Positron Emission Tomography Drugs: Product Quality, Regulatory Submissions, Facility Inspections, and Benefit-Risk Considerations

November 13, 2023 08:00 am to 05:30 pm

November 14, 2023 08:00 am to 12:00 pm

All times EST

FDA White Oak Conference Center
Bldg 31 Conference Center, The Great Room 1503 (B+C)
10903 New Hampshire Ave
Silver Spring, MD 20993

Monday, November 13, 2023

8:00-8:25 **Welcoming Remarks and Summary from First Workshop**
Louis Marzella, Sue Bunning, Cathy S. Cutler, Charles Metzger

Session I **Considerations and Trends in Facility Inspections and Compliance**
Moderators: Krishna Ghosh, FDA and Steve Zigler, PETNET Solutions

8:25-8:45 **Manufacturing Process Assessment and Pre-/Post-approval Inspections**
Speaker: Krishna Ghosh, FDA

8:45-9:05 **FDA Inspections: Commercial Perspective**
Speaker: Keith Bowen, Avid/Eli Lilly

9:05-9:25 **FDA Inspections: Academic Perspective**
Speaker: Robin Ippisch, UCSF

9:25-9:40 **BREAK**

9:40-10:00 **PET Surveillance Inspections and Training Update**
Speaker: Nicholas Violand, FDA

10:00-10:20 **Community-based Training Efforts**
Speaker: Sally Schwarz, Washington U. School of Medicine

10:20-10:45 Panel Discussion and Questions
Moderators: Steve Zigler and Krishna Ghosh
Panelists: Keith Bowen, Chris Ignace, Robin Ippisch, Ravi Kasliwal, Sally Schwarz, Tim Pohlhaus., Nick Violand, and Laura Wasil

Session II Product Quality and Regulatory Submissions
Moderators: Danae Christodoulou, FDA and Ashley Mishoe, Pharmalogic

10:45-11:05 Product Quality Considerations for PET Regulatory Applications
Speaker: Danae Christodoulou, FDA

11:05-11:25 Microbiological Considerations for PET Regulatory Applications
Speaker: Laura Wasil, FDA

11:25-11:45 Chemistry, Manufacturing, and Control Issues
Speakers: Daniel Yokell, Telix Pharmaceuticals and Peter Scott, Univ of Michigan School of Medicine

11:45-12:05 Aseptic Controls in PET Manufacturing – PET Community Perspective
Speakers: Ashley Mishoe, Pharmalogic and Reiko Oyama, Washington U. School of Medicine

12:05 -12:30 Panel Discussion and Questions
Moderators: Danae Christodoulou and Ashley Mishoe
Panelists: Ravi Kasliwal, Reiko Oyama, Chris Parr, Peter Scott, Laura Wasil, and Daniel Yokell

12:30-1:30 LUNCH

Session III Product Safety and Risk Assessment
Moderators: Ravi Kasliwal, FDA, Henry VanBrocklin, UCSF

1:30-1:50 Safety and Benefit/Risk Considerations at Various Stages of Product Development
Speaker: Jonathan Cohen, FDA

1:50-2:10 Safety and Risk Management of PET Drugs
Speakers: Henry VanBrocklin, UCSF and Steve Zigler, PETNET Solutions

2:10-2:30 Postmarketing Safety and Risk Management
Speaker: Samantha Cotter, FDA

2:30-3:00 Panel Discussion and Questions
Moderators: Ravi Kasliwal and Henry VanBrocklin
Panelists: Jonathan Cohen, Samantha Cotter, Steve Zigler

3:00-3:15 BREAK

Session IV Management of PET Drug Lifecycle
Moderators: Louis Marzella, FDA and Michael Nazerias, PETNET Solutions

3:15-3:35 **Recalls and FARs: the PET Community Perspective**
Speakers: David Dick, University of Iowa and Chris Ignace, Cardinal Health

3:35-3:55 **Introduction of New Manufacturing Sites in a Regulatory Submission**
Speakers: Jill Wilson, Ionetix and Julian Nwoko, SOFIE

3:55-4:15 **Clarifying 21 CFR 212 and 211 – the Evolving Regulatory Landscape**
Speakers: Serge Lyashchenko, MSKCC and Michael Nazerias, PETNET

4:15-4:35 **Compliance Update – Microbiological Quality Deviations and Failures – Robust CAPAs and Real-Life Success Stories**
Speaker: Tim Pohlhaus, FDA

4:35-4:55 **PET Product Availability: Drug Shortage Mitigation and Prevention Efforts**
Speaker: Leo Zadecky, FDA

4:55-5:15 **Panel Discussion and Questions**
Moderators: Louis Marzella and Michael Nazerias
Panelists: David Dick, Samantha Cotter, Cathy Cutler, Krishna Ghosh, Chris Ignace, Robin Ippisch, Jill Wilson, Julian Nwoko, Serge Lyashchenko, Michael Nazerias, Ravi Kasliwal, Tim Pohlhaus, Ramesh Raghavachari, Leo Zadecky

5:15 **Closing Remarks and Next Steps**
Louis Marzella and Steve Zigler

5:30 **Adjourn for the Day**

Tuesday, November 14, 2023

08:00 am to 12:00 pm

Tuesday morning will be devoted to an extended Q&A session. Organizers have begun gathering questions for FDA representatives through an online questionnaire. These questions will form the basis for our extended Q&A session. **A proposed schedule follows, which simply groups questions and answers according to the four sessions of the prior day plus an "Other" category. Durations of each session may be adjusted based on the number and/or importance of questions per category.**

8:00-8:45 **Q&A Related to Considerations and Trends in Facility Inspections and Compliance**
Moderators: Steve Zigler and Krishna Ghosh

8:45-9:30 **Q&A Related to Product Quality and Regulatory Submissions**
Moderators: Danae Christodoulou and Ashley Mishoe

9:30-9:50 **Break**

9:50-10:35 Q&A Related to Product Safety and Risk Assessment
Moderators: Ravi Kasliwal and Henry VanBrocklin

10:35-11:20 Q&A Related to Management of PET Drug Lifecycle
Moderators: Louis Marzella and Michael Nazerias

11:20-12:00 Q&A Related to "Other" Questions (ones which don't fit neatly in the other four categories above)
Moderators: Cathy S. Cutler and Ravi Kasliwal