COBBLESTONE

COURSE ID 3138

Regulatory Guidance and Requirements for Analytical Methods Validation

DIRECTED BY

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4 HOUR

ACCREDITED COURSE

- Methods Validation Overview
- ICH/USP/FDA Guidelines
- FDA, ICH, USP, EMA Method Development/Validation
- Comparison of Regulatory Guidelines
- Historical Validation Parameters

about the course

One of the most crucial aspects of developing and marketing pharmaceutical drug substances and products is ensuring that the analytical methods used for testing provide accurate and reliable data. This data is essential for making informed business decisions and meeting regulatory requirements. Recognizing the significance of robust analytical methods, regulatory agencies such as the FDA, ICH, and USP have progressively strengthened method validation standards in recent years. These updates emphasize the need for precision, accuracy, and consistency in testing procedures throughout the drug development process.

However, despite these expanded validation requirements, the guidance provided by these agencies remains somewhat limited, leaving pharmaceutical companies to interpret the best practices for compliance. As a result, the industry faces challenges in aligning with these evolving standards while ensuring that their analytical methods meet both business and regulatory expectations. Companies must invest time and resources into understanding and applying these guidelines to avoid potential regulatory scrutiny, product recalls, or delays in bringing new drugs to market.

This accredited 4-hour course provides a concise and practical overview of analytical methods validation, focusing on regulatory agency guidance and requirements. Participants will gain a comprehensive understanding of FDA, ICH, USP, and EMA validation guidelines and key factors such as development, validation, verification, and transfer.

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The course covers the similarities and differences between regulatory agencies' guidelines and how they impact method development and validation. Participants will also explore critical validation parameters like selectivity, bias, sensitivity, reproducibility, and ruggedness. Real-world applications, regulatory inspections, and historical context will be highlighted.

Ideal for professionals involved in analytical methods, this course offers valuable insights for ensuring compliance with evolving regulatory standards.

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 2: Development, Validation and Application for Analytical Methods

Part 3: Process, Application, and Data Analysis for Analytical Method 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 such as validation, verification, and transfer.
- Explain the purpose and benefits of method validation in regulatory compliance.
- Compare key validation factors across different regulatory bodies.
- Assess the role of regulatory agencies in method inspections and how validation impacts these reviews.
- Identify and analyze historical parameters.
- Develop a validation approach that incorporates key factors.

course outline

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

ICH/USP/FDA Validation Requirements

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

Historical Validation Parameters

- Selectivity
- Bias
- Sensitivity
- Reproducibility
- Ruggedness

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