U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health (CDRH) WELCOME

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CDRH MISSION

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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CDRH SHARED VALUES:

- **Public Health Focus**
  - We focus on activities and outcomes that protect and promote public health.
- **Innovation**
  - We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.
- **Science-Based Decisions**
  - We make decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.
- **Transparency**
  - We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.
- **Our People**
  - We value individual excellence, teamwork, and personal and professional diversity.
- **Honesty and Integrity**
  - We maintain the public trust by acting with integrity and honesty.
- **Accountability**
  - We hold ourselves accountable for the actions we do and do not take.

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Collaboration

❖An essential element of many approaches we apply to achieve our public health mission

❖ Proactively working with stakeholders in the medical device ecosystem to solve both shared problems and problems unique to others, allows us to serve the American public better and to achieve our vision

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How to Expedite Innovation of Laser-Based Imaging Devices?

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Forum on Laser-Based Imaging

- Session 1 – OCT
  - FDA Regulation of OCT
  - Novel applications of leading edge OCT for Dx and Rx of glaucoma, anterior segment and retina diseases
  - Clinical standards for assessment
  - AI-assisted segmentation
- Session 2 – AO
  - Clinical uses
  - Research applications and how they can lead to clinical trials
  - Regulatory considerations
- Session 3 –Nonclinical Data Sources
  - Synthetic Datasets and their utility
  - Medical Device Development Tool Program
- Session 4 – Reimbursement
  - Reimbursement Considerations
  - CDRH Payer Program

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TODAY's GOAL

- Deliver transformational change by combining the best internal and external talent to shorten the time from conception to market

You are the Change Agents!

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CDRH VISION

- Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

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