Coalition for PET Drug Approval

Radiopharmaceutical Sciences Council

Current Topics in FDA Reviews and Inspections of PET Drug Manufacturers

SNMMI Annual Meeting
Baltimore, MD USA
June 8, 2015
4:45 PM – 6:15 PM

Session Organizer: Steve Zigler
Learner Outcomes for this Session

• How to respond to common questions that arise during the review of an NDA/ANDA or during and FDA inspection
• Outline methods to change or modify an approved NDA or ANDA and provide tangible, real-world examples
• Understand appropriate measures for sterility assurance in PET drug manufacturing and adopt procedures to incorporate these measures into routine practice and operations
Agenda

4:45 PM - 5:10 PM  Current topics in FDA reviews and inspections from the small entity perspective  
Steve Mattmuller, Kettering Medical Center

5:10 PM - 5:30 PM  Current topics in FDA reviews and inspections from the commercial perspective  
David Wilson, NorthStar Medical Radioisotopes

5:30 PM - 5:50 PM  Reporting Changes to an Approved NDA or ANDA  
Michael Nazerias, PETNET Solutions

5:50 PM - 6:15 PM  Overview of a sterility assurance program for PET drugs  
Eric Webster, PETNET Solutions

6:20 PM - 6:50 PM  Ad-hoc meeting to describe current and future USP topics related to nuclear medicine  
(not part of CE session)  
Steve Zigler and Ravi Ravichandran