PET Drugs: A Workshop on Inspections Management and Regulatory Considerations

Friday, February 21, 2020
08:00 am EST to 05:00 pm EST

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

8:00 **Welcoming Remarks**

Sally Schwarz, R.Ph., Henry VanBrocklin, Ph.D., Sue Bunning, M.A., Louis Marzella, M.D., Ph.D.

Session I: Considerations and Trends in Inspections and Compliance

Moderators: Steve Zigler, Ph.D., Krishna Ghosh, Ph.D.

8:15-8:50 **Manufacturing Process Assessment and Pre-approval Inspections**

Speaker: Krishna Ghosh, Ph.D., FDA

8:50-9:10 **Recent Experience with PET Surveillance cGMP Inspections of PET Manufacturers**

Speakers: Rick Friedman, M.S., FDA

9:10-9:50 **Current Trends and Observations on Inspections**

Speakers: Sally Schwarz, R.Ph., BCNP, and Peter Webner

9:50-10:05 **BREAK**

10:05-10:45 **PET Surveillance Inspections: FDA Pilot Program for Tablet-Based Inspections for PET Drugs**

Speakers: CDR Binh Nguyen, Pharm.D., MS Reg Sci, BCSCP and CAPT Ileana Barreto-Pettit, R.N., M.P.H., FDA

10:45-11:15 Panel Discussion and Questions: Current Trends and Observations

Moderators: Steve Zigler and Krishna Ghosh

Panelists: Ravi Kasliwal. Sally Schwarz, Ileana Pettit, Peter Webner, Tim Pohlhaus, Rick Friedman and Michael Nazerias

Session II: Lifecycle Management of PET Drug Applications

Moderators: Peter Scott, Ph.D., and Ramesh Raghavachari, Ph.D.

11:15-11:35 Management of PET Drug Applications (NDA or ANDA)

Speakers: Ramesh Raghavachari, Ph.D. and LCDR Yen Anh Bui, Pharm.D.

11:35-11:55 Management of PET Drug Applications – PET Community Perspective

Speakers: Peter Scott, Ph.D. and Sarah DeMare, Ph.D.

11:55 -12:20 Panel Discussion and Questions: Lifecycle Management of PET Drug Applications

Moderators: Peter Scott and Ramesh Raghvachari

Panelists: Peter Scott, Sarah DeMare, Kyong "Kaye" Kang, Pharm.D., Ravi Kasliwal, LCDR Yen Anh Bui, Pharm. D., Bankim Patel, RPh, Alyssa Carter, M.A., RAC and Ron Niles, Ph.D.

12:20-1:20 LUNCH

Session III: Chemistry and Product Quality Assurance

Moderators: Steve Mattmuller, R.Ph., BCNP, and Ravi Kasliwal, Ph.D.

1:20-1:40 Product Quality Assurance: Microbiological Regulatory Perspective

Speaker: Laura Wasil, Ph.D.

1:40-2:00 Product Quality and Sterility Assurance

Speakers: Henry VanBrocklin, Ph.D. and David Hussong, Ph.D.

2:00-2:20 Chemistry and Product Quality Assurance

Speaker: Christopher Ignace, Pharm.D., Ph.D.

2:20-2:50 Panel Discussion and Questions: Product Quality Assurance

Moderators: Steve Mattmuller and Ravi Kasliwal, Ph.D.

Panelists: Laura Wasil, Henry VanBrocklin, Christopher Ignace. David Hussong, Rick Friedman, Krishna Ghosh, and David Jaworski

2:50-3:10 BREAK

Session IV: Changing Landscape of PET Drugs, Labeling Requirements, and Electronic Filing Requirements

Moderators: Michael Nazerias, M.S., and Louis Marzella, M.D., Ph.D.

3:10-3:30 Changing Landscape of PET Drugs

Speaker: Ravi Kasliwal, Ph.D., FDA

3:30-3:50 Labeling Requirements for NDAs

Speaker: Michelle Fedowitz, M.D., FDA

3:50-4:10 Requirements for Electronic Filing of Regulatory Applications

Speaker: Mathilda Fienkeng, Pharm.D., FDA

4:10-4:45 Panel Discussion and Questions: Changing Landscape, Labeling Requirements, and Electronic Filing

Moderators: Michael Nazerias and Louis Marzella

Panelists: Ravi Kasliwal, Michele Fedowitz, Mathilda Fienkeng

4:45 Closing Remarks, Next Steps

Steve Zigler, Ph.D. and Louis Marzella, M.D., Ph.D.

5:00 Close