Introductions and Day Two Postmarket Overview

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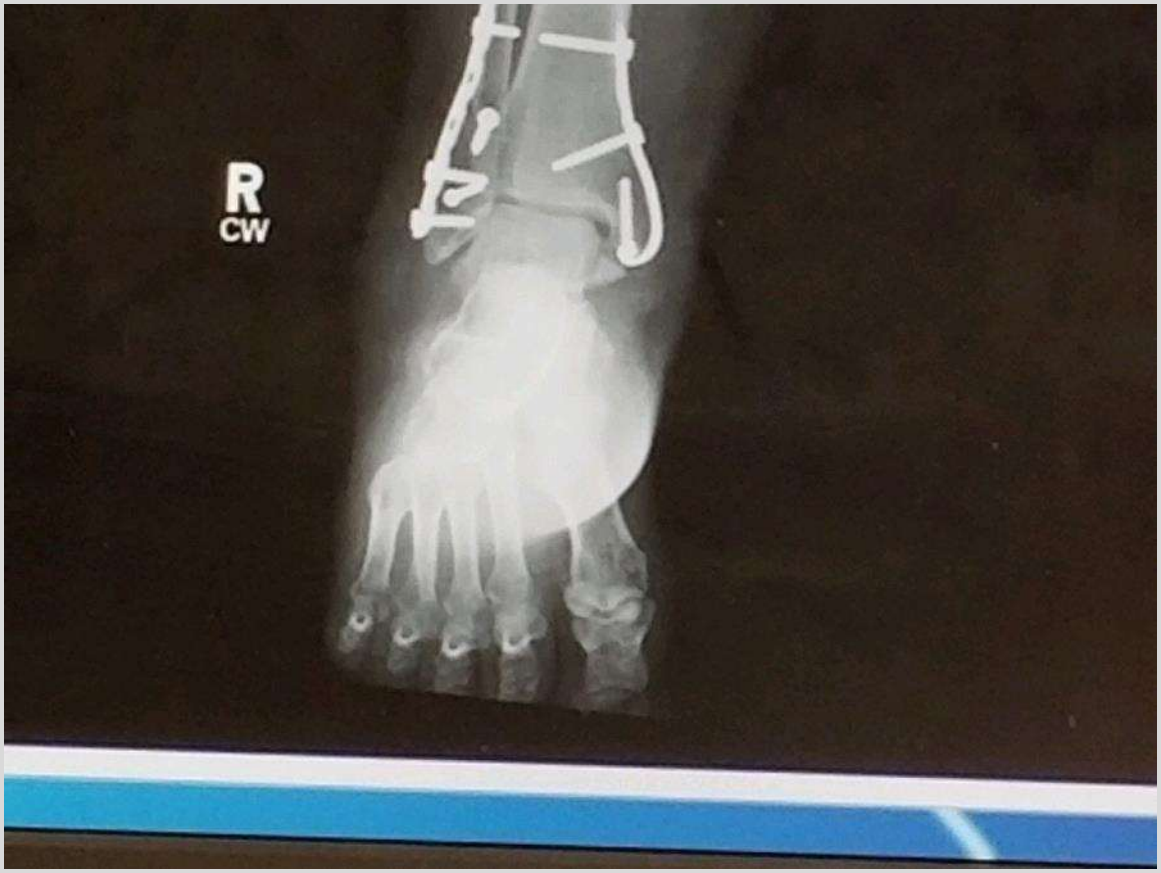


The Impact of Medical Devices in Our Lives

Learning Objectives

- Review Today's Agenda and Meet Today's Speakers
- Introduce three timely postmarket items
- Discuss Housekeeping
- Enjoy the day, ask questions and learn something new

Agenda – Day 2 Device Track

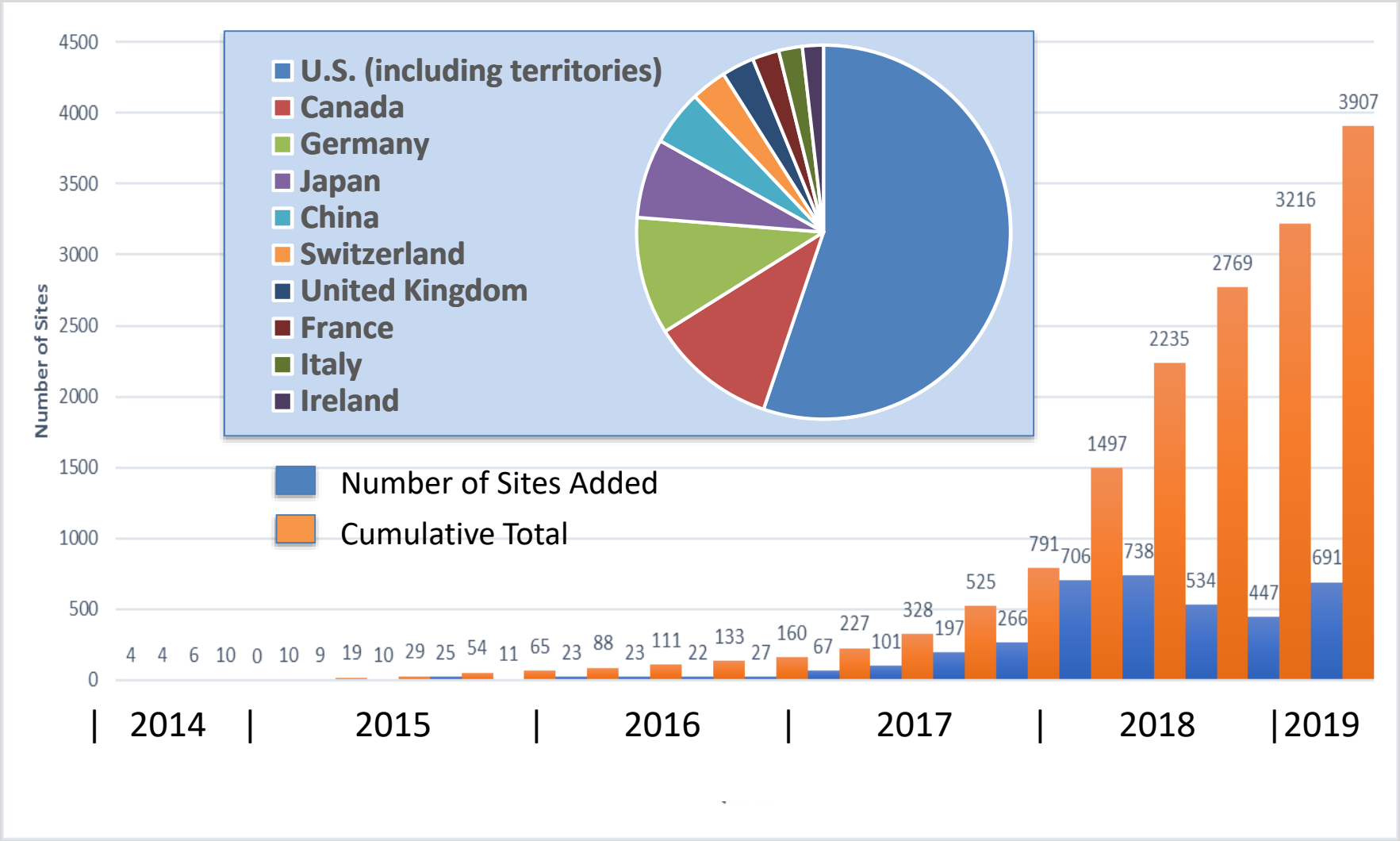
Time	Topic	Speaker
9:00 – 9:40:	Quality System Regulation and ISO 13485 Comparison: CAPA	Joseph Tartal
9:40 – 10:20:	Corrective and Preventive Action (CAPA) Case Study	Tonya Wilbon
10:20 – 10:40:	Break	
10:40 – 11:20:	Quality Systems: FDARA, 21st Century Cures Act and Recent Postmarket Updates	Vidya Gopal
11:20 – 12:00:	Medical Device Single Audit Program (MDSAP) Overview	Kenneth Chen
12:00 – 1:15:	Lunch	
1:15 – 1:55:	FDA's Import Requirements for Devices	Terri Garvin
1:55 – 2:35:	Overview of the FDA Exports Program	Ethny Obas
2:35 – 2:55:	Break	
2:55 – 3:35:	FDA Medical Device Inspections	Maura Rooney
3:40 – 4:20:	1:1 Q&A Session with Day Two Speakers	In Person Attendees

FDA Quality System Regulation and ISO 13485:2016

- FDA announced its intention to harmonize and modernize the Quality System regulation for medical devices.
- The revision will supplant the existing requirements with the specifications of ISO 13485:2016.
- The revision will help harmonize domestic and international requirements.
- This approach is consistent with and complements MDSAP.
- Target 2019 for NPRM.

See Spring 2018 Unified Agenda of Regulatory and Deregulatory Actions

MDSAP Participating Manufacturer Sites



Novel Approaches to Promoting Product Quality

Case for Quality 2011

MDIC Collaborative Forum 2014

Voluntary Quality Maturity Appraisal Pilot 2018

- Third-party certified by Capability Maturity Model Integration Institute (CMMI) conducts appraisal
- Collaboration and feedback on quality objectives
- Removal from the surveillance work plan
- Reduction in manufacturing submission requirements and faster approval for implementation
- Waive some pre-approval inspections

- ✓ 18 participating firms
- ✓ 32 appraisals
- ✓ 86% report appraisal had a positive impact on product quality

Stay Informed!
Start with the Web

- **CDRH Learn**

  www.fda.gov/Training/CDRHLearn

- **Device Advice**

  www.fda.gov/DeviceAdvice

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

Housekeeping Items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