



# 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 Radiopharma, 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 Amartei, , 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
- 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