



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

3. Division of Industry and Consumer Education (DICE)

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

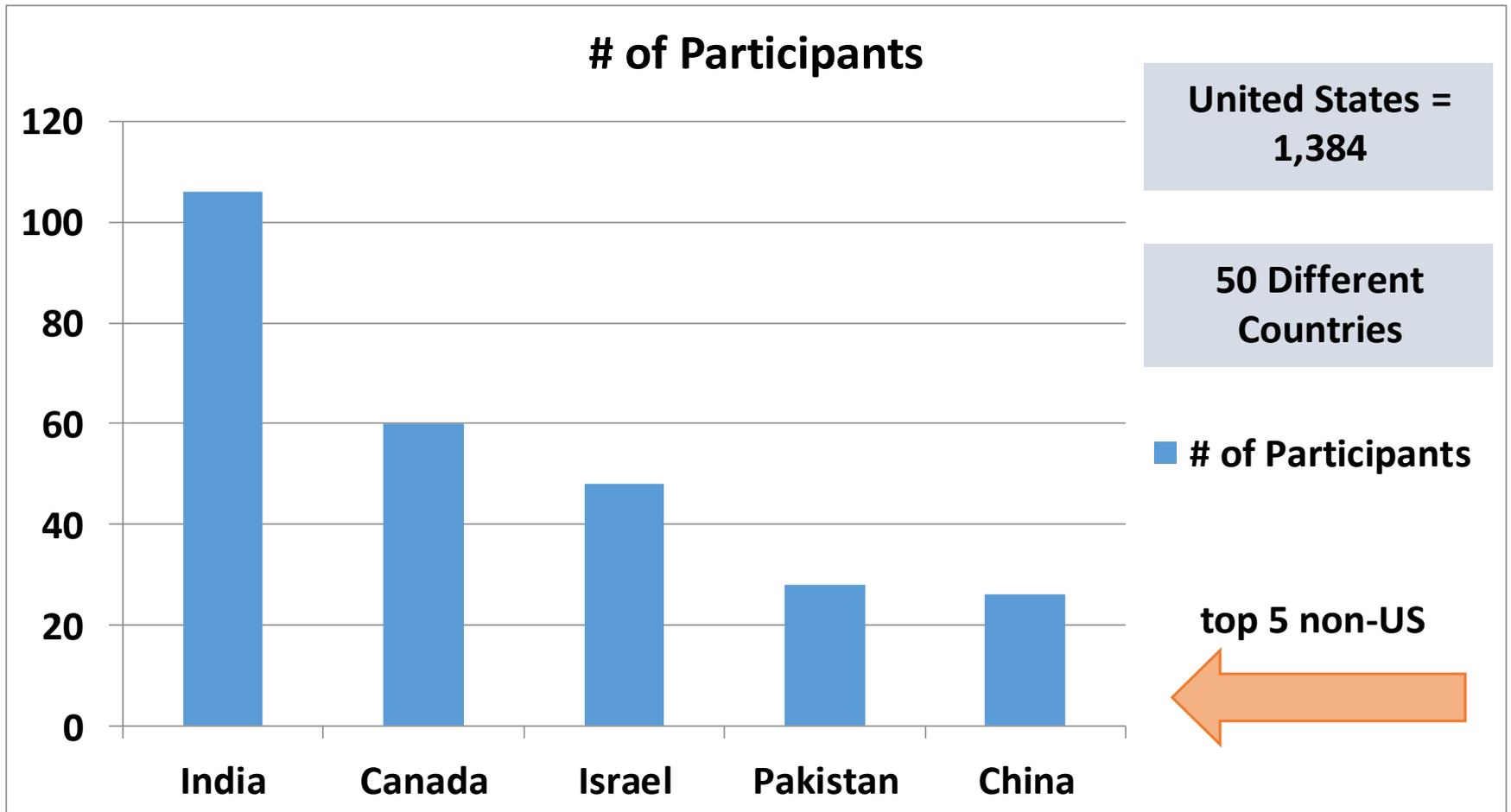
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>



REdI Audience Demographics

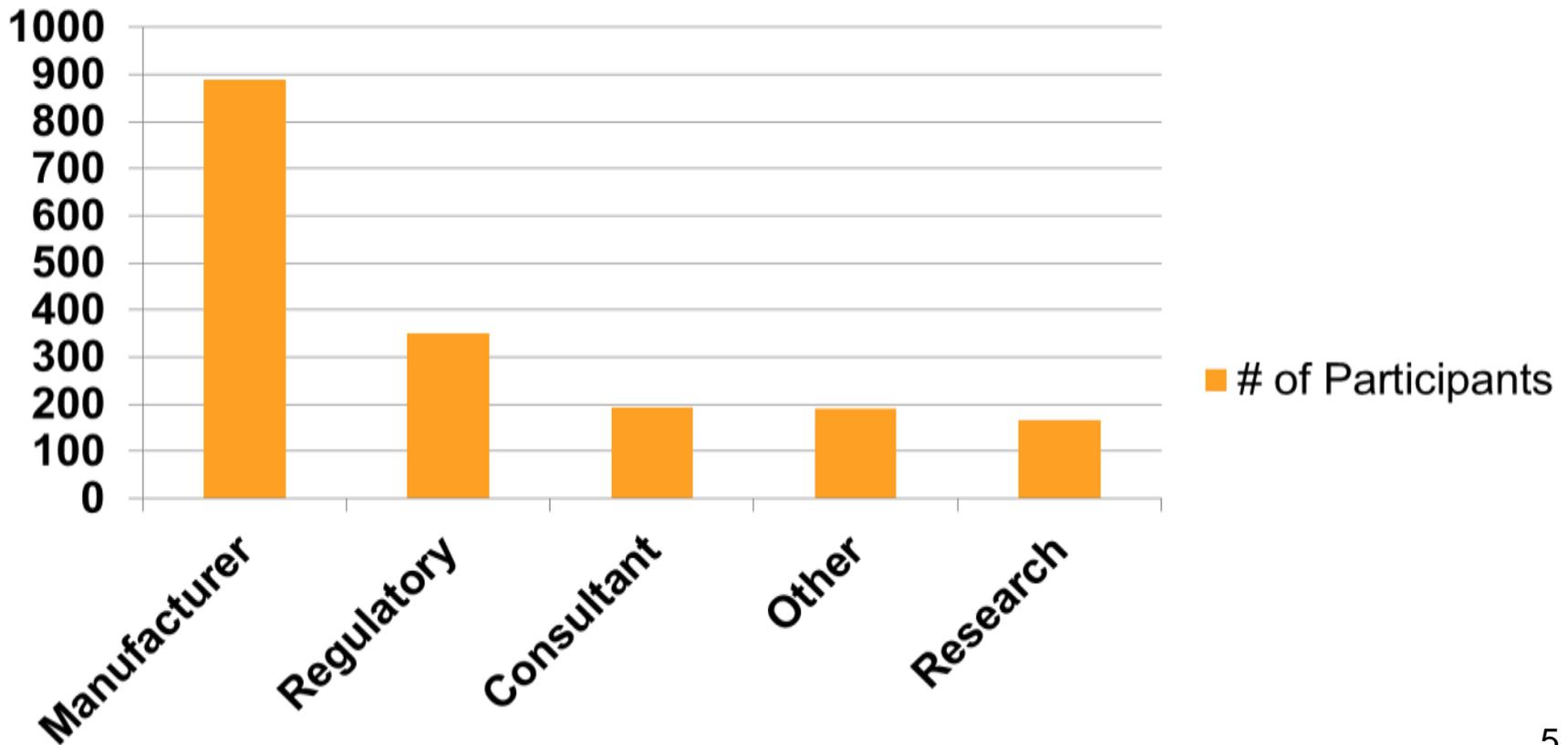
Total: 1,790

Where You are Located

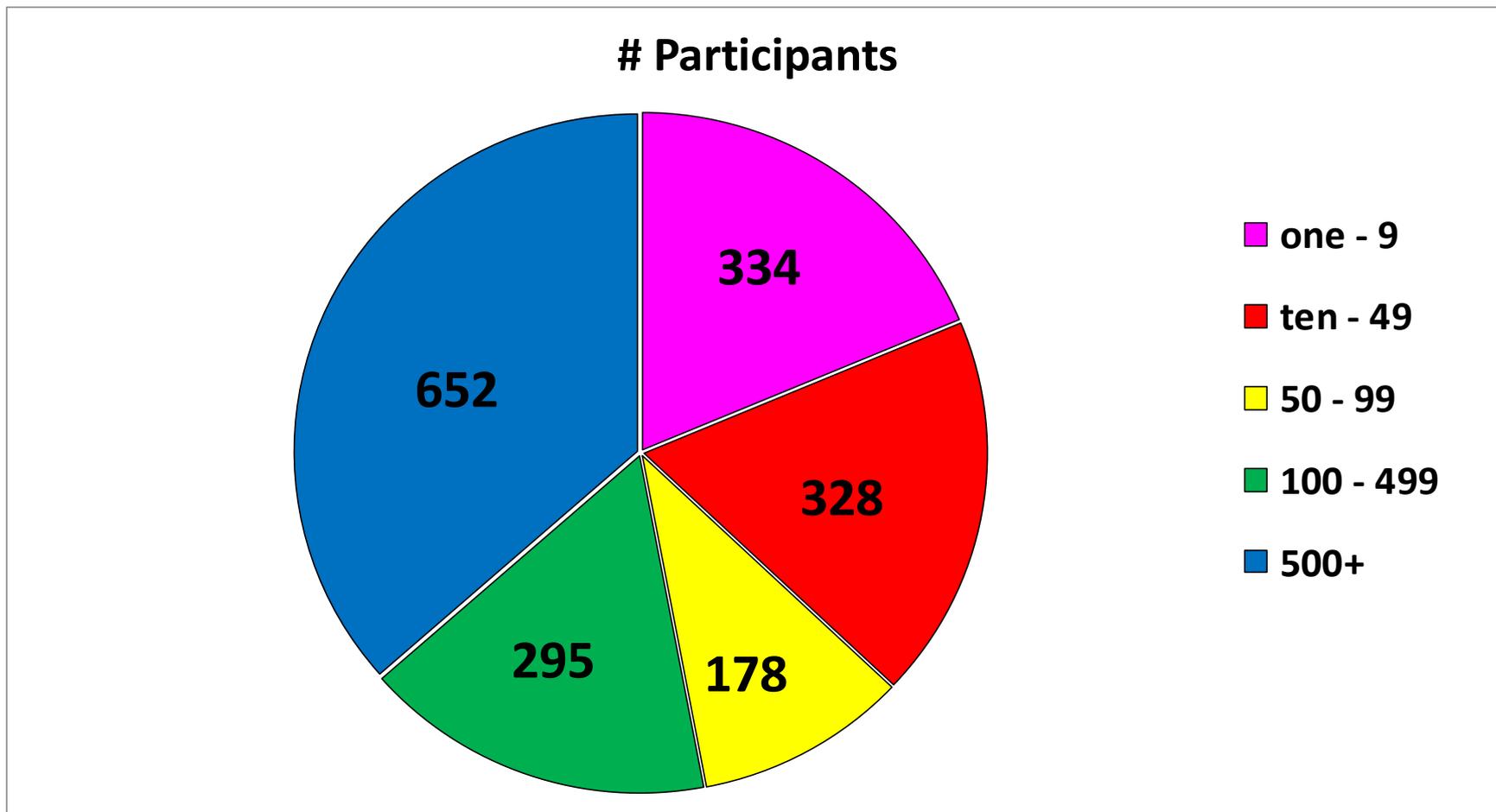


Business Type

of Participants



Business Size





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 |