



# **FDA Small Business Regulatory Education for Industry (REdI)**

## **Device Track – Day 1 (Premarket)**

Silver Spring, Maryland  
September 29, 2015



# Industry Education Resources

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

- Over 80 modules
- Videos, audio recordings, power point presentations, software-based “how to” modules
- Mobile-friendly: access CDRH Learn on your portable devices

<http://www.fda.gov/Training/CDRHLearn>

## 2. Device Advice – Text-Based Education

- Comprehensive regulatory information on premarket and postmarket topics

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

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

- Contact DICE if you have a question
- Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)

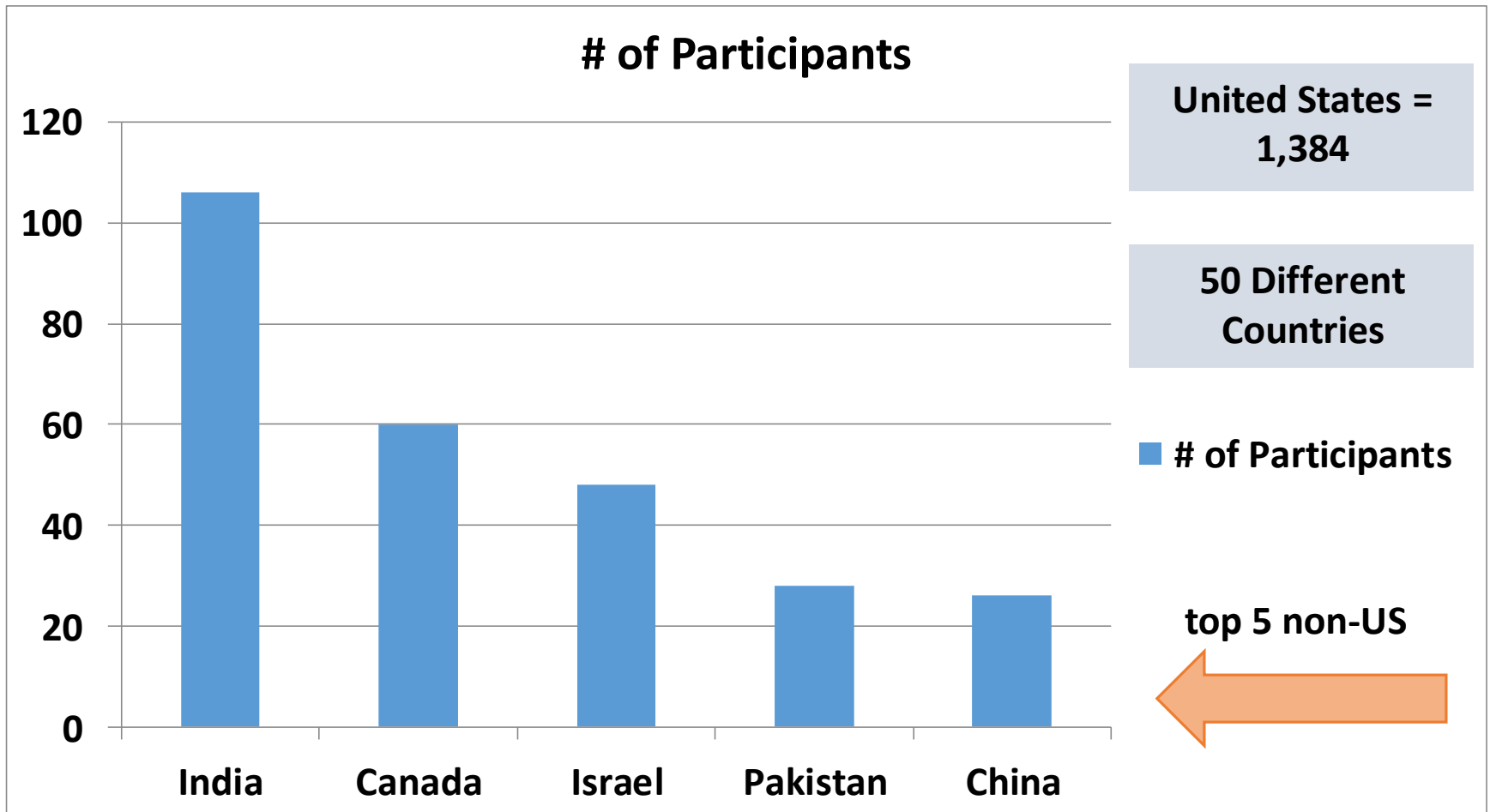
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>

# **REdI Audience Demographics**

**Total: 1,790**

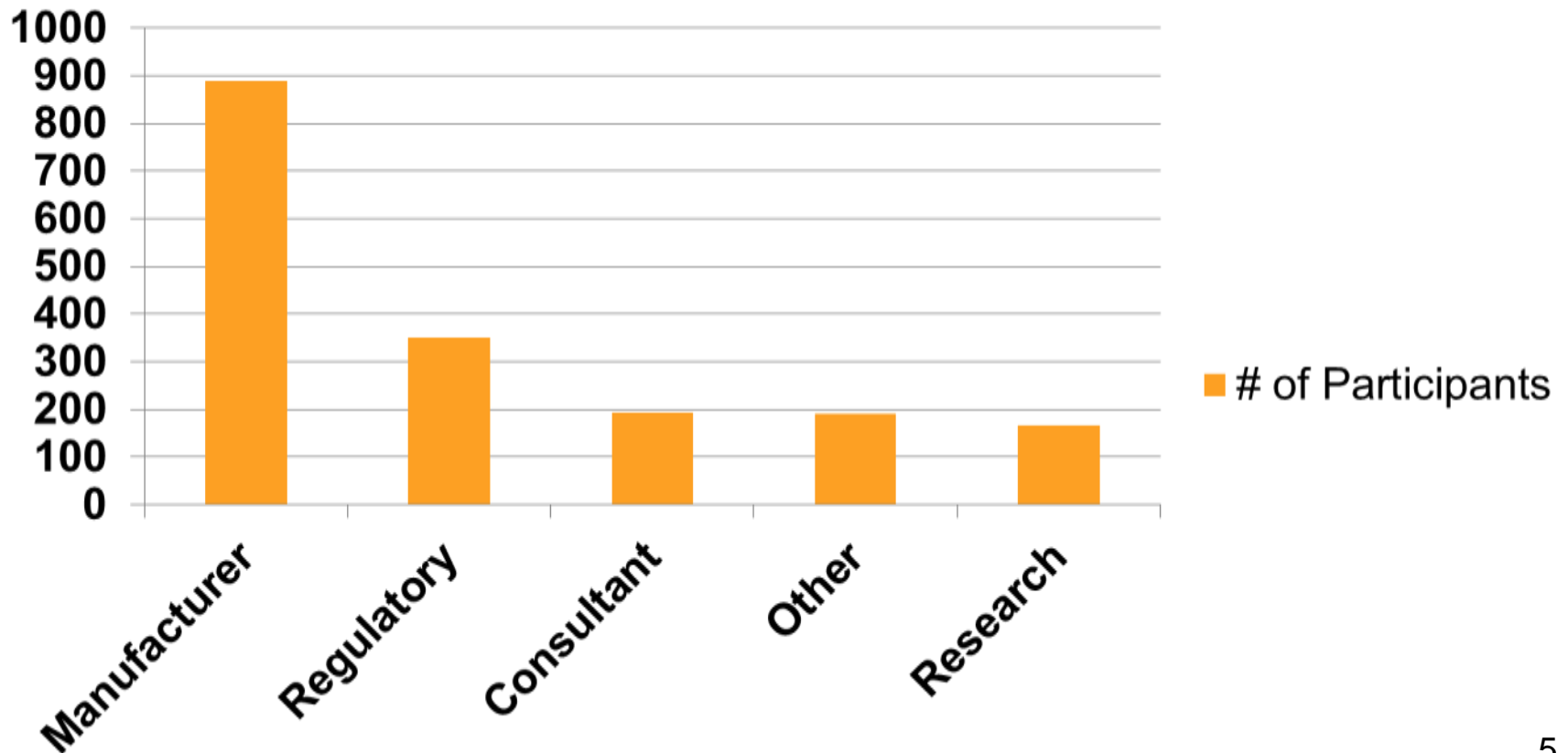


# Where You are Located



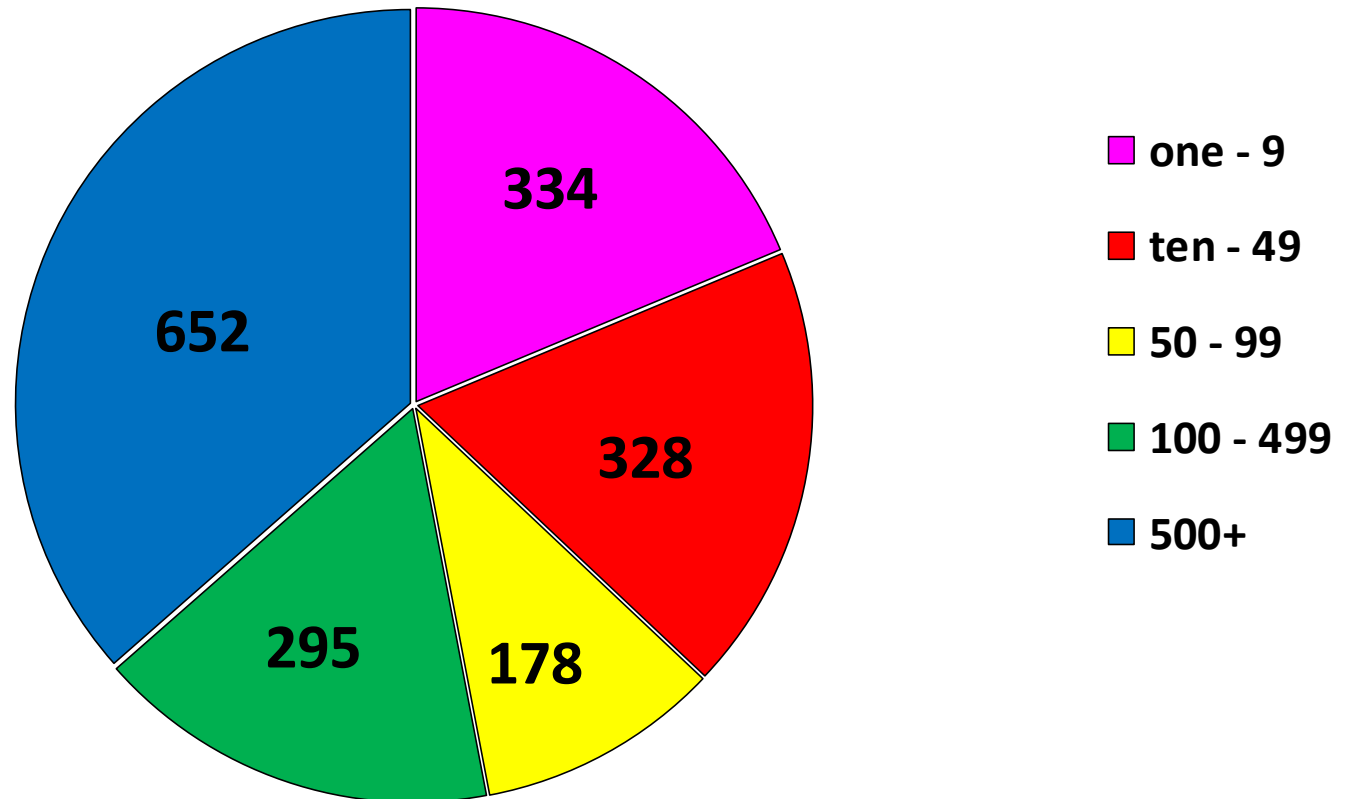
# Business Type

# of Participants



# Business Size

# Participants





# Agenda – Day 1

## Device Track

Time	Topic	Speaker
9:55 – 10:55:	Classification	William Sutton
10:45 – 11:45:	Clinical Trials and IDE Program	Soma Kalb, PhD
11:45 – 1:00:	Lunch	
1:00 – 2:15:	510(k) Program	LCDR Kimberly Piermatteo
2:15 – 2:30:	Break	
2:30 – 3:00:	Best Practices and Interactions	Sergio de del Castillo
3:00 – 3:30:	Labeling	Eric Richardson
3:30 – 4:15:	Wrap-Up: Question and Answers	All