

Day 1 Introductions: Premarket

**FDA Small Business
Regulatory Education for Industry (REdI)
Burlingame, CA
May 15, 2018**

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Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Agenda – Day 1

Device Track



Time	Topic	Speaker
9:50 - 9:55:	Day 1 Introductions	Elias Mallis
9:55 - 10:30:	Medical Device Framework	Donna Headlee, RN, BSN, CCRP
10:30 - 11:10:	Successful Clinical Trial Strategies	Stanley Liu
11:10 - 12:25:	Lunch	
12:25 - 1:05:	CDRH BIMO Inspections	Marisa M. White, BS, CCRP
1:05 - 1:50:	510(k) Program: Case Study	CDR Kimberly Piermatteo
1:50 - 2:10:	Break	
2:10 - 2:50:	De Novo Classification Requests	Sergio de del Castillo
2:50 - 3:30:	Fostering Digital Health Innovation: FDA's approach to Mobile Apps	Simon Choi, PhD, MPH
3:30 - 4:00:	1:1 Q&A Session	In Person Attendees

Day 2 Faculty

- Joseph Tartal, Day 2 Moderator
- Tonya Wilbon
- Vidya Gopal
- Andrew Durfor
- Loretta Chi
- Anike Freeman
- Maida Henesian

FDA Online Moderator

- Joseph Hillring
- Online Attendees:
 - send questions to Joseph via the **Q&A Pod**

Program Format

- Presentation: around 25 minutes
- Question and Answer: 15 minutes
- Welcome questions from online and in-house
- Participate, engage and ask!
- Recordings available for at least 6 months after broadcast, for future resource

Industry Education Resources



Three Resources

1. CDRH Learn: Multi-Media Industry Education

- over 125 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

www.fda.gov/Training/CDRHLearn

2. Device Advice: Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

www.fda.gov/MedicalDevices/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: www.fda.gov/DICE

Thank You for Attending!!!

**Let's Learn and Enjoy the Next
Two Days Together**

