REdI Device Track: Part 1

Innovation in Medical Device Development

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

May 29, 2024

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U.S. Food and Drug Administration

Your FDA CDRH Faculty
REdI Device Track - Part 1
Day 1 (May 29)

CDR Kim Piermatteo, MHA
Moderator

Michelle Gabriele Sandrian, PhD
Online Moderator: Questions and Answers





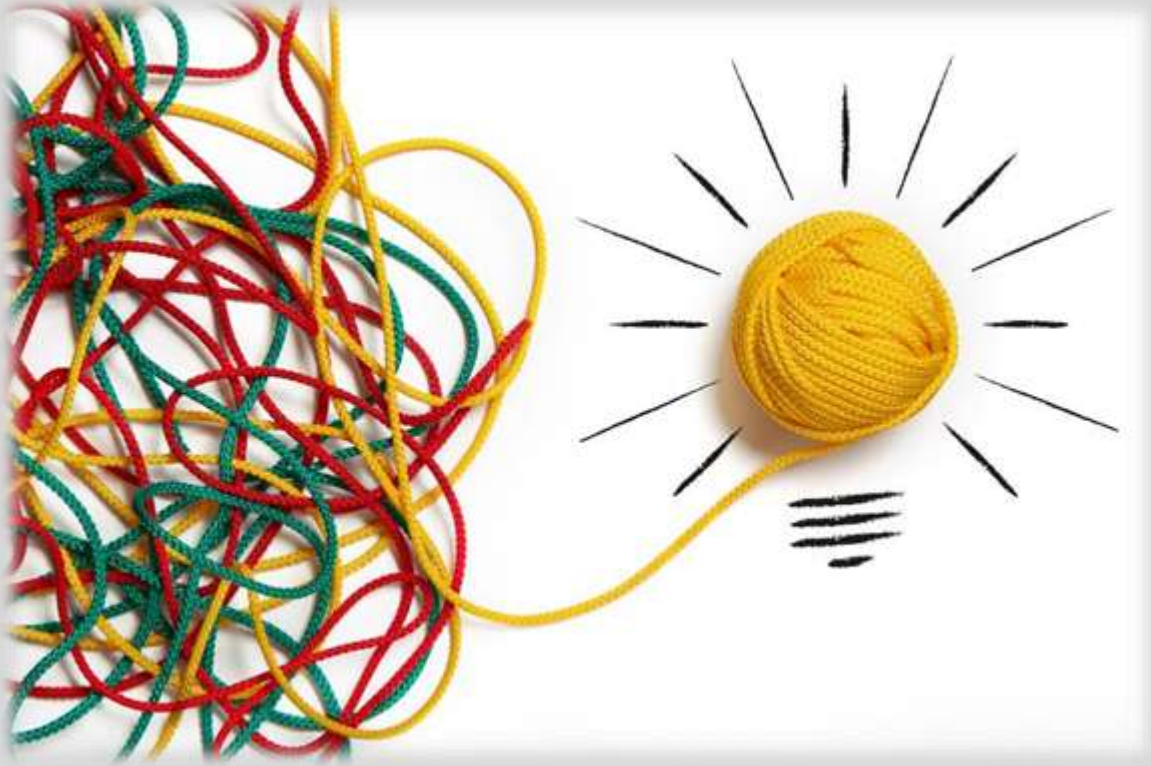






Getting from A to B

What is Innovation to You



LEARN

APPLY

INNOVATE

(and repeat)

Dream BIG = Innovate

Program Format

- **Presentation:** 25 minutes
- **Live Question and Answer:** 15 min
  - Please ask your general questions!
  - This is your workshop!
  - Identify speaker/session and type in question
- **Learning Objectives**
- **Knowledge Checks**
- **Your Call to Action!**

REdI Device Track Part 1: Agenda

Time	Topic	Speaker
10:20 – 10:30	Welcome and Introductions	CDR Kim Piermatteo, MHA
10:30 – 11:10	Foundations of Medical Device Regulation in a World of Change	Kendra Holter, MSN, RN
11:10 – 11:50	Accelerating Medical Device Innovation with Regulatory Science Tools	Edward Margerrison, PhD
11:50 – 1:05	**Lunch Break**	
1:05 – 1:45	Recognized Consensus Standards: The Ultimate Weapon to Streamline Conformity Assessment and Advance Innovation	Simon Choi, PhD, MPH
1:45 – 2:25	Regulation of Medical Device Clinical Trials and Innovation in Clinical Evidence Generation	Christina Savisaar, PhD
2:25 – 2:45	**Break**	
2:45 – 3:25	The 510(k) Program: Overview and Updates	Kathryn J De Laurentis, PhD
3:25 – 4:05	Advancing Innovation in Healthcare with Combination Products	Hina Pinto
4:05 – 4:10	Day One ONLINE Closing	CDR Kim Piermatteo, MHA
4:10 – 4:35	1:1 Question and Answer Discussion – Onsite Attendees Only	Day One Speakers

CDRH Organizational Acronyms

- OCE: Office of Communication and Education
- OPEQ: Office of Product Evaluation and Quality
- ORP: Office of Regulatory Programs
- OCEA: Office of Clinical Evidence and Analysis
- OSEL: Office of Science and Engineering Laboratories
- OST: Office of Strategic Partnerships and Technology Innovation

CDRH Learn: How is CDRH Structured? (CDRH Learn)

Suggested Pre-requisites

Foundations of Medical Device Regulation in a World of Change

- How to Determine if Your Product is a Medical Device (Device Advice)
- How to Study and Market Your Device (Device Advice)
- Is My Product a Medical Device? (CDRH Learn)
- How is My Medical Device Classified? (CDRH Learn)

Recognized Consensus Standards: The Ultimate Weapon to Streamline Conformity Assessment and Advance Innovation

- Division of Standards and Conformity (Device Advice)
- Appropriate Use of Voluntary Consensus Standards (Guidance Document)

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

CDRH Learn

Device Advice

Email DICE

Your Call to Action

- Learn, Apply, Innovate! Dream Big!
- Take advantage of the many FDA resources
- Ask us your questions
- Give us feedback on what you need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