COBBLESTONE

COURSE ID 3140

Process, Application, and Data Analysis for Analytical Method Validation

With a Focus on United States Pharmacopoeia (USP) Requirements

DIRECTED BY

Ahmad Farhad – Managing Director, Atlas BioPharma Consulting LLC

4 HOUR

ACCREDITED COURSE

- Experimental Documentation, IND/NDA Reports
- USP <1226>, Procedures, Results Interpretation
- USP <1224>, Lab Readiness, Training
- Methods Validation Workshop
- IND Phase Methods Validation

about the course

This 4-hour accredited course provides a comprehensive overview of key practices and regulatory requirements for method validation in pharmaceutical development. Focusing on data documentation, reporting, and compliance with FDA and USP guidelines, this session explores the essentials of experimental documentation, IND/NDA reporting, method verification (USP <1226>), and method transfer (USP <1224>). Participants will engage in workshops to develop validation plans and acceptance criteria. The course also covers FDA guidance on IND phase methods validation, highlighting timelines, real-world examples, and addressing common validation challenges.

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 2: Development, Validation and Application for Analytical Methods

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 the key elements of Experimental Documentation and IND/NDA Reports in the context of method validation.
- Explain the USP <1226> guidelines for method verification, including the procedure and interpretation of results.
- Discuss the differences among the four options for method transfer under USP <1224>.
- Apply FDA guidance to develop experimental plans for IND phase methods validation.
- Assess method validation experimental plans and acceptance criteria through a workshop setting, evaluating the feasibility and accuracy of various approaches.

course outline

Review of Learning Objectives

Method Validation Data and Reports

- Experimental Documentation
- Elements of a Good Report
- IND/NDA Reports

Method Verification

- USP <1226>
- Verification procedure
- Interpretation and Recording of Results
- Other Considerations

Method Transfer

- Four Options from USP <1224>
- Method and Lab Readiness
- Training, Testing and Data Evaluation

Methods Validation Workshop

- Participants will develop and discuss method validation experimental plans and acceptance criteria

IND Phase Methods Validation

- IND timeline
- FDA Guidance on IND Phase Validations
- Examples of Development/Validation Studies
- Questions and Answers Relating to Participants' Own
- Validation Problems

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