



LAB125

Data Validation in Analytical Laboratories

Course Introduction:

Validation and qualification for analytical methods and equipment are required by many regulations, quality standards and company policies. If executed correctly, they can also help to improve the reliability, consistency and accuracy of analytical data. *Data Validation in Analytical Laboratories* guides analyst, laboratory managers and quality assurance managers through the validation and qualification processes in analytical laboratories.

This course takes into account most national and international regulations and quality standards. Participants of this course will learn how to speed up their validation and qualification process, thereby avoiding troublesome reworking and gaining confidence for audits and inspections.

The validation and qualification procedures presented in this course help to ensure compliance and quality but with minimal extra cost and administrative complexity. The purpose of this course is to answer the key question regarding validation: *How much validation is needed and how much is sufficient?* The recommendations are complementary rather than contradictory to any standards or official guidelines. They are based mainly on common sense and can be used in cases where information from official guidelines and standards is insufficient for day-to-day work.

Course Objectives:

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

- ✓ Apply and gain an in-depth knowledge on data validation in analytical laboratories
- ✓ Assess how much validation is needed and how much is sufficient
- ✓ Discuss the regulations, quality standards and guidelines pertaining to national and international organizations such as ISO, EN and US
- ✓ Define the terminology involved in data validation and carry out strategies for the development and implementation of qualification and validation systems in laboratories
- ✓ Carry out the recommended protocols and steps for the qualifications in design, pre installation & installations of systems, operations, performance and maintenance
- ✓ Acquire an in-depth knowledge on the operational qualifications of software and computer systems such as computer networks, user-contributed software, existing systems and systems without vendor validation
- ✓ Explain the validation of analytical methods such as the validation of standard & non routine methods, quality control plans, revalidation and parameters for methods validations well as data validation and evaluation of uncertainty
- ✓ Employ proper procedure when utilizing certified reference material

- ✓ Perform proficiency testing and auditing for external laboratory qualification

Who Should Attend?

This course is intended for all Laboratory Quality Managers, Quality Professionals, Laboratory Managers, Superintendents, Supervisors, Chemists, Analysts and Technicians.

Course Outline:

Day 1:

Pre Test

Develop rugged GC or HPLC methods

- Time
- Cost effect
- Systematic manner

Day 2:

Develop a preliminary chromatographic method in less than one day

- Real chromatographic analysis problems
- Method development tools

Systematic troubleshoot of GC or HPLC

- Methods
- Cost effect

Day 3:

The applications and limitations of, and how to use more than 100 chromatographic and sample preparation techniques to develop new, modified, and/or validated methods

Day 4:

Building method validation and QA into chromatographic methods

Simplified method development tools

- Best techniques
- Method development process

Recognize good results from poor results

- How to improve performance

Method Development Process for GC and HPLC

Method Development Parameters,

- Based on the Sample Matrix and Analytes

Day 5:

Method Validation

Preventative Maintenance and Troubleshooting

Case Studies with Real Analytical Method Problems

Post Test

Course Fees:

To be advised as per course location. This rate includes participant's manual, and-Outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Course Methodology:

A variety of methodologies will be used during the course that includes:

- (30%) Based on Case Studies
- (30%) Techniques
- (30%) Role Play
- (10%) Concepts
- Pre-test and Post-test
- Variety of Learning Methods
- Lectures
- Case Studies and Self Questionnaires
- Group Work
- Discussion
- Presentation

Course Certificate:

International Center for Training & Development (ICTD) will award an internationally recognized certificate(s) for each delegate on completion of training.

Course Requirement:

"Hand's on practical sessions, equipment and software will be applied during the course if required and as per the client's request".

Course Timings:

Daily Course Timings:

08:00 - 08:20	Morning Coffee / Tea
08:20 - 10:00	First Session
10:00 - 10:20	Coffee / Tea / Snacks
10:20 - 12:20	Second Session
12:20 - 13:30	Lunch Break & Prayer Break
13:30 - 15:00	Last Session

