

Validation, Verification and Transfer of Analytical Procedures

Course Overview

Learn about parameters for validating analytical procedures for small molecules based on USP–NF General Chapters <1225> Validation of Compendial Procedures and <1226> Verification of Compendial Procedures. Topics include comparing <1225> and <1226> and understanding the differences between <1225> and ICH guidelines. Elements on Method transfer and the complementary chapter USP–NF <1210> Statistical Tools for Procedure Validation will also be discussed in this course.

Learning Objectives

Upon completion of this course, you will be able to

- Understand how approaches to validation depend on the intended application of the procedure
- Learn when each is appropriate - validate versus verify
- Evaluate the characteristics to consider for validation of various analytical procedure
- Gain an understanding of the design of validation experiments and interpretation of results
- Understand how to review techniques to minimize resources required
- Gain an understanding of the different approaches for transfer of procedures.
- Understand the differences and the relationship between validation, verification and transfer of analytical procedures
- Identify methods and statistical tools used for procedure validation

Who Should Participate

- Analytical Chemists
- QA/QC Staff
- R&D Staff
- Regulatory Professionals
- Technical liaison, who are involved in the validation and verification of analytical procedures.
- Project Management
- Manufacturing Staff
- CRO's

USP Approved Instructor

Sharad D. Mankumare, Ph.D.
United States Pharmacopeia
Director, RSL and Verification
Programs
Mumbai University



Why Choose USP Education?

USP Education provides year-round courses and programs on how to effectively interpret and apply USP's internationally recognized quality standards. The standards help ensure the quality and safety of medicines, dietary supplements and foods.

USP courses are created by the scientists and experts who help develop the USP standards that are used worldwide. Courses are presented by approved instructors with practical, first-hand knowledge of the subject area and related standards. The insights they share will not only make your daily work easier, but will also connect you to an independent, nonprofit scientific body with the goal of creating a strong foundation for a healthier world.

Note: You should have at least 2 years' experience in pharmaceutical industry to get the full benefit of this course.

Duration:	3 Day
Format:	WebEx
Course ID:	CM-1225-02
Date:	November 3-5, 2020 2:00 p.m. – 4:00 p.m. GMT+9 (Japan)
Fee:	US \$55.00

To register or for information on group pricing, please visit <https://education.usp.org> or email education@usp.org.