Uncertainty Of Measurement And Method Validation In Accordance With ISO 17025

Course Description:

Good laboratory practice means different things to different people. This course covers the advanced topics in Good Laboratory Practice (GLP). All the practices that ensure that laboratory testing is planned, performed, monitored, recorded and reported in an organized and controlled manner, will be discussed in general and the Uncertainty Measurement (GUM) in particular.

The course addresses the requirements of EN ISO / IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories as well as the common requirements of GLP, as applicable to QC/QA/Production Control Laboratories. The different GLP standards set out the requirements for technical competence and proper management of the analytical laboratories. The standards usually cover a variety of topics, which will be covered during this course: Laboratory Organization; Personnel; Safety Assurance; Laboratory Facility; Testing and Measuring Equipment; Apparatus and Reagents; Test Methods and Procedures; Calibration; Samples and Test Data Storage, Inspection, Assessment and Uncertainty Measurement (UM). The course will also discuss the requirements to be met by a laboratory supporting its organizations quality system to the ISO 9000 series of standards.

The course provides training of the Good Laboratory Practice (GLP) for personnel of laboratories who wish to produce test results that are fit for the purpose and which would stand up to the scrutiny. Obviously, the primary objective of the GLP is to ensure the generation of high quality data. Statistical tools play an important role in GLP to calculate the Uncertainty Measurement. This course will focus on the latest techniques and standards developed to measure the uncertainty of the data. The Guideline for Uncertainty Measurement (GUM) will be introduced in a simple way. Every effort is made in this course to eliminate unnecessary complications, to apply the GUM at its simplest level and to take away apparent mystery. Participants who have never drawn up uncertainty budgets before usually develop the required skill well before the end of the course. Others who seek explanations of GUM complexities obtain clarifications expressed in simple terms. Measurement uncertainty problems are solved by brainstorming methods so as to generate interaction by all participants. The course will use the Statistical Process Control (SPC) module as a tool to validate the uncertainty measurement. It covers control charts and their applicability to uncertainty before covering a step-by-step process of calculating uncertainty for a typical application. Methods of reporting uncertainty, the uncertainty budget and applicable standards and guidelines for expressing measurement uncertainty are covered income detail. Successful completion of this course will enable participants to understand, evaluate and express measurement uncertainty

Course Certificate:

BTS Competency Certificate will be issued to participants who successfully completed the course and passed the exams at the end of the course.

Who Should Attend?

This course is aimed at all staff of Laboratories. This includes laboratory managers, superintendents, supervisors, scientists, doctors, physicians, chemists, analysts, officers, coordinators and technicians. R&D and government statutory employees are encouraged to attend this outstanding

course. Further, this course is very important for QA/QC employees and Third-Party Inspection and certification companies.

Course Objectives:

Upon the successful completion of this course, participants will be able to:-

- Acquire an up-to-date knowledge on the quality assurance in laboratories and the importance of the ISO 17025 system
- Describe Good Laboratory Practice (GLP) and its importance in modern laboratories and in technology transfer
- Determine the cost of GLP non-compliance
- Gain knowledge on the various GLP standards and regulations that set out the requirements for technical competence and proper management of analytical laboratories
- Identify the common requirements of GLP.
- Discuss the critical GLP compliance issues
- Describe the GLP requirements related to organization, personnel, facilities, equipment, operations, testing, control, protocols, records and reports
- Recognize the scope, field of application, components & sources of uncertainty and carry out analytical measurement & experimental studies of method performance
- Review & improve the process of measurement uncertainty estimation and be able to analyze the specification of the measured
- Identify uncertainty sources and employ the process of quantifying uncertainty
- Carry-out the process of calculating the combined uncertainty and be able to review the procedure on reporting uncertainty
- Explain Statistical Process Control (SPC) and identify its applications
- Apply method validation techniques in accordance with ISO17025