Day 2 Introductions: Postmarket

FDA Small Business
Regulatory Education for Industry (REdI)
Rockville, MD
September 28, 2017

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Learning Objectives

- Review Today's Agenda and Meet Today's Speakers
- Virtual Attendees Learn to Use the Polling Option
- Promote Case for Quality and Upcoming Public Meeting
- Discuss any Housekeeping items
- Enjoy the day, ask questions and learn something new

Agenda – Day 2 Device Track

Time	Topic	Speaker
9:00 – 9:40:	Introduction to Quality System	Aileen Velez Cabassa
9:40 – 10:20:	Risk in the Quality System	Joseph Tartal
10:20 – 10:40:	Break	
10:40 – 11:20:	Non-conformances	Vidya Gopal
11:20 – 12:00:	Complaints	Stanley Liu
12:00 – 1:15:	Lunch	
1:15 – 1:55:	Medical Device Reporting	Anike Freeman
1:55 – 2:35:	Regulatory Actions	Tonya Wilbon
2:35 – 2:55:	Break	
2:55 – 3:55:	FDA Medical Device Inspections	LCDR Thomas A. Peter, ASQ, CBA
3:55 – 4:30:	1:1 Question and Answer Session	In Person Attendees

Poll Question

Do you currently market or distribute a medical device?

1) **Yes**
2) **No**
3) **Not Sure**

Poll Question

Has your facility been inspected by FDA?

1) Yes

2) No

Poll Question

Do you know about the Case For Quality?

1) Yes

2) No

2017 CDRH Strategic Priority

- **Promote a Culture of Quality and Organizational Excellence**

GOAL: Strengthen product and manufacturing quality within the medical device ecosystem

- **By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.**

www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm

FDA Public Workshop: Voluntary Device Manufacturing and Product Quality Program

Date: October 10, 2017

Location:
FDA White Oak Campus
Building 31 – Great Room
Silver Spring, MD

Federal Register Notice:
www.federalregister.gov/documents/2017/07/25/2017-15542/voluntary-medical-device-manufacturing-and-product-quality-program-public-workshop-request-for

Registration:
https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm

Case For Quality Link

Want to learn more about CDRH Case For Quality?

Device Advice – Case for Quality Section

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm

Housekeeping Items


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