



Proposed Revision to General Chapter <823> Radiopharmaceuticals for Positron Emission Tomography–Compounding

February 21, 2011
1:00 pm EST/10:00 am PST
Presented live online
FREE

The U.S. Pharmacopeia (USP) is currently seeking comments on proposed revisions to quality assurance standards for compounded radiopharmaceuticals used in positron emission tomography (PET) that appear in General Chapter <823> of the *USP–NF* compendia. To help clarify the revisions and facilitate feedback from professionals involved in PET drug production and compounding, USP is hosting a free, interactive webcast.

Through this live event, participants will learn about the proposed revisions, how these changes will affect industry and professional practice, and how to provide comments that can help shape the final revisions. Questions can be asked at any time during the webcast. Ravi Ravichandran, Principal Scientific Liaison at USP; Steve Zigler, Director of PETNET's Development and Engineering Group and chair of USP's Expert Panel on General Chapter <823>; and other USP scientific experts involved in the revisions will lead the discussion and provide answers.

Discussion topics include

- ▶ Proposed Revisions to USP General Chapter <823>
- ▶ Intent and Scope of the Revisions
- ▶ Enforcement of <823> Provisions
- ▶ Compliance with FDA cGMP
- ▶ Impact on Investigational and Research PET Drugs
- ▶ Comment Period: Procedure and Deadline

Don't miss this opportunity to provide input on PET drug standards!

Register for the webcast and review the proposed <823> revisions, FAQs, and other details at www.usp.org/goto/usp823.

Presenters

Steve Zigler

PETNET Solutions, Inc., Director, Development and Engineering Group

PhD, Organic Chemistry—University of Wisconsin–Madison

Over the past 20 years, Dr. Zigler has worked with PET technology in varying capacities: radio chemistry, cyclotron operation, R&D chemistry, and regulatory affairs. He played a key role in gaining FDA approval of PET Drug [18F]FDG and is interested in technologies for the production and testing of PET imaging probes. Since 1994, Dr. Zigler has worked in the CTI family of companies in Knoxville, TN, including CTI Cyclotron Systems and PETNET.

Ravi Ravichandran

USP, Principal Scientific Liaison

PhD, Analytical Chemistry—University of Louisville

Dr. Ravichandran has more than 20 years' experience in the diagnostic and pharmaceutical industries and government. His work has included analytical methods development, methods-technology transfer to manufacturing sites, QC lab management, and research of nuclear gamma resonance spectroscopy applications for the Indian Atomic Energy program. Dr. Ravichandran is an active member of the American Chemical Society and the board of Washington Chromatography Discussion Group.