



# **Setting the Stage for Collaboration**

## **Battery-Powered Medical Devices Workshop**

**July 30-31, 2013**

Ken Skodacek

Co-Leader, CDRH's Battery Working Group

FDA/CDRH, Office of Device Evaluation

# Acknowledgements

- Battery Working Group
- Supporting FDA Staff
- Stakeholder Presenters and Supporters
- Innovation Lab Staff
- Workshop Registrants

# What's the focus?



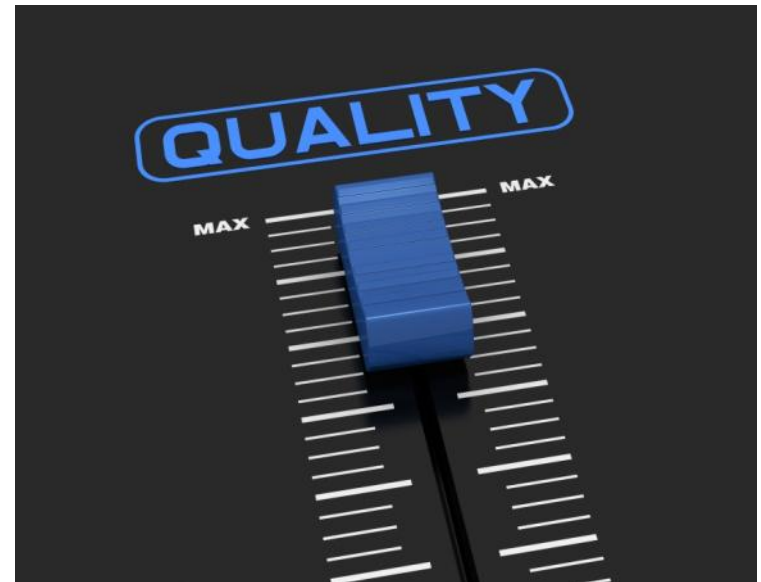
Batteries



Battery-Powered  
Medical Devices

**BPMD**

# Why are we here today?

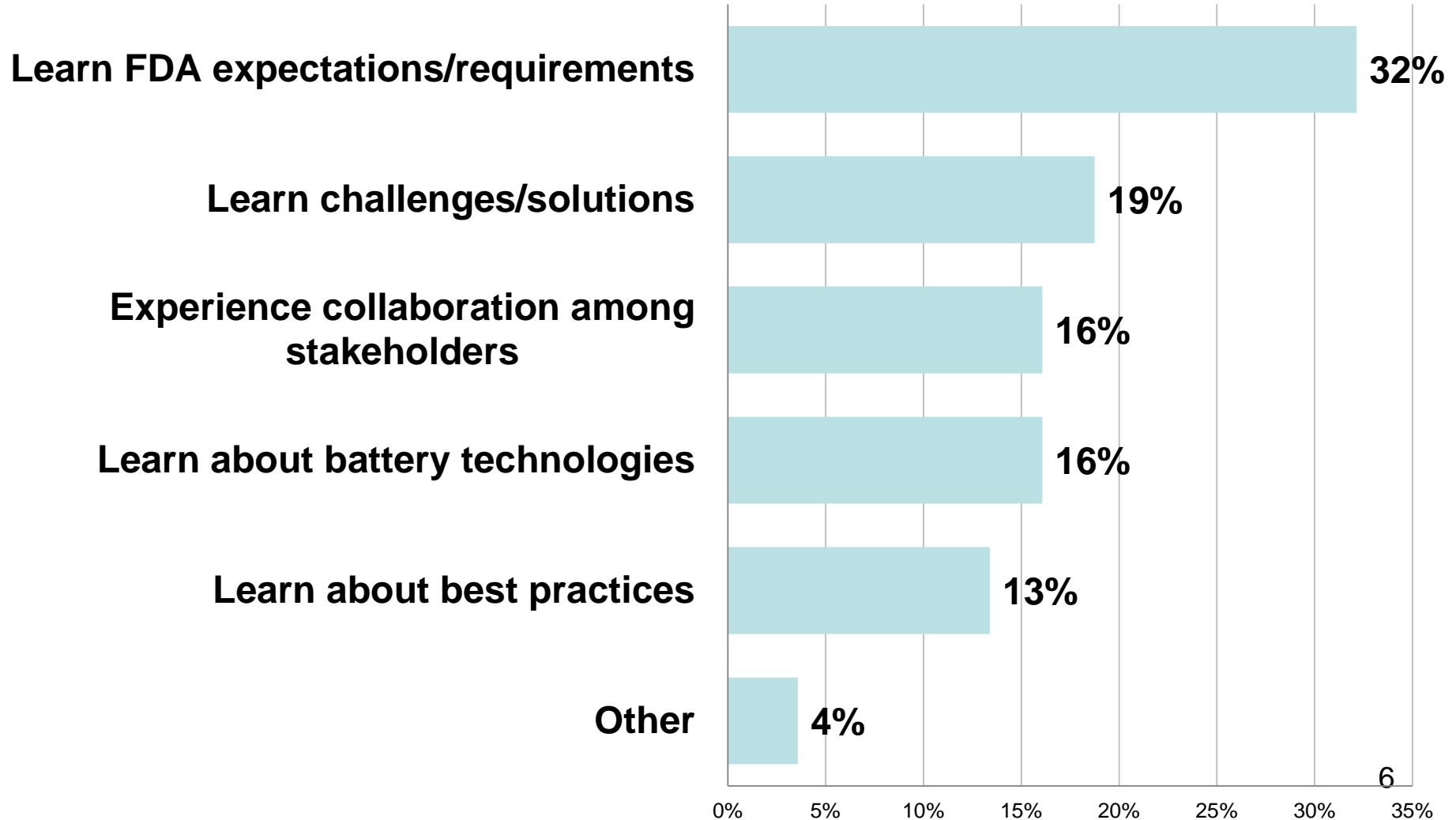


# Workshop Goals

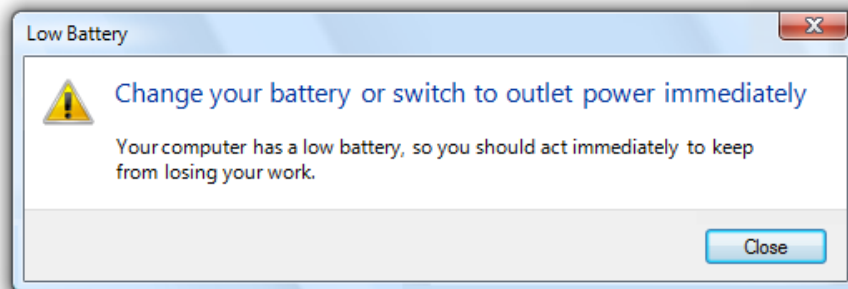
- Create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.
- Create a forum for open dialogue among stakeholders to share lessons learned and best practices for overcoming battery-powered medical device challenges.
- Promote better design, manufacturing, testing, system integration, maintenance and standardization of battery-powered medical devices.
- Understand the challenges of hospitals, health care providers, and patients in selection, purchase, use, and maintenance of battery-powered medical devices.
- Promote innovation in technology and processes to improve device performance and reliability.
- Coordinate future collaboration in the development of educational materials, standards, and guidance.



# Pre-Meeting Survey: Goals



# What could possibly go wrong?



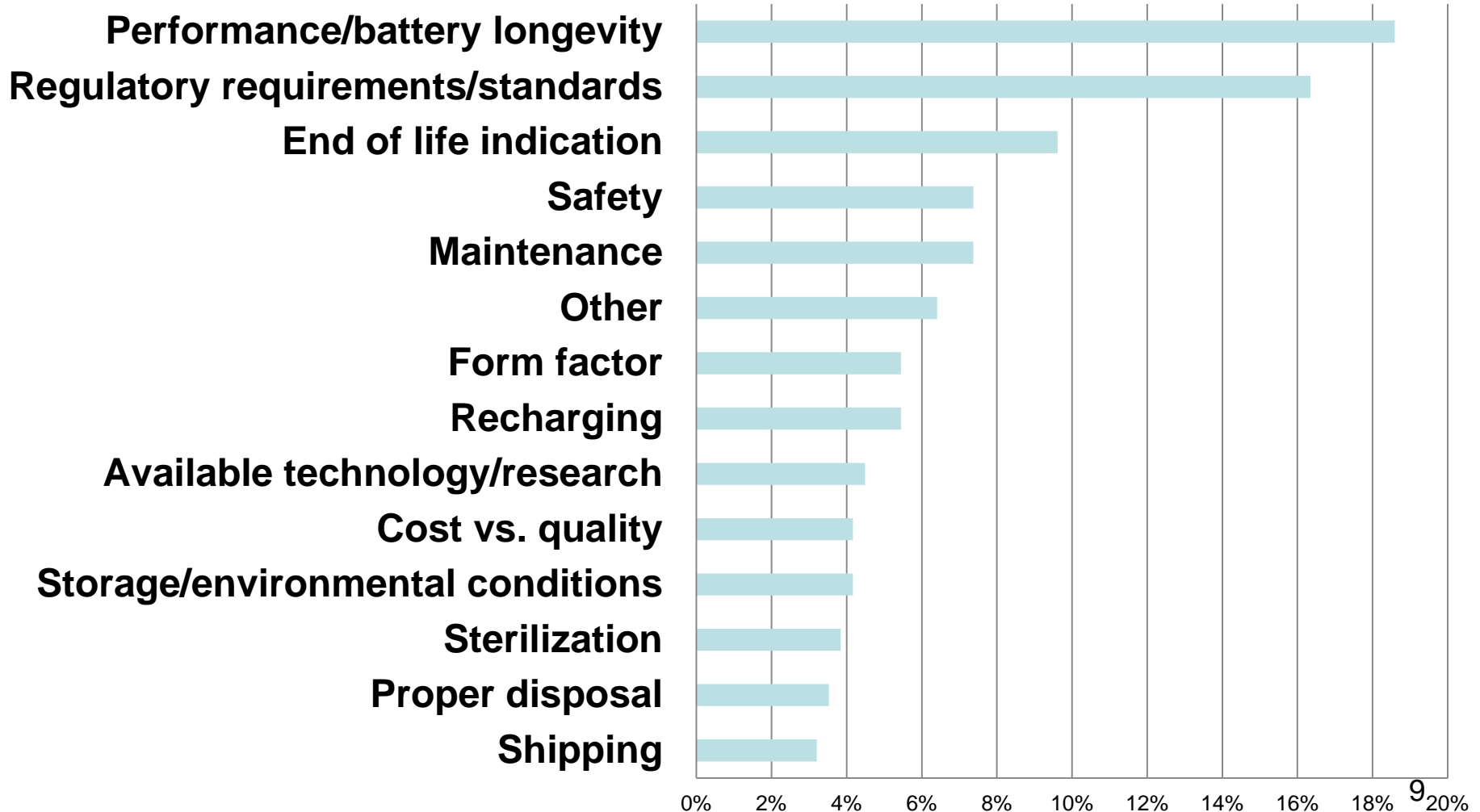


# What about medical devices?





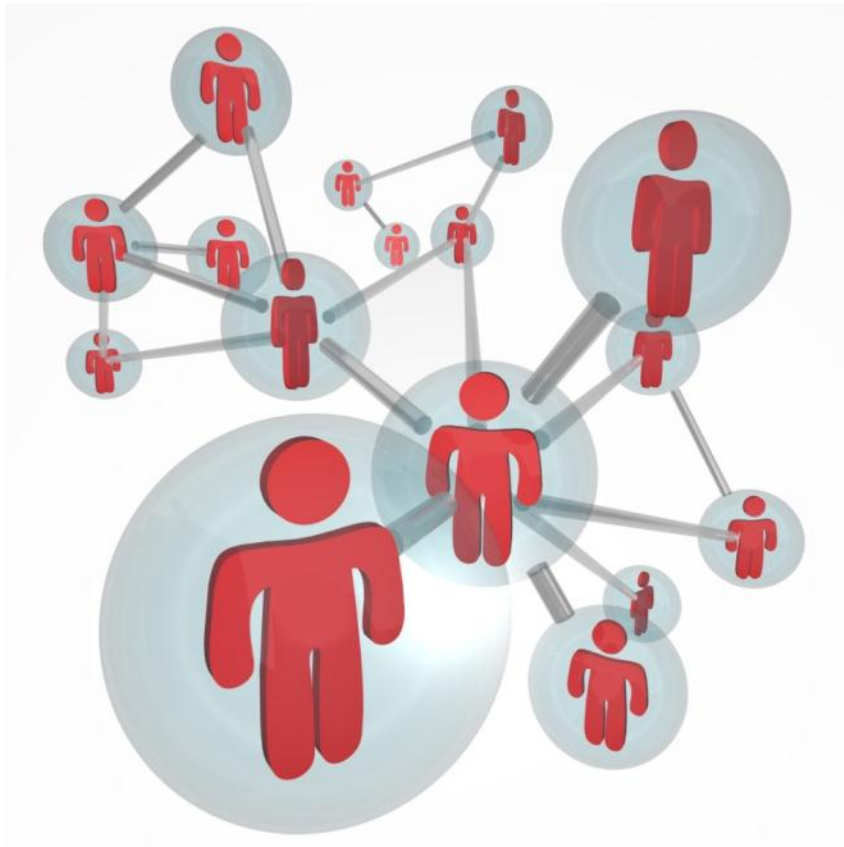
# Pre-Meeting Survey: Challenges



# What are some examples?



# What are the underlying challenges?



## Multiple

- Stakeholders
- Device Types
- Battery Types
- Issues
- Environments

# We have a choice...

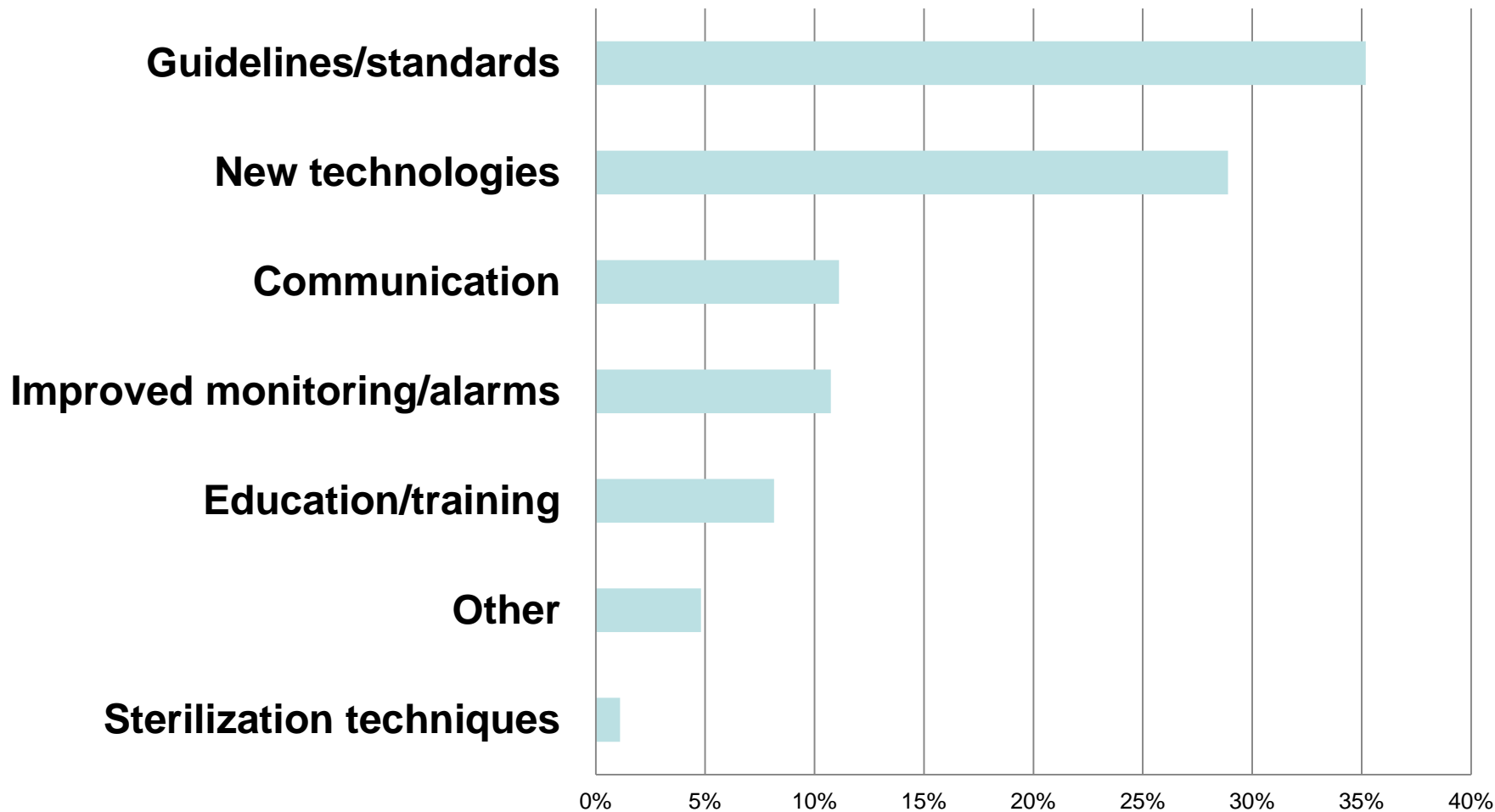


# What can FDA do?



- Train FDA staff
- Ask more questions
- Develop guidance
- Recognize standards
- Create new standards
- Clarify MDR process
- Alert public earlier
- Increase inspections

# Pre-Meeting Survey: Actions



# What can we do, together?



# What can we accomplish?



“Spirit of Cooperation”



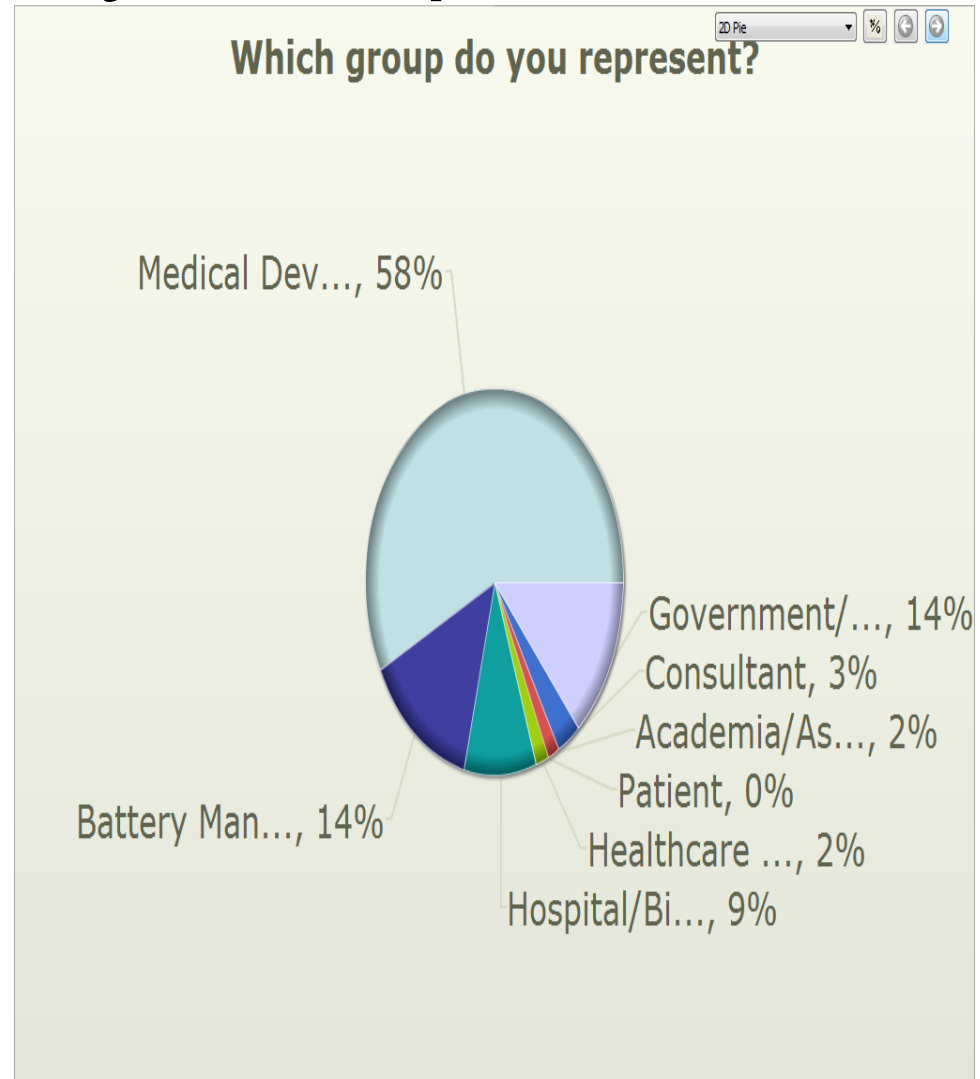


# How will we collaborate?

- Facilitated Breakout Sessions
- Turning Technologies
- Adobe Connect
- Email: [CDRHBatteries@fda.hhs.gov](mailto:CDRHBatteries@fda.hhs.gov)
- Public Comments: [Regulations.gov](https://www.regulations.gov)

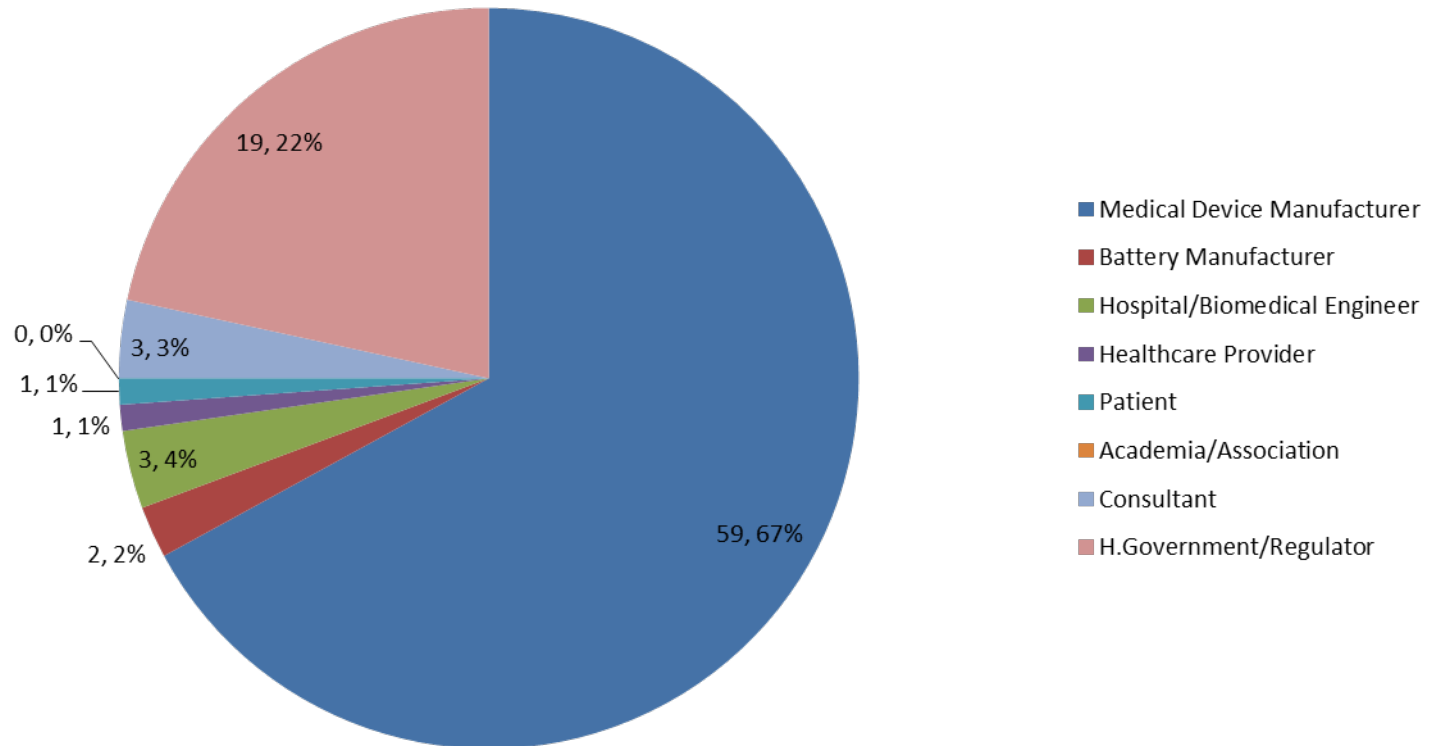
# Which group do you represent?

- A. Medical Device Manufacturer
- B. Battery Manufacturer
- C. Hospital/Biomedical Engineer
- D. Healthcare Provider
- E. Patient
- F. Academia/Association
- G. Consultant
- H. Government/Regulator



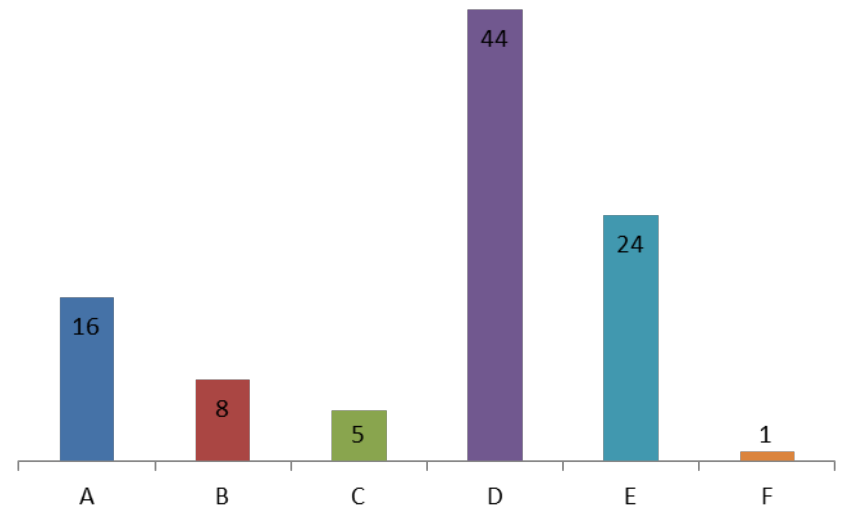
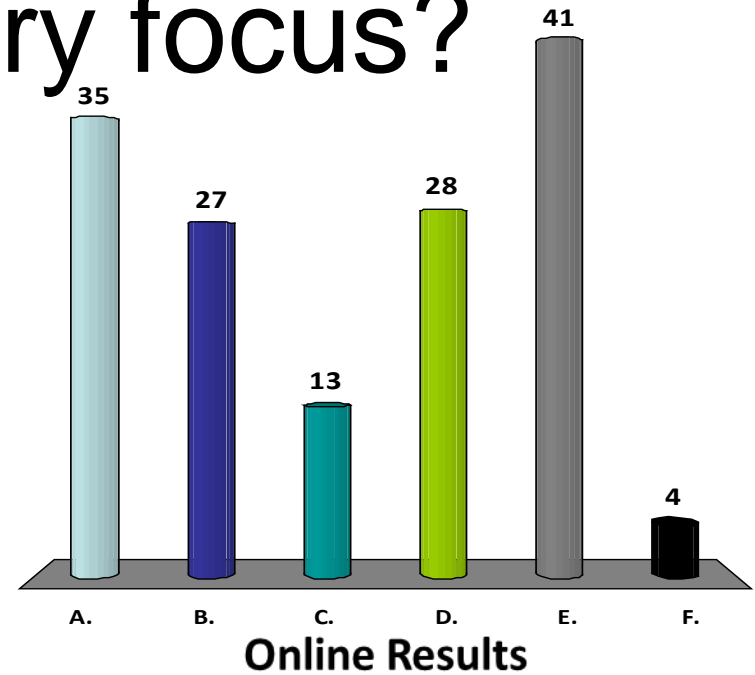


# Which group do you represent? Online results



# What is your primary focus?

- A. Optimize performance of BPMD
- B. Optimize performance of batteries
- C. Maintenance of BPMD & batteries
- D. Fulfill regulatory requirements
- E. Learn about topic in general
- F. Other





Thanks for  
your support

