



Center for Devices and Radiological Health (CDRH)

Presented by:

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Regulatory Mandate of Center (1)

- 190,000 types of product
 - Medical Devices
 - In Vitro Diagnostics
 - Radiation Emitting Products
- Pre-market regulatory authority, manufacturing facilities, post market safety

Regulatory Mandate of Center (2)

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Research Interests (1)

- AR/VR - extended reality (XR)
- Artificial Intelligence (AI) / Machine Learning
- Biocompatibility/Toxicology
- Closed Loop Physiological Systems
- Computational Modeling
- Digital Pathology
- Electrical Safety
- Electromagnetic Compatibility
- Materials Performance
- Medical Alarms
- Medical Imaging
- Microfluidics
- MRI Safety
- Nanotechnology
- Photoacoustics
- Sterility and Infection Control
- Therapeutic ultrasound
- Wireless Compatibility

Research Interests (2)

- Translational Research
 - Majority of innovation comes from small companies
 - Failure means no second chance
 - Development of standardized tools has a double advantage in reducing risk and accelerating testing cycles

Potential Areas of Future Potential

Collaboration with NCTR

- Materials Performance
 - Advisory Committee Held in November
 - Are there at risk sub-populations for specific materials, including alloys?
 - What factors are important for assessing material safety?

Summary

- 2 of CDRH major interests are currently:
 - How do we stimulate innovation?
 - What really happens to materials in the body?



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