Updated October 5, 2020

FDA-NRC Workshop: Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiological Devices

Wednesday, October 14, 2020
08:00 am EST to 5:00 pm EST
Virtual Workshop

Objectives

1. ***Develop collaborative approaches among stakeholders in development of new drug products and devices with emphasis on addressing unmet medical needs for serious and life-threatening conditions.***
2. ***Expedite regulatory reviews and increase the overall efficiency of the development process to ensure timely access for patients to novel therapies.***

Welcome and Introductions

8:00am - 8:15am — Louis Marzella, FDA
Kevin Williams, NRC
Vincent Holahan, RRS

Session I: Overview of Regulatory Process for Marketing and Licensing of Radiopharmaceutical Products,

Moderator: Danae Christodoulou, FDA

8:15am – 8:35am **Product Jurisdiction: Devices, Drugs and Combination Products**

- **FDA Product Jurisdiction**
  James Bertram, FDA

- **NRC Jurisdiction: Sealed and Unsealed Materials, Generators**
  Donna-Beth Howe, NRC

8:35am – 8:55am **Clinical Development of Radiopharmaceutical Products: Regulatory Considerations for FDA Approval and NRC licensing**

- **FDA Approval**
  Frank Lutterodt, FDA

- **NRC Licensing**
  Katie Tapp, NRC

Session II: Novel Radiopharmaceuticals: Standards Development, Product Quality Considerations, Supply and Demand

Moderator: Danae Christodoulou, FDA

8:55am – 9:15am **DOE Isotope Program Production of Radioisotopes for Medical Applications**
- Marc Garland, DOE

9:15am– 9:30am **Development of Physical Standards for Novel Radionuclides: Experience with Alpha-Emitters**
- Denis Bergeron, NIST

9:30am – 9:40am **Product Quality Considerations: FDA Perspective on Diagnostic and Therapeutic Radiopharmaceuticals**
- Danae Christodoulou, FDA

9:40am – 9:50am **Special Considerations for Ge-68/Ga-68 Mo-99/Tc-99m Generators**
- John Amartey, FDA

9:50am - 10:20am **Product Quality Considerations: Recent Experiences with Radiopharmaceuticals Approval and Licensing.**
- **Ge-68/Ga-68 Generators**
  Hugh Evans, Eckert & Ziegler Radiopharmaceutical, Inc.

- **Mo-99/Tc-99m Generators**
  James Harvey, NorthStar Medical Technologies

- **Ga-68 Dotatate, Lu-177 Dotatate**
  Maurizio Mariani, Advanced Accelerator Applications

10:20am - 10:35am **Break**

10:35am - 11:05am **Sessions I and II Panel:**
Kaye Kang, Frank Lutterodt, James Bertram, Kristina Lauritsen, Donna-Beth Howe, Katie Tapp, Marc Garland, Denis Bergeron, Danae Christodoulou, John Amartey, , Hugh Evans, James Harvey, Maurizio Mariani

Session III: Safety and Efficacy Considerations for Radiopharmaceutical Products

Moderator: Anthony Fotenos, FDA

11:05am - 11:15am **Pharmacology and Biodistribution of Radiopharmaceuticals**
- Christy John, FDA

11:15am - 11:30am **Extravasation Events: Imaging Drugs and Radiopharmaceuticals**
- Kish Chakrabarti, FDA

11:30am - 11:40am **NRC Perspective on Extravasation**
- Lisa Dimmick, NRC

11:40am - 11:50am **Role of Individualized Dosimetry to Optimize Safety and Efficacy of Radiopharmaceutical Therapies**
- Mitchel Anscher, FDA

11:50 am - 12:00 **Role of Dosimetric Studies in Clinical Development of Radiotherapeutic Products-Industry Perspective**
- Bill Goeckler, Bayer Healthcare

12:00pm - 12:45pm **Lunch**

12:45pm - 1:15 pm **Session III Panel:**
Christy John Kish Chakrabarti, Lisa Dimmick, Mitchel Anscher, Bill Goeckler, Joseph Rajendran

Session IV: The Evolving Landscape—Radiological Devices

Moderator: Ralph Lieto, ACR

1:15pm - 1:35pm **Radiological Devices: Total Product Life Cycle**
- Julie Sullivan and Mike Ohara, FDA

1:35pm - 1:45pm **Sealed Sources and Device Registry**
- Tomas Herrera, NRC

1:45pm - 2:00pm **Gammaknife and Microspheres-NRC Perspective**
- Katie Tapp, NRC

2:00pm - 2:15pm **Industry Experience in Regulatory Process for Radiological Devices**
Diana Thompson, Sirtex

2:15pm - 2:45pm **Session IV Panel:** Julie Sullivan, Mike Ohara, Diana Thompson, Tomas Herrera, Katie Tapp

2:45pm - 3:00pm **Break**

Session V: Clinical Trial Design Considerations for Radiopharmaceuticals:

Moderator: H. Timothy Hsiao, ASTRO

3:00pm - 3:15 pm **Safety Assessment for Radiotherapeutics**
- Denise Casey, FDA

3:15pm - 3:30pm **Efficacy Considerations for Theranostic Pairs**
- Sue-Jane Wang, FDA

3:30pm - 3:45 pm **Clinical Trial Considerations from Academic Perspective**
- Ana Kiess, ASTRO

3:45pm - 4:15pm **Patient and Physician Perspectives on Advancements in Therapeutics**
- Josh Mailman
- Hossein Jadvar

4:15pm - 4:45pm **Session V Panel:** Denise Casey, Sue-Jane Wang, Josh Mailman, Hossein Jadvar, Ana Kiess

4:45pm - 5:00pm **Closing Remarks**

- Louis Marzella, FDA