USP <1469> *Nitrosamines Impurities*

Course Overview

Nitrosamines are a critical topic for regulators and industry given the recent safety recalls of several products containing this impurity. This one-day course will provide attendees with an understanding of current regulatory guidelines and *USP* General Chapter <1469> *Nitrosamine Impurities.* The course will provide an overview of sources of nitrosamines including their formation from the presence of other impurities and how to eliminate or reduce levels of nitrosamines. Tools to assess and control nitrosamines in drug substances and drug products as well as in depth analytical procedures in *USP* <1469> including the use of the *USP* Reference Standard and precautions to be used during procedures will also be covered. The course will also address risk assessment methodology as per ICH9, control strategy development, calculation of nitrosamine limits as per ICH M7 as well as test method performance characteristics.

Attendees will engage in learning via a live virtual webinar.

Learning Objectives

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

- Describe the background, scope and approach of *USP* <1469> *Nitrosamine Impurities* and applicable regulatory guidelines.
- Explain pathways and sources of nitrosamine formation along with risk assessment tools and a high-level process flow to develop control strategies.
- Describe how to select the appropriate analytical procedures based on test method performance characteristics for nitrosamine methods.
- Discuss the proper use and handling of the USP reference standard in the respective analytical procedures.
- Identify factors which impact sensitivity and selectivity of methods.
- Summarize key considerations, challenges and method conditions along with sample and standard preparation of the four test methods described in *USP* <1469>.

Who Should Participate?

- Research and Development
- QC managers
- QC staff scientists (DS, DP)
- Excipient manufacturers
- Research scientists
- QA staff who authorize drug product release

USP Approved Instructors

Dr. Edmond Biba
Scientist, USP
Dr. Mrunal A. Jaywant
Senior Director R&D, India-Science, USP
Marcus Obeng
Senior Scientist I, Reference Standards Lab, USP
Amanda Mesquita Guiraldelli
Scientific Affairs Manager, Brazil, USP
Eswara Raju Kosuri
Senior Scientist II, India - Science, USP

Mark Han
Senior Scientist I, Reference Standards Lab, USP

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 also will connect you to an independent, nonprofit scientific body with the goal of creating a strong foundation for a healthier world.

Duration: 1 Day (6 hours)

Location: Online

Format: Virtual

Course ID: CM-1469-01

Date: October 13, 2022

Time: 10:00 a.m.–17:00 p.m (1 hr Lunch 12:00~13:00)

Fee: US$ 375.00 (Early bird: $225 by Sep30)

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