

REdI Device Track: Part 2

Innovation in Medical Device Development

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

May 30, 2024

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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 2

Day 2 (May 30)



Joseph Tartal
Moderator



Joseph Hillring
Online Moderator: Questions and Answers

REdI Housekeeping Items

- Speaker and Final Evaluations
- Continuing Education and Certificates
- Recordings

Evaluations

Please complete all evaluations. We use this valuable information to:

- Share with our speakers
- Improve our program
- Plan for next years program
- And, most importantly, meet your needs

Continuing Education for Health Professionals

- **CE for RAPS, SOCRA, SQA, and ACRP**
- **CE for Physicians, Nurses, and Pharmacists**

Conference Recordings

- Recordings posted within 5-7 business days

www.fda.gov/cdersbia

What is Innovation



What is Innovation to You



LEARN

APPLY

INNOVATE

(and repeat)



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!**

Submit a CDRH Question



bit.ly/CDRH-Q

Slides & Resources

SBIAevents.com/redi2024

REdI Device Track Part 2: Agenda



Time	Topic	Speaker
8:50 – 9:00 am	Welcome and Introductions	Joseph Tartal
9:00 – 9:40 am	Overview of the Final Review and the Quality Management System Regulation	Joseph Tartal
9:40 – 10:20 am	An Innovative Approach to Navigating the Quality Management System Regulation	Tonya Wilbon
10:20 – 10:40 am	AM Break	
10:40 - 11:20 am	UDI for Patient Safety Innovation and Transformation	Indira Rao Konduri, MS
11:20 – 12 pm	Global Market Innovation with Medical Device Export Certificates	Ruth Bediakoh
12:00 pm – 1:15 pm	Lunch	
1:15 pm - 1:55 pm	Medical Device Reporting: Viewing Adverse Events as Opportunities for Transformation	Dianna Kenner-Staves, PharmD
1:55 - 2:35 pm	Innovations in Medical Device Remanufacturing and Servicing	Katelyn Bittleman, PhD
2:35 - 2:55 pm	PM Break	
2:55 - 3:35 pm	Step into the Closing Meeting: Navigating an FDA Closeout and Beyond	LCDR Sara Onyango, DHSc, MPH, MSN
3:35 – 3:40 pm	Closing Remarks	Joseph Tartal

CDRH Organizational Acronyms

- OCE: Office of Communication and Education
- OPEQ: Office of Product Evaluation and Quality
- ORA: Office of Regulatory Affairs (FDA Office of Commissioner)
- ORP: Office of Regulatory Programs

[CDRH Learn: How is CDRH Structured? \(CDRH Learn\)](#)

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