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AL016:
Data & Method Validation in Analytical Laboratories

Training Description:

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 intensive course considers 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.

Training Objectives:

By the end of the training, participants 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 and 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

Training Designed for:

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

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Training Requirements:

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

Contents can be adapted to your specific wishes. It is therefore possible to focus on specific modules of the training course as per client's learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Program:

DAY ONE:

- Develop rugged GC or HPLC methods
  - Time
  - Cost effect
  - Systematic manner

DAY TWO:

- 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 THREE:

- 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 FOUR:

- 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 FIVE:

- Method validation
- Preventative maintenance and troubleshooting
- Case studies with real analytical method problems
- Course Conclusion
- POST-ASSESSMENT and EVALUATION

Training Methodology:

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Gamification, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

CMCT Internationally recognized certificate(s) will be issued to each participant who completed the course.

Training Fees:

TBA as per the course location - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01st of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

Training Timings:

Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:00	Recess (Prayer Break & Lunch)
13:00 - 14:00	Last Session

For training registrations or in-house enquiries, please contact:

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