



Empowering & Inspiring Excellence

Company Registration No. 2014/063827/07

ONLINE Course

ISO/IEC 17025:2017 Method Validation (Analytical Chemistry or Microbiology)

Course Code: FBQM05-02

Course Overview

Laboratory accreditation to ISO/IEC 17025:2017 by a recognized accreditation body e.g. South African National Accreditation System (SANAS), provides any laboratory with adequate evidence of technical competence to perform specific types of tests according to international standards. Laboratory accreditation also provides laboratory managers and customers with adequate assurance of the quality of results reported by the laboratory. Customers need to have confidence in the accuracy and reliability of the laboratory test results in order to make important decisions.

Method validation and uncertainty of measurement are difficult concepts that most testing laboratories struggle to implement to fully comply with ISO 17025 accreditation requirements. This course is focused only on test method validation and is aimed at equipping participants to understand this concept and practical implementation.

Objectives:

1. To understand and implement method validation in testing laboratories
2. To design protocols and experiments of method validation parameters including precision (reproducibility, and repeatability), ruggedness/robustness, accuracy, bias, limit of detection, limit of quantification, linearity and range.
3. To collate, analyze and interpret validation data from validation experiments for testing laboratories
4. To write a test validation method report

Course Content

- Quality control and quality assurance in the laboratory
- Overview of Laboratory Accreditation (ISO 17025:2017)
- Why method validation
- Methods Validation Vs Verification
- Critical considerations for Methods Validation
- ISO/IEC 17025 principles of method validation in testing laboratories
- Parameters for methods validation and selection of methods validation parameters
- Matrix effect on microbiological analysis (For Microbiological Methods validation)

- Use of Test Kits and rapid test methods
- Methods validation plan
- Methods Validation Process
- Method validation requirements in ISO/IEC17025:2017 and SANAS documents
- Protocols for method validation experiments: Quantitative and qualitative tests
- Validation criteria for:
 - Chemical Analysis: Quantitative and qualitative tests
 - Microbiological tests: Quantitative and qualitative tests
 - Molecular Microbiological analysis
- Interpretation and analysis of data from validation experiments
 - Statistical tools for data analysis
- Methods Verification
- Method capability studies
- Determination of uncertainty of measurement in chemical and microbiology laboratories
- Proficiency test results, use and control charts
- Trend analysis
- Methods Validation Report

Who should attend?

- Laboratory personnel including supervisors, Scientists, Chemists, Microbiologists, Biotechnologists, Biochemists, Laboratory Analysts and anyone responsible for implementing or maintaining the Laboratory Quality System
- Quality persons including Quality Managers, Quality Managers and Quality team leaders
- Laboratory Managers and Middle management

Entry requirements

- Participants should have a good comprehension of English and be able to read, write and communicate in English
- Participants should be working in the laboratory environment or have knowledge of the laboratory environment

Assessment

- Formative assessment through quizzes, online discussions, case studies and student activities/exercises
- Examination at the end of the course may be given.
- Portfolio of Evidence
- Full attendance of all contact sessions is essential for a certificate to be issued

Course duration: 2 days with 4 hours contact /lecture time per day

Cost: R 2 500 per person

For Further Information on our training courses, or to register for a course, please contact us on:

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