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, Henry VanBrocklin

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, Krishna Ghosh, Chris Ignace, Robin Ippisch, Ravi Kasliwal, Sally Schwarz, 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: Industry Speaker TBD 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: David Dick, 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, Ravi Kasliwal, Henry VanBrocklin, 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: Academic Speaker TBD and Jill Wilson, Ionetix

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: Samantha Cotter, Cathy S. Cutler, Krishna Ghosh, Chris Ignace, Robin Ippisch, Mark Jacobsen, 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. The agenda and format are still under development, but organizers have begun gathering questions for FDA representatives through an online questionnaire. These questions will form the basis for our extended Q&A session.