

Battery-Powered Medical Devices Critical to Quality

CAPT Kimberly Lewandowski-Walker
National Expert, Medical Devices
FDA/ORA/OMPTO



Objectives

- Provide examples of battery-related challenges in medical devices
- Discuss FDA inspectional activities
- Introduce the Critical to Quality concept and Focus on Quality initiative within the Case for Quality

Associated Risks

- Batteries are used in many types of higher risk devices, including infusion pumps, pacemakers, and implantable cardioverter defibrillators.
- Risks associated with devices such as infusion pumps, pacemakers, pulse generators, and implantable cardioverter defibrillators include premature explant of the device and inability to deliver therapy (which can result in patient death).

Inspections

- Corrective and Preventive Actions
- Design controls
- Production and Process Controls
 - Purchasing controls
 - Acceptance activities
 - Handling
 - Storage

Quality Issues with Batteries

- Observed during inspections
 - Battery depletion
 - Battery leakage
 - High internal resistance

Background on Case for Quality

- The 2011 Understanding Barriers to Medical Device Quality report suggests that the FDA's regulatory framework is misaligned with assuring Quality outcomes.
- The report identifies 3 specific issues that Industry relates to the misalignment of the regulatory framework:
 - 1) over-emphasis on pure compliance versus quality outcomes,
 - 2) barriers to implementing safety related improvements, and
 - 3) lack of enforcement specificity on highest-risk areas within the medical device space.

Key points from the report

Industry priorities:

- Device design and development
- Post production feedback
- Supplier management

Industry perception of FDA priorities:

- Production and process controls

The report suggests that FDA rethink its interaction with industry in these areas.

2012 Activities: Stakeholder Feedback

- Manufacturer feedback:
 - FDA focuses purely on compliance – not device quality.
 - Variety of means to focus on quality, including defining what is Critical to Quality.
- Foreign official feedback:
 - Focus on what is Critical to Quality.
 - Prioritize audit findings based on criticality.
- Internal FDA feedback:
 - Chosen not to focus on quality – have compliance programs
 - Need more interaction with firms on quality

Onwards to 2013/2014

- What is this term, “Critical to Quality” we heard about?

“...the key output characteristic of a process. An example may be an element of a design or an attribute of a service that is critical in the eyes of the customer.”

- *Implementing Quality: A Practical Guide to Tools and Techniques*. By Ron Basu

“A CTQ is a product or service characteristic that must be met to satisfy a specification or requirement.”

- *Six Sigma Best Practices*. By Dhirendra Kumar

“Its purpose is to start with the high-level strategic goal of customer satisfaction and determine how this goal “flows down” into measureable goals.

- *The Certified Six Sigma Handbook*. By TM Kubiak and Donald W. Benbow

Critical to Quality

- Engage stakeholders to start discussions on....
 - What is critical to quality for medical device batteries?
 - How can batteries be designed and manufactured for better reliability?
 - How can medical device manufacturers engage their battery suppliers to better meet the needs of medical devices?

Plan for 2013/2014

Initiate pilot for “Critical to Quality”

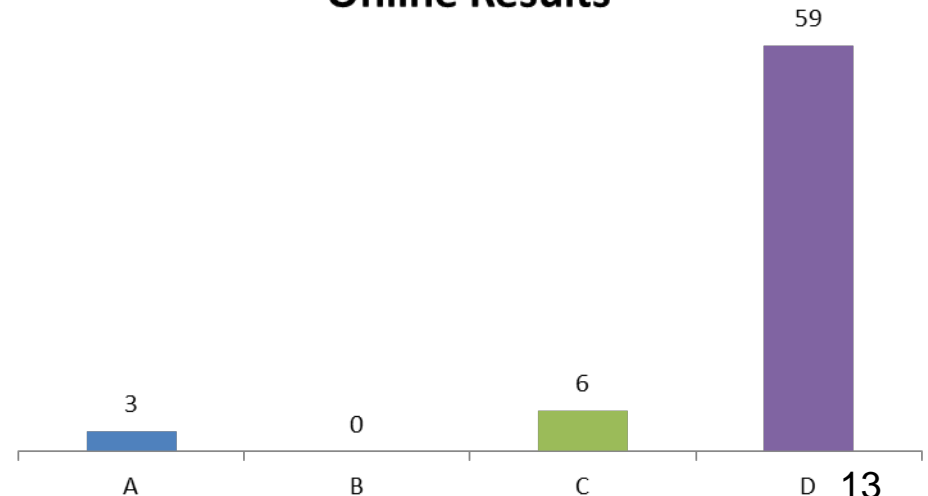
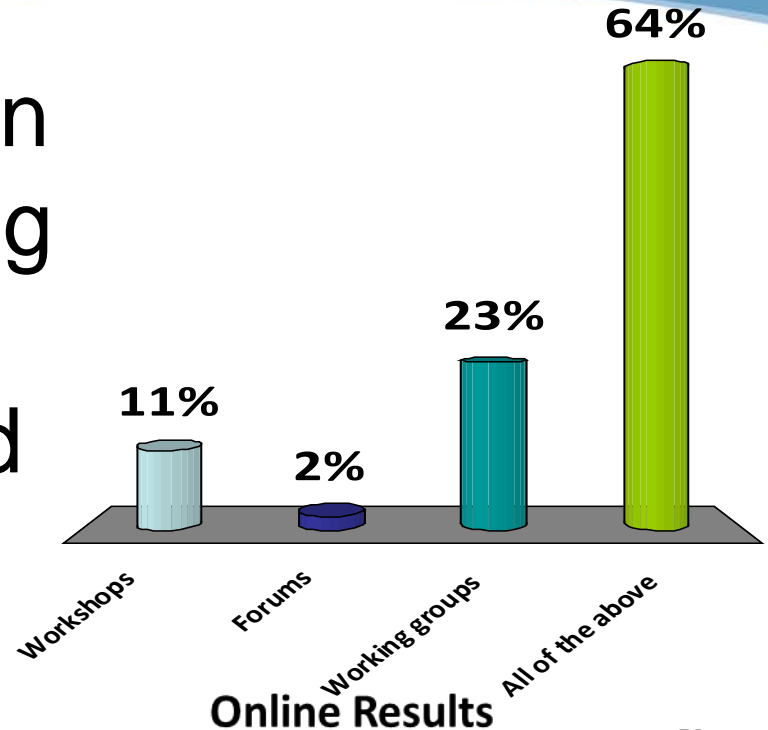
1. Generate CtQ inspectional guidance
 - Cross functional teams
 - Discussion of CtQ concept with industry
 - Initial concept: implantable battery-powered devices
2. Utilize risk-based inspectional allotment
3. Prep investigators with CtQ guidance
4. Prioritize feedback based on CtQ

Focus on Quality

- CtQ approach is just a start
- FDA envisions interaction with industry identifying other approaches to focus on quality

FDA envisions interaction with industry in identifying appropriate CtQ topics and content. How could this interaction best be performed?

- A. Workshops
- B. Forums
- C. Working groups
- D. All of the above





Thank You