FDA Small Business Regulatory Education for Industry (REdI)

Device Track – Day 2 (Postmarket)

Silver Spring, Maryland
September 30, 2015

Division of Industry and Consumer Education

- **Vision:** "Our stakeholders always have the best educational information about medical devices…"

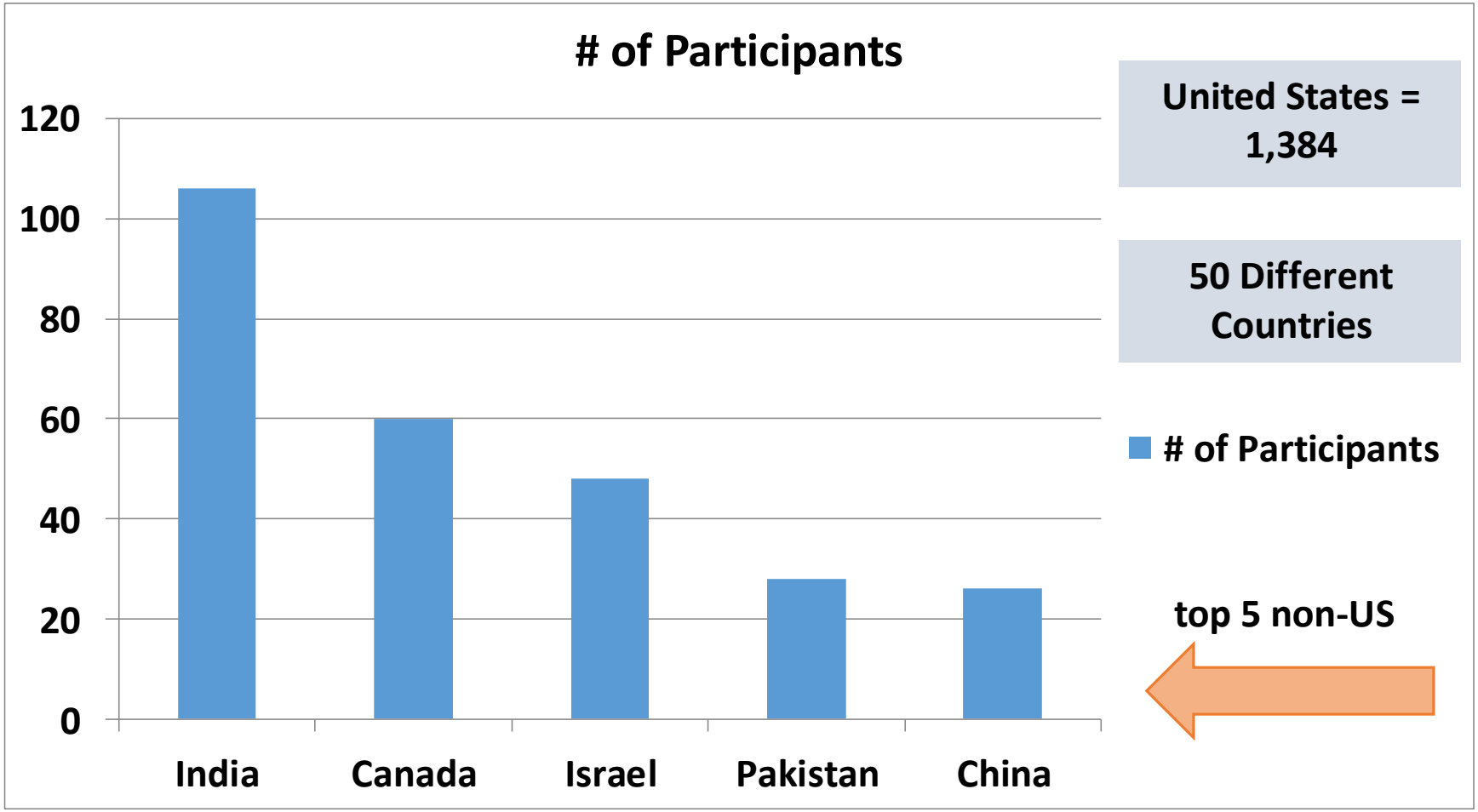
- **Who We Are**
  - Staff of 20 professionals with diverse backgrounds (medicine, engineering, quality systems)
  - Total Product Life Cycle Experiences (FDA premarket review, industry (including IVD), clinical practice)

- **What We Do**
  - Answer approximately 1000 written questions per month (within 2 days)
  - Answer 2200 phone calls/month
  - Develop educational resources, presentations, and workshops

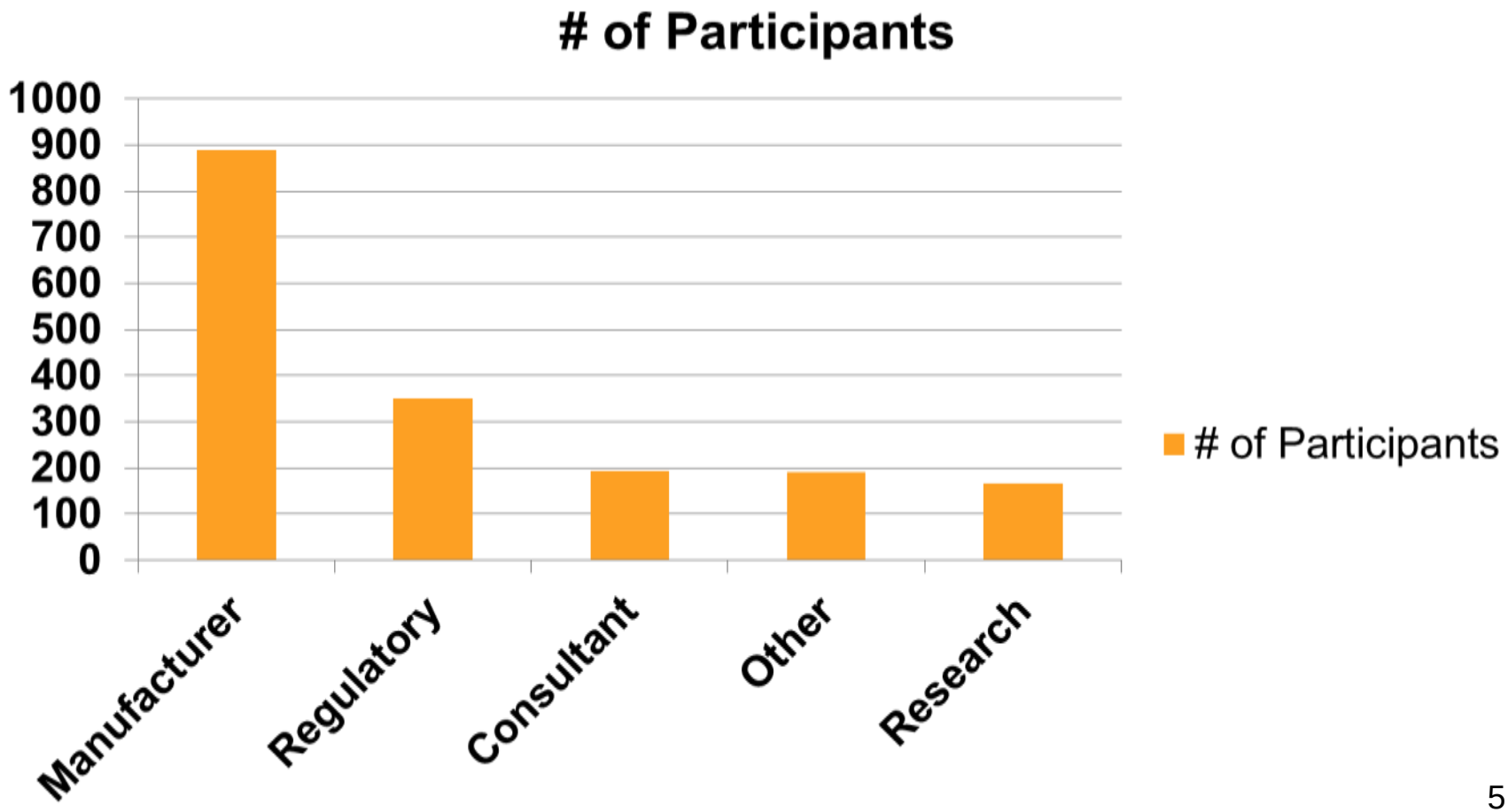
REdI Audience Demographics

Total: 1,790

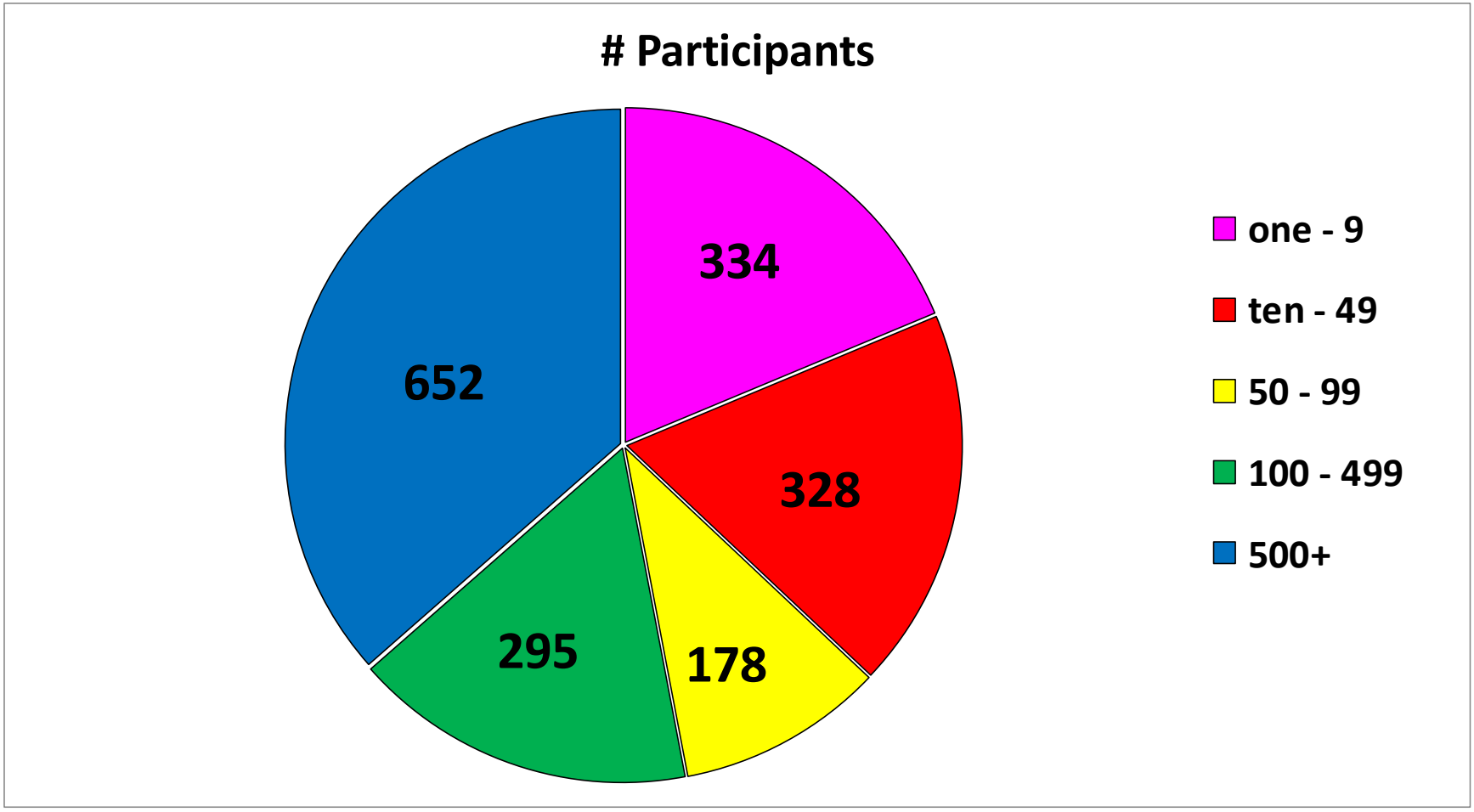
Where You are Located



Business Type



Business Size



Agenda – Day 2
Device Track

Time	Topic	Speaker
8:30 – 9:30:	Quality System Regulation	Tonya Wilbon
9:30 – 9:45:	Break	
9:45 – 10:15:	Design Controls	Stanley Liu
10:15 – 10:45:	Purchasing Controls	Aileen Velez Cabassa
10:45 – 11:45:	Process Validation	Joseph Tartal
11:45 – 1:00:	Lunch	
1:00 – 1:45:	UDI	Loretta E. Chi, JD
1:45 – 2:15:	eMDR	Andrew Xiao
2:15 – 2:30:	Break	
2:30 – 3:30:	FDA Medical Device Inspections	Marc Neubauer
3:30 – 4:14:	Wrap Up: Question and Answers	All