 Sources of measurement uncertainty
- 8.3 Approaches to uncertainty estimation-Bottom-up vs top-down approach

Module 9: Rules for calculating uncertainty of measurement.

- 9.1 Converting data to standard uncertainties.
- 9.2 Combining uncertainties.
- 9.3 Reporting uncertainty of measurement
- 9.4 Handling uncertainties for large concentration ranges

Module 10: Method validation report

Prerequisites:

Passed Mathematics at matric level.
Experience working in an analytical testing laboratory.

Course requirements:

A scientific calculator for each delegate
A laptop for where the ANOVA calculations will be done. (Maximum 2 people per laptop/desktop).

Course Evaluation:

100% mandatory attendance for each delegate for the full duration of the training.
A week will be given to complete a written assessment, which will require 80% pass mark in order to obtain a certificate of competence after the completion of the course.