Day 1 Introductions: Premarket

FDA Small Business
Regulatory Education for Industry (REdI)
Boston, MA
May 29, 2019

Elias Mallis
Director
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
Day 1 (May 29)
Moderator

Elias Mallis

Your FDA CDRH Faculty
Day 1 (May 29)

William Maisel, MD, MPH

CDR Kim Piermatteo

Angela DeMarco

CAPT Scott Colburn

Maureen Dreher

Donna Headlee

Your FDA CDRH Faculty
Day 2 (May 30)
Moderator

Joseph Tartal

Your FDA CDRH Faculty
Day 2 (May 30)

Tonya Wilbon

Vidya Gopal

LCDR Kenneth Chen

Terri Garvin

Ethny Obas

Maura Rooney

Your FDA CDRH Faculty

Online Moderator

Anike Freeman

The Washington Post

Capitals win Stanley Cup, Washington's first major sports championship since 1992

Device Themes

- Globalization
- Harmonization
- Standardization

- Convergence of total product life cycle
- Advancement of Public Health

Safe, effective, and high quality medical devices

Agenda – Day 1

Time	Topic	Speaker
10:20 – 10:30:	Day 1 Introductions	Elias Mallis
10:30 – 11:10:	Keynote: Incorporating a Total Product Life Cycle Approach	William Maisel, MD, MPH
11:10 - 11:50:	Case Study on Device Determination and Product Classification	CDR Kimberly Piermatteo
11:10 – 1:05:	Lunch	
1:05 - 1:45:	510(k) Program Updates	Angela DeMarco
1:45 – 2:25:	Voluntary Consensus Standards in Premarket Submissions	CAPT Scott Colburn
2:25 - 2:45:	Break	
2:45 - 3:25:	Patient Access: Expanded Access, Early Feasibility, and Breakthrough	Maureen Dreher, PhD
3:25 – 4:00:	Building Quality Clinical Data into PMA Program	Donna Headlee, RN, BSN, CCRP
4:00 – 4:30:	Question and Answer Session (in person attendees)	All

Did You Do Your Homework? Suggested Pre-requisites

510(k) Program Updates (1:05 pm)

- 510(k) Program

fda.yorkcast.com/webcast/Play/d91af554691c4260b5eca0b2a28e636b1d

Appropriate Use of Voluntary Consensus Standards and the Conformity Assessment Program (1:45 pm)

- Standards Overview

fda.yorkcast.com/webcast/Play/19fb4aaf3db5441898df39fe5af7d1b11d

Did You Do Your Homework? Suggested Pre-requisites

Facilitating Patient Access to Medical Devices: Expanded Access, Early Feasibility Study, and Breakthrough Devices Program (2:45 pm)

- IDE Basics

fda.yorkcast.com/webcast/Play/696d857b34334d5389364ed8c2db3ded1d

- Early Feasibility Study Program

www.accessdata.fda.gov/cdrh_docs/presentations/EFS/story.html

Did You Do Your Homework? Suggested Pre-requisites

Quality System and ISO 13485 Comparison: CAPA (May 30-9 am)

- Overview of the Quality System Regulation

fda.yorkcast.com/webcast/Play/4abbbeeb0f76423998cab8c782c3e4181d

- Corrective and Preventive Action Basics

fda.yorkcast.com/webcast/Play/c78cfebf72774163a59f8f6f197435451d

Overview of FDA Exports Program (May 30: 1:55 pm)

- Exporting Medical Devices

fda.yorkcast.com/webcast/Play/e7f8611bd06b40e890d6031ea1b1ee3a1d

Program Format

- **Presentation:** 25-30 minutes
- **Live Question and Answer:** 10-15 minutes
  - Encourage questions from BOTH in person and online
  - Anike Freeman: online moderator

- **Learning Objectives**
- **Your Call to Action**

Stay Informed!
Start with the Web

- **CDRH Learn**

  www.fda.gov/Training/CDRHLearn

- **Device Advice**

  www.fda.gov/DeviceAdvice

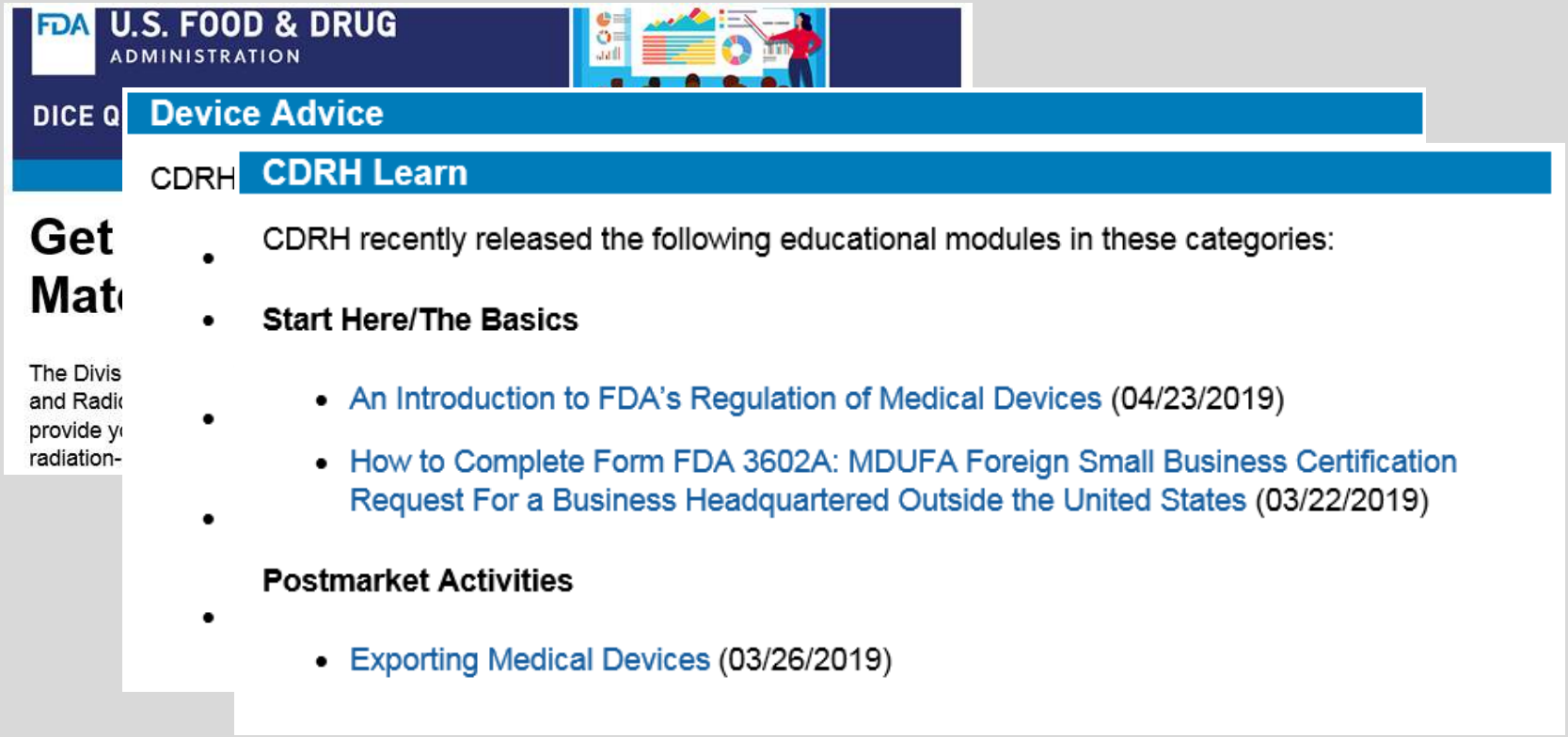
CDRH Learn

- Multi-media, video training modules
- Presentations, computer-based training, webinars
- 150 modules
- Produce 10-20 modules each year
- Give us feedback!

Device Advice

- Written content
- **over 300 pages** of premarket/postmarket regulatory information
- **30 regulatory categories**

DICE Quarterly Newsletter



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Go to www.fda.gov/about-fda/about-center-devices-and-radiological-health/subscribe-cdrh-mailing-lists

Industry Basics

- Format: presentation, live moderated Q+A (phones, emails)
- Usually November
- Recent Topics: Quality System, Unique Device Identification

What to do next - Contact DICE

- **Phone: (800) 638-2041**

  - **Press “1” for consumer questions**
  - **Press “2” for industry questions**
  - hours of operation: 9 am-12:30 pm; 1-4:30 pm

- **Email: dice@fda.hhs.gov**

  - respond within 2 business days

www.fda.gov/DICE

Your Call to Action

- Enjoy the program with us
- Ask lots of questions
- Take advantage of the FDA resources after the program ends
- Give us feedback on what you need


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