MDICx Series

MDIC

Informative series of workshops featuring emerging trends in medical technology regulatory science, MDIC projects and subject matter experts sharing perspectives, progress and opportunities.

CDRH PMA Critical to Quality (CtQ) Pilot

Speakers:

- **Bleta Vuniqi, Quality System Specialist, CDRH Office of Compliance, Division of Manufacturing and Quality**
- **Roxane Modares, Reviewer, CDRH Cardiovascular Device Branch**

The last 15 minutes are reserved for Q&A. Please enter your questions for the panel through the chat feature on Zoom

PMA Critical to Quality (CtQ) Pilot
MDIC Webinar

FDA/CDRH/OC/Division of Manufacturing and Quality

-Bleta Vuniqi
-Roxane Modares
-William MacFarland
-Phillip Lafleur

Objectives

- Introduction:
  - Case for Quality and Critical to Quality Initiatives
- PMA Critical to Quality (CtQ) Pilot Structure
- Concepts and Definitions
- Examples
- Q/A

Case for Quality

Why

Risk to patients from quality issues and hampered innovation in manufacturing and product development practices

- No stakeholder engagement across the medical device ecosystem
- High industry focus on meeting regulatory requirements versus adopting best quality practices
- No competitive market around medical device quality

What

Collaborative effort that focuses on organizational excellence and product quality

- New ways to assess organizational performance, focusing on quality, shifting from inspection
- Adapt regulatory oversight to increase agility, responsiveness, simplification, error-proofing, and enable continuous rapid improvement
- Drive connections within systems, increase visibility into product quality to enable market drivers

Introduction

- 2011 – The FDA launched the Critical for Quality Initiative
  - CDRH published a in-depth report, "Understanding Barriers to Medical Device Quality," which provides an in-depth look at challenges industry and the FDA face in implementing well-integrated, best-quality manufacturing practices.
    - In simple terms, the review identified that an investment in quality has long-term payoffs.
- 2013 – The FDA initiated the “Implantable Devices that Contain Batteries Critical to Quality Inspection Pilot”
  - Feedback received: inspection efficiency, resource utilization, open dialogue, engagement, transparency, and overall device quality.
- 2014 – The FDA decided to draft “More CtQs”
  - FDA and AdvaMed drafted 13 “Technical Documents” including the PMA CtQ document.

Case for Quality Pilot Programs

- Voluntary Medical Device Manufacturing and Product Quality Pilot Program
- Premarket Approval (PMA) Critical-to-Quality Pilot Program

A company may volunteer and participate on both pilot programs

PMA CtQ Pilot

- PMA CtQ pilot program is voluntary
- The program aims to promote quality in device manufacturing, evaluate device design and manufacturing process quality information early on to assist FDA in its review of the PMA manufacturing section and postmarket inspections.
- It is a joint effort between the FDA's Center for Devices and Radiological Health (CDRH) and Office of Regulatory Affairs (ORA).

PMA CtQ Pilot

- Based on six sigma principle of ensuring awareness of critical features and controls.
- Build on lessons learned from implantable devices with batteries Pilot.

  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM469128.pdf
- CtQ Pilot would allow enrollment of 9 PMAs that meet the enrollment criteria.
- This pilot program is scheduled to run from September 29, 2017, to December 31, 2018.

PMA CtQ Pilot

- Process starts with a Pre-PMA Q-submission

  FDA Guidance for Industry and FDA Staff "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf

- The applicant must meet the participation criteria including defining critical features and controls in PMA submission
  - FDA checks the CtQ information for clarity, completeness, and relevance

PMA CtQ Pilot

- CDRH and ORA can use this information to prioritize time spent in
  - Manufacturing section review
  - PMA site inspections
    - In lieu of preapproval inspections, conducting postmarket inspections
- CDRH OC/OIR provides a postmarket inspectional assignment to the investigator and makes necessary technical expertise available to the ORA.
  - The critical characteristics and controls will help guide the investigator and streamline their activities during the postmarket inspection.

PMA CtQ Pilot

- Federal Register Notice

  https://www.federalregister.gov/documents/2017/09/12/2017-19258/center-for-devices-and-radiological-health-premarket-approval-application-critical-to-quality-pilot

Concepts and Definitions

- The feedback received shows that there appears to be a misconception regarding the CtQ concept and essential design output or critical characteristic.
  - Clarify CtQ concept and other key definitions
  - Examples

Critical to Quality

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

“…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

Concepts and Definitions

- Critical Characteristic
  - **Six Sigma:** product characteristics or product features that are comprehensively defined by both the internal as well as the external customers.
  - **FDA - Where we are today:** features and characteristics of the device most likely to impact its safety and effectiveness
    - Aspects of the device that fulfill the user's needs

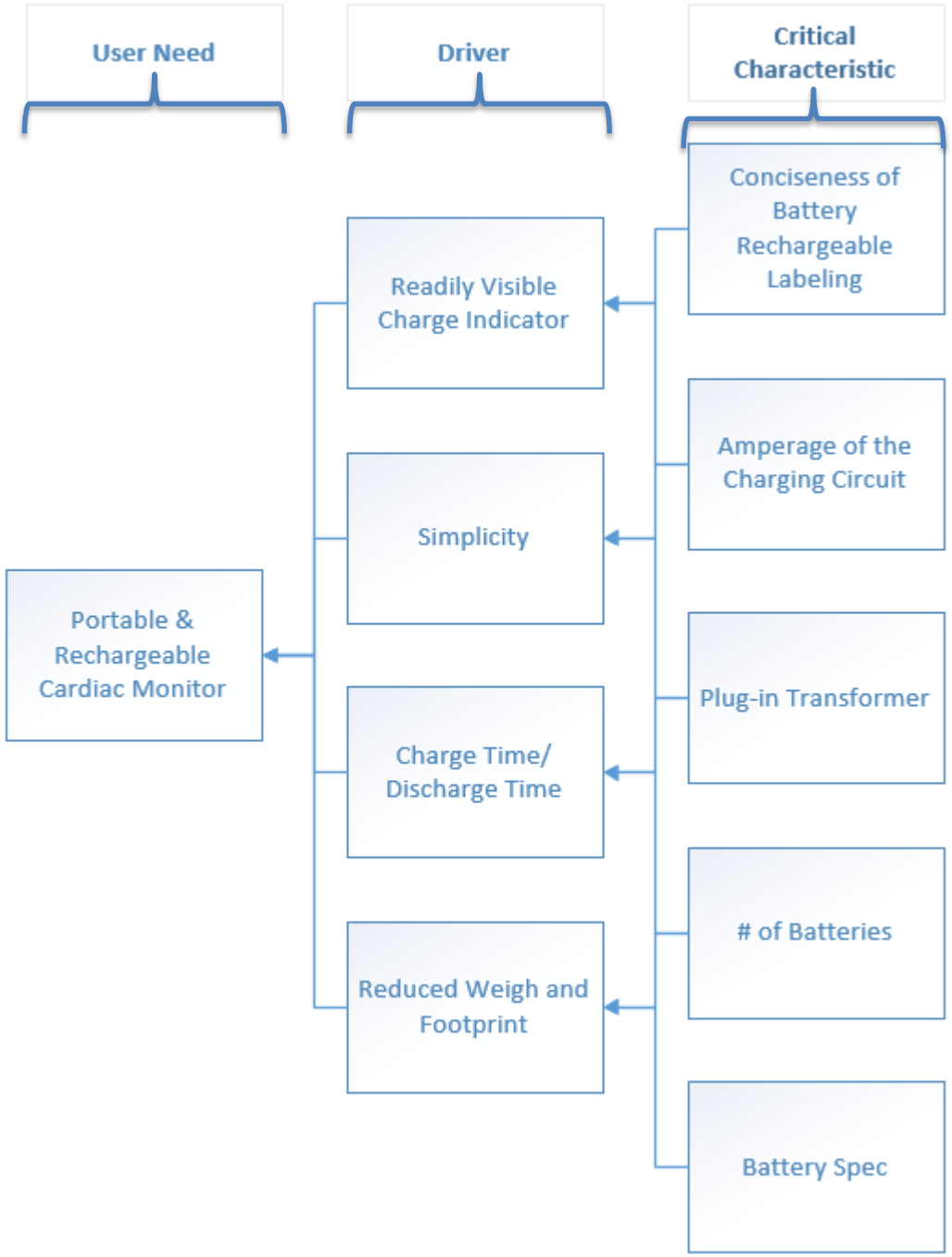
CtQ other definitions

- Design Output
  - Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record. (21 CFR 820.3(g))
- Essential Design Output
  - Design output that are essential for the proper functioning of the device

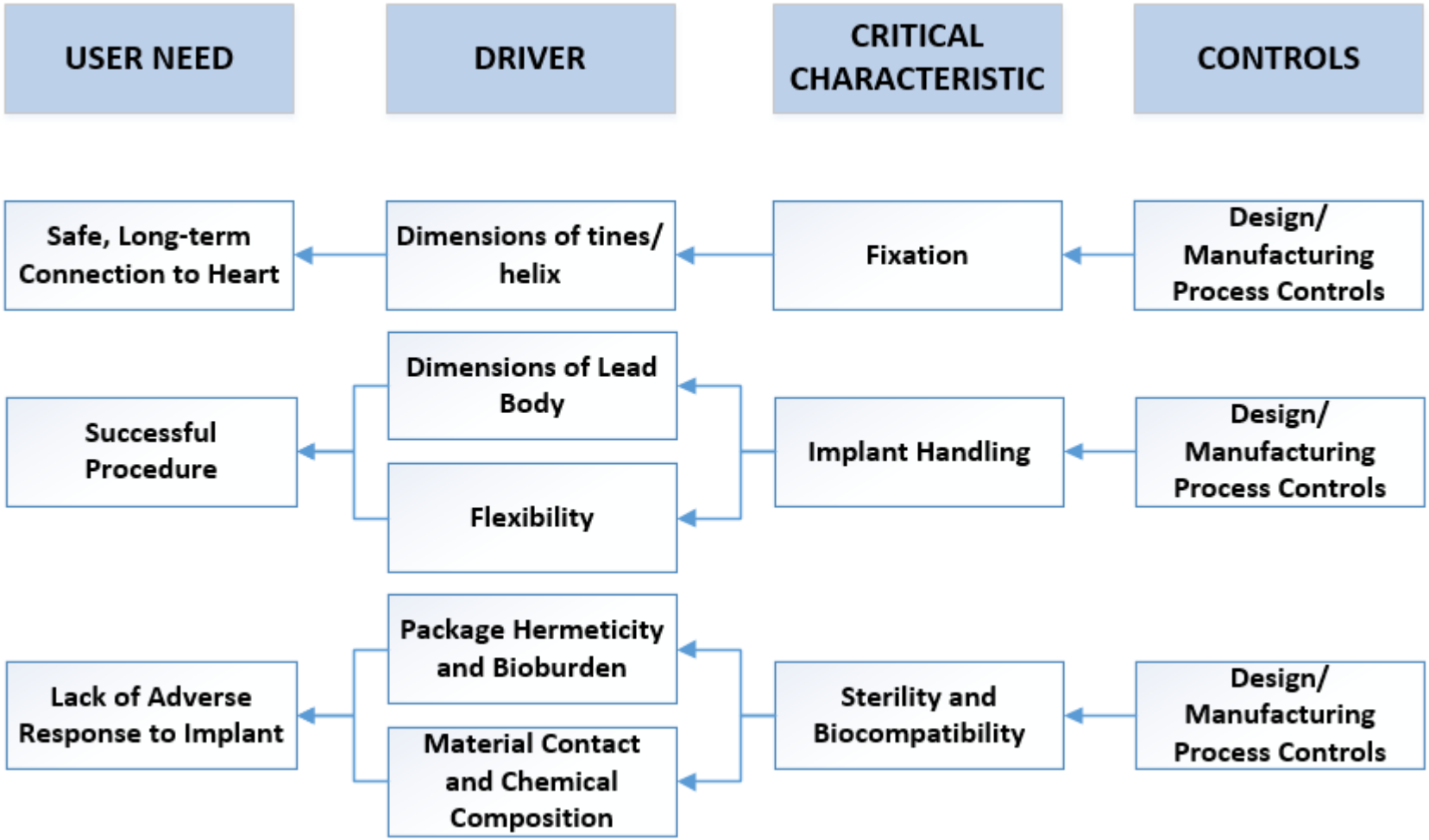
FDA's Approach to CtQ

- An individual CtQ is a control that ensures that a critical feature/characteristic is consistently achieved in order for the device to be safe and effective

Six Sigma "CtQ tree"



FDA Approach to CtQ - Defibrillation Leads - EXAMPLE



Surgical Mesh - Example

Critical Product Characteristic – (CtQ)

- Mesh thickness, mesh weave characteristics, pore size, mesh density, tensile strength, device stiffness, suture pull-out strength, burst strength and tear resistance.
  - Inadequate control of these critical product characteristics can lead to adverse events and failures of the device that include physical degradation of the mesh, migration, erosion, and granulomas.
    - *Identify these product characteristics during the design stage along with the acceptance criteria. [21 CFR 820.30(d)]*
    - *Perform acceptance activities to ensure that acceptance criteria for these critical product characteristics are being met. [21 CFR 820.80]*

Format – Example

Critical to Quality Information, EXAMPLE				
#	Key Critical Characteristic	Importance (User Need)	Impact of Failure (Driver)	Control Information
				Identify the controls in device design features design and quality manufacturing control practices.

Summary

- PMA CtQ pilot program is voluntary
  https://www.federalregister.gov/documents/2017/09/12/2017-19258/center-for-devices-and-radiological-health-premarket-approval-application-critical-to-quality-pilot
- Pilot would allow enrollment of 9 PMAs that meet the enrollment criteria including defining critical features and controls in PMA submission
- A company can voluntarily enroll in the Voluntary Medical Device Manufacturing and Product Quality Pilot Program and Premarket Approval (PMA) Critical-to-Quality Pilot Program
- This pilot program is scheduled to run from September 29, 2017, to December 31, 2018.
- Process starts with a Pre-PMA Q-submission
  https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf

QUESTIONS?

EMAIL: CTQ@FDA.HHS.GOV

Questions and Discussion

Submit your questions via the Chat Box

Next MDICx webinar August 15