Chrom Africa

Bringing Scientific & T echnical Resources to the Africa Continent

ANALYTICAL METHODS VALIDATION FOR FDA COMPLIANCE

22nd - 26th JUNE 2026

Course Topics Include: – FDA, ICH and USP Validation Requirements – Applying Validation Studies Consistent with Method Purpose – GMP Compliance during Validation – Validation Acceptance Criteria – Validation Statistics – Validation Protocol Workshop – Validation Reports – Revalidation – Method Transfer.

Course description One of the most critical factors in developing and marketing pharmaceutical drug substances and drug products today is ensuring that the analytical methods used for analysis can generate valid data upon which business and regulatory decisions can be made. FDA, ICH and USP have each recognized the importance of this to the drug development process and have separately expanded method validation requirements in recent years. However, with only limited guidance, industry has been left to interpret how to adequately comply with the regulations. Whether involved in method development, method validation, method verification or method transfer, this course will provide a broad understanding and "hands-on" knowledge of the method validation process and the difficulties encountered in validating methods to comply with today's upgraded FDA CDER requirements. Lectures will include not only theoretical basis and practical applications, but actual validation examples of HPLC, GC, UV/Vis, AA and titration methods for small organic molecules. Some of the more common mathematical and statistical treatments of validation data will also be discussed. Because of the tremendous effort that can be expended in conducting validation studies, efficiency of experimental design and documentation will be stressed throughout the discussions.

Although the general principles in this course may be applied to methods for testing biological molecules and medical devices, the focus of this course is on the validation of methods for the analysis of small molecules and not the unique analytical procedures often used for testing products of a biological nature. who should attend This course is intended for individuals who have the responsibility for establishing the integrity of analytical methods for active pharmaceutical ingredients (APIs) or finished pharmaceutical dosage forms.

This course will benefit individuals in:

- R&D
- Quality Control
- Quality Assurance
- Technical Operations Regulatory affairs personnel as well as regulatory authorities who are responsible for the review of such data will also benefit from this course.

Learning objectives Upon completion of this course, you will be able to:

- Identify the current method validation requirements from FDA, ICH and USP guidance documents and from industry practices
- Design focused and efficient method validation protocols that meet all FDA CDER regulatory requirements
- Demonstrate the knowledge to confidently establish validation acceptance criteria
- Explain the GMP expectations for validation
- Describe the key issues in documenting validation work and writing reports
- Explain the requirements and common issues in method transfer and revalidation.

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Day 1	22tnd	EVENTS
8.30 – 09.30 am		**Registration and Climate Setting**
09.30 – 10.00 am		• Review of Learning Objectives/Methods Validation Background • Definitions, Purpose and Benefits • Key Validation Factors • Development, Validation, Verification, and Transfer • Regulatory Requirements and FDA Inspections • ICH/USP/FDA Validation Guidelines
10.00 – 10.30 am		**TEA- BREAK**
11.00 – 12:30 p.m		• ICH/USP/FDA Validation Requirements
		• Specificity • Range • Precision • Linearity • Accuracy • Robustness • DL/QL
13:00 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 16.30 p.m		• ICH/USP/FDA Validation Requirements
		• Specificity • Range • Precision • Linearity • Accuracy • Robustness • DL/QL
Day 2	**23rd**	
9.00 – 10.30 am		• Historical Validation Parameters
		• Selectivity • Bias • Sensitivity • Reproducibility • Ruggedness
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 13.00 p.m		• Methods Validation cGMP Practices • FDA Warning Letters and 483 Citations • Validation SOPs and Protocols
13.00 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 16.30 p.m		• Validation Samples and Standards • Instrument Qualification • Training
Day 3	**24th**	
9.00 – 10.30 am		• Methods Validation Applications • Test Selection • Product Specification • Development vs. Validation • Method Write Up • Experimental Design
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 12.30 pm		• Methods Validation Statistics and Acceptance Criteria • Application of Statistics to Validation Data • Statistical Power • Commonly Used Acceptance Criteria •
12.30 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 15.30 p.m		• Critical Concepts Regarding Validation Data and Criteria • Recommended Approach for Setting Criteria.

Day 4	25th	
9.00 – 10.30 am		• Methods Validation Workshop • Participants will develop and discuss method validation experimental plans and acceptance criteria
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 12.30 p.m		• IND Phase Methods Validation • IND timeline • FDA Guidance on IND Phase Validations • Examples of Development/Validation Studies • Questions and Answers Relating to Participants' • OwnValidation Problems
13.00 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 15.30 p.m		• Method Transfer • Four Options from USP • Method and Lab Readiness • Training, Testing and Data Evaluation
Day 5	**26th**	
9.00 – 10.30 am		• Methods Validation Applications • Test Selection • Product Specification • Development vs. Validation • Method Write Up • Experimental Design
10.30 – 11.00 am		**TEA- BREAK**
11.00 – 12.30 p.m		• Revalidation and Methods Update • Drug Substance Changes • Drug Product Changes • Method/Site Changes • Technology Changes • FDA Mandated Update Assessment Opportunity
12.30 – 14.00 p.m		**LUNCH - BREAK**
14.00 – 15.00 p.m		• Directors speech and issue of certificates

Deadline: 10th June 2026

22nd - 26th JUNE 2026

Cost Kes. 125,000.00 or USD 1,200.00 exclusive of taxes

NAIROBI

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