

Methods Development, Validation Procedures and Conformity Assessment in the Analytical Laboratory

Workshop Abstract

This one-day course is designed with a fundamental grass roots approach to understanding measurement uncertainty and approaches validation in a very generic style.

The presentation aims at understanding basic elements of an analytical method both from the Quality Systems perspectives and with the more fundamental approach of measurement, errors and uncertainties in the analytical measurement process in particular.

A goal-oriented method development will be introduced with a generic, iterative and modular approach to understand validation in general at the same time establishing the capabilities of the analytical method as the method is being developed. The various stages of scoping out the method initially followed by an informed strategy of design, development and optimization to arrive at the validation parameters will be presented elaborately and lucidly.

The guidances from USP, ICH, AOAC and other international standards will be discussed.

This very structured presentation continually builds on data handling, documentation and regulatory requirements for regulatory compliance issues. There is extensive guidance provided during the course for preparing validation protocols for various stages of IND, NDA and laboratory control, QA, QC inside companies. A brief discussion on statistical tools, SQC, SPC and stability indicating assays are included.

Learning Objectives

- Increase your knowledge of conformity assessment, quality control and quality assurance.
- Consult with a knowledgeable instructor about your current technical problems and preparation and requirements for submission of regulatory packages (NDA, ANDA, IND, MMA and others for FDA & OECD).
- Learn a generic approach for developing an analytical method and optimizing it.
- Become acquainted with practical approaches for validating new analytical procedures.
- Familiarize yourself with methods development and optimization in HPLC.
- Be exposed to the latest international requirements and guidelines: ICH, ISO 17025, OECD, & FDA guidelines for analytical validation.
- Learn about the FDA's new initiatives in systems-based inspection and risk-based assessment.
- Understand the training and supervision requirements of chemists and technicians and other lab personnel for GLP.
- Receive helpful hints to help prepare you for a visit from an auditor's perspective.
- Participate in discussions on cGMP, GLP, WHO and OECD requirements and expectations.
- Learn about general validation and qualification requirements for analytical instruments such as HPLC, TOC, CE, LC-MS, AA, UC/VIS, Dissolution and other emerging techniques.

Who should attend

- Scientists, managers, and technicians involved in methods development and optimization, analytical research and development, meeting FDA requirements and regulations, validating analytical methods, application of newer analytical methods, and those involved in quality control, quality assurance, and quality assessment.

Workshop instructor

The instructor for this workshop is Shib Moorherjea, President of ValQual International. In his career covering three decades, he has held senior scientist and management positions with multinational organizations, including Colgate Palmolive, Johnson & Johnson, Troy Corporation, BASF, and several academic institutions.

Workshop approach and style

Highly interactive and participative.

Methods Development Workshop Outline

- Quality : QA/QC and Basics of Quality Systems
- Analytical Methods and CQA's
- Relevance of Data and Data Integrity
- Measurement, Measurement Uncertainty and Errors
- Understanding Methods Validation: Basic Approach
- Process Model in Analytical Measurement
- Detection and Quantification
- Relationship of Method vs. Analytical Techniques
- Rationale of Methods of Development and Validation: A Generic Iterative Approach in a Sequential Manner
- Definitions: Validation Parameters
- Basic Statistical Applications (SPC, SQC, etc.)
- Validation Guidelines (AOAC, USP, ICH, WHO, etc.)
- Development of Validation Protocols and Reports
- Analytical Development : Drug Substance, Excipients, Drug Products
- Tables of Data Requirements for Various Products and Applications
- Quantitation and Validation in GC Methods
- Quantitation Issues in GCMS
- Examples of GCMS applications
- Robustness and System Suitability Issues
- Concept of Holistic Validation
- Regulatory Compliance Issues
- Review of Internal Documentation
- Summary and Conclusions
- References and Acknowledgements