

# **Day 2 Introductions: Postmarket**

**FDA Small Business  
Regulatory Education for Industry (REdI)  
Atlanta, GA  
May 10, 2017**

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

## 3 Poll Questions:

- **Do you currently market or distribute a medical device?**
- **Has your facility been inspected by FDA?**
- **Do you know about FDA's Case For Quality Initiative?**

# 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](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm)



# Case For Quality

To learn more about Case For Quality, please visit  
**Device Advice:**

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm)



# 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	CDR Dawn M. Braswell
3:55 – 4:30:	Question and Answer Session (in person attendees)	All



# Housekeeping Items

# 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](mailto:dice@fda.hhs.gov)**



- respond within 2 business days

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