

# **Introductions and Day Two Postmarket Overview**

**FDA Small Business  
Regulatory Education for Industry (REdI)  
Silver Spring, MD  
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# Learning Objectives

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



## Agenda – Day 2 Device Track

Time	Topic	Speaker
8:30 – 9:30:	Quality System Overview	Aileen Velez-Cabassa
9:30 – 9:45:	<i>Break</i>	
9:45 – 10:45:	Management Controls	Tonya Wilbon
10:45 – 11:45:	Basics of Risk Management	Joseph Tartal
11:45 – 1:00:	Lunch	
1:00 – 2:00:	FDA Medical Device Inspections	Marc Neubauer
2:00 – 2:15:	Break	
2:15 – 2:45:	Complaints	Anike Freeman
2:45 – 3:30:	Wrap-Up: Question and Answer	All

# Poll Questions

D2S1-1

View Votes

Edit

End Poll

D2S1-1: Do you currently market or distribute a medical device?

<input type="radio"/> Yes	<div></div>	0%	(0)
<input type="radio"/> No	<div></div>	0%	(0)
<input type="radio"/> Not Sure	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results



# Case For Quality Link

To Learn more about the CDRH Case For Quality please visit the following linked webpage in Device Advice

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm>



# Housekeeping Items

# Industry Education Resources

## Three Resources

### 1. CDRH Learn – Multi-Media Industry Education

- over 115 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](http://www.fda.gov/Training/CDRHLearn)

### 2. Device Advice – Text-Based Education

- over 250 pages
- comprehensive regulatory information on premarket and postmarket topics

[www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

### 3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question about medical devices
- Email: [DICE@fda.hhs.gov](mailto: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](http://www.fda.gov/DICE)

