

Impurities in Drug Products and Drug Substances - A USP Approach

Course Overview

This 3-day course integrates ICH Guidance and FDA policy for impurities, relevant USP General Chapters about impurities, and USP's approach to impurities in monographs. It also provides insights to USP–NF General Chapters <476> and <1086> and include case studies for impurities in the development and revision of USP monographs.

Learning Objectives

Upon completion of this course, you will be able to

- Discuss the origin and classification of impurities in pharmaceuticals.
- Explain global guidance's for impurities.
- Describe the USP approach to impurities in drug substances and drug products.
- Discuss the USP general chapters on impurities.
- Explain the USP approach to harmonization across pharmacopeia.
- Demonstrate knowledge of USP's approach for impurities in documentary standards via case studies.

Who Should Participate

- Analytical scientists
- CMC submission and review scientists
- Formulators
- Manufacturing scientists
- QA/QC
- Regulatory professionals

USP Approved Instructor



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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.

Duration: 3 Days

Format: Live Webcast

Course ID: CM-476-01

Date: March 29 - 31, 2022, 3:00 p.m.-5:30 p.m. SGT

Fee: US\$199

Early Bird price valid through February 28: US\$160

Register: Contact your USP Authorized Distributor or visit [here](#)