

# **REdI Device Track: Part 1**

## **Innovation in Medical Device Development**

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

May 29, 2024

**Kimberly Piermatteo, MHA**

Education Program Administrator  
Division of Industry and Consumer Education  
Office of Communication and Education  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# Your FDA CDRH Faculty

## REdI Device Track - Part 1

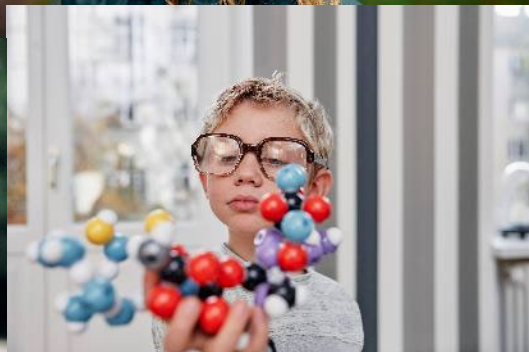
### Day 1 (May 29)



**CDR Kim Piermatteo, MHA**  
**Moderator**



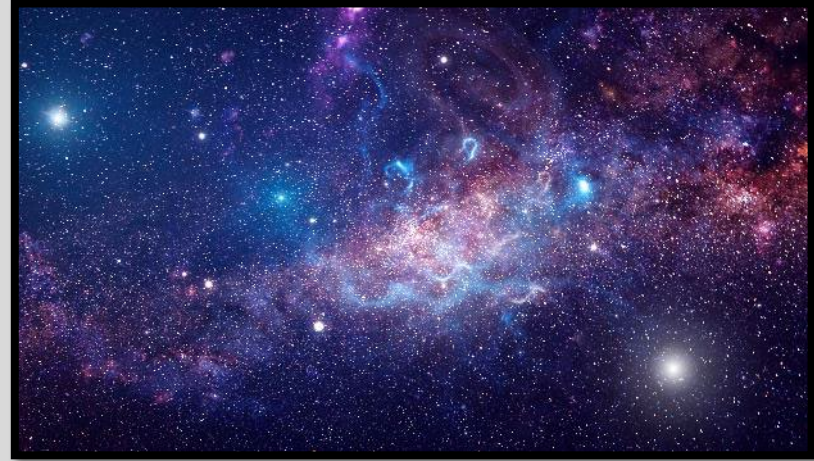
**Michelle Gabriele Sandrian, PhD**  
**Online Moderator: Questions and Answers**







# Getting from A to B



# What is Innovation to You



**LEARN**

**APPLY**

**INNOVATE**

**(and repeat)**



# Dream BIG = Innovate





# Program Format

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- **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!**

## Submit a CDRH Question



[bit.ly/CDRH-Q](https://bit.ly/CDRH-Q)

## Slides & Resources

[SBIAevents.com/redi2024](https://SBIAevents.com/redi2024)

# 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
<b>11:50 – 1:05</b>	<b>Lunch Break</b>	
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
<b>2:25 – 2:45</b>	<b>Break</b>	
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](http://www.fda.gov/CDRHLearn)

## 2. Device Advice – Text-Based Education

- comprehensive regulatory information across the device total product life cycle: [www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

## 3. Division of Industry and Consumer Education (DICE)

- Email: [DICE@fda.hhs.gov](mailto: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

