COBBLESTONE

COURSE ID 3139

Development, Validation, and Application for Analytical Methods

DIRECTED BY

Ahmad Farhad – Managing Director, Atlas BioPharma Consulting LLC

4 HOUR

ACCREDITED COURSE

- ICH/USP/FDA Validation Requirements
- Method Development
- Method Validation Process
- Validation Statistics

about the course

This accredited 4-hour course offers a streamlined overview of analytical method validation, focusing on key regulatory requirements set by ICH, USP, and FDA. Participants will gain practical knowledge of essential validation elements, including accuracy, precision, specificity, linearity, range, robustness, LOD/LOQ, and system suitability.

The course covers method development processes, from test selection and experimental design to the distinction between development and validation. Emphasis will be placed on writing up methods and creating standard operating procedures (SOPs).

Further topics include the validation process and application, such as product specifications, validation protocols, instrument qualification, and analyst training. The course concludes with statistical analysis of validation data, common acceptance criteria, and recommended approaches for setting criteria.

Consider attending this course as part of the four-part series or as a stand-alone option for your personal career advancement and training. To deepen your understanding of analytical methods validation, the instructor recommends completing the entire series.

Part 1: Regulatory Guidance and Requirements for Analytical Methods Validation

Part 3: Process, Application, and Data Analysis for Analytical Methods Validation

Part 4: Revalidation and Compliance in Life Cycle Management for Analytical Methods Validation

Live interaction with the instructor enables dynamic discussions and immediate clarifications. To verify attendance and encourage active interaction, those participating in the live training are required to have their webcams on during the course. The use of microphones and speakers or headsets is also strongly recommended.

who should attend

This course is tailored for professionals entrusted with ensuring the quality and reliability of pharmaceutical/biopharmaceutical products, medical devices, diagnostics, cosmetics, and food products.

Individuals working in Quality Control, Quality Assurance, Technical Operations, and Research and Development (R&D) departments stand to gain significant benefits.

Additionally, personnel involved in Regulatory Affairs and Regulatory Agencies responsible for reviewing quality data may also find this course valuable.

learning objectives

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

- Define key terms of ICH/USP/FDA validation requirements.
- Identify appropriate types of methods and development parameters.
- Differentiate between method development and validation in real-world scenarios.
- Develop a complete method write-up and SOP.
- Assess validation samples, standards, and instrument qualifications.
- Compare commonly used acceptance criteria.

course outline

Review of Learning Objectives

ICH/USP/FDA Validation Requirements

- Accuracy
- Precision
- Specificity
- Linearity
- Range
- Robustness
- LOD/LOQ
- System Suitability

Method Development

- Types of methods
- Application
- Method development parameters
- Test Selection
- Experimental Design
- Development vs. Validation
- Method Write Up and SOP

Method Validation Process and Application

- Product Specification
- Validation Protocols, Reports, and SOPs
- Validation Samples and Standards
- Instrument Qualification
- Experimental Design
- Qualified/Training Analysts

Methods Validation Statistics and Acceptance Criteria

- Application of Statistics to Validation Data
- Commonly Used Acceptance Criteria
- Critical Concepts Regarding Validation Data and Criteria
- Recommended Approach for Setting Criteria

Question and Answer Session

Assessment Opportunity

course instructor

Ahmad Farhad, is a seasoned Consultant in the Biopharmaceutical industry, specializing in Analytical Chemistry, method development, and validation for cGMP and Compliance. Previously, Mr. Farhad held the position of Director of Quality Control at Bachem Americas Inc. Prior to joining Bachem, he amassed over 20 years of experience in leading method development and validation roles at esteemed biotechnology and healthcare firms, including Xencor, Amgen, Quest Diagnostics, and Mannkind Corporation. Additionally, Mr. Farhad serves as a consultant for a venture capital investment firm and holds a seat on the board of directors for a non-profit organization.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 4 contact hours, or 0.4 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

The American Society for Quality (ASQ)-Recertification Opportunities

Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may be helpful in obtaining required ASQ's recertification education units.

For more information, visit: www.asq.org