FDA-NRC Workshop: Collaboration for Medical Radiation Safety

Tuesday, October 15, 2019
10:00 am EST to 4:30 pm EST

FDA White Oak Conference Center
Bldg. 31 Conference Center, The Great Room (Rm 1504)
10903 New Hampshire Ave
Silver Spring, MD 20993

10:00-10:15 Welcome and Introductions
Libero Marzella, MD, Ph.D., and Kevin Williams

10:15-10:30 FDA-NRC MOU
Mike O'Hara, Ph.D.

Session I: FDA overview of Drug Development Process

10:30-10:50 Drug Development Regulatory Processes: Phase 1 to Phase 3, and the Review process
Kyong Kang, PharmD

10:50-11:00 Dosimetry: Regulatory Framework and Applications
Christy John, Ph.D.

11:00-11:20 CDRH Devices, Combination Products and Labeling
Mike O'Hara, Ph.D.

11:20-11:50 PET agents at the CDRH: Review process and Labeling Considerations
Xin He, Ph.D.

11:50-12:10 FDA 101: Drug Product Pharmaceutical and Microbiologic Quality, Manufacturing
Danae Christodoulou, Ph.D.

12:10 – 12:30 Data and Other Information Required for Labeling.
Michele Fedowitz, M.D.

12:30-1:30 Lunch

Session II NRC overview of Licensing Process

1:30 – 2:00	Regulating the Medical Use of Byproduct Material Donna-Beth Howe, Ph.D.
2:00 – 2:30	Radioactive Materials Licensing: Diagnostic and Therapeutic Uses Donna-Beth Howe, Ph.D.
2:30 – 2:45	Radioactive Materials Licensing of Emerging Medical Technologies Lisa Dimmick
2:45 – 3:05	Sealed Source and Device Evaluations Tomas Herrera
3:05 – 3:30	Medical Event Reporting Lisa Dimmick
3:30-4:20	Open forum, Q&A on presented information November 12 (planning meeting) and February 10 (public workshop) Panelists: Danae Christodoulou, Ph.D., Michele Fedowitz M.D., Kyong Kang, PharmD, Lisa Dimmick, Donna-Beth Howe, Ph.D., Tomas Herrera
4:25 to 4:30	Closing Remarks and Next Meetings Danae Christodoulou, Ph.D., Lisa Dimmick