The 12 Days of Device Quality

MedCon
Xavier University
Cincinnati, Ohio
May 6, 2015

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FDA/CDRH/Office of Compliance

On the First Day of Device Quality the FDA Gave to Me….

CDRH Office of Compliance Director Vacancy Announcement

- Closing on May 22, 2015
- https://www.usajobs.gov/GetJob/ViewDetails/384650100

On the Second Day of Device Quality the FDA Gave to Me...

Important Public Meetings

- April 21, 2015

  Interactive Discussion on the Clinical Considerations of Risk in the Post market Environment

  http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm436365.htm

- May 14-15, 2015

  Gastroenterology and Urology Devices Panel

  Committee will discuss recent reports and epidemiologic investigations of transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals in the United States.

  http://www.fda.gov/advisorycommittees/calendar/ucm437500.htm

On the Third Day of Device Quality the FDA Gave to Me…

CDRH 2015 Strategic Priorities

- Strengthen the Clinical Trial Enterprise
- Strike the Right Balance Between Premarket and Postmarket Data Collection
- Provide Excellent Customer Service

On the Fourth Day of Device Quality the FDA Gave to Me…

Benefit Risk Framework Subgroups

Benefit Risk Framework- Overview

- Development of broad principles by FDA and stakeholders for the purpose of weighing benefits vs. risks with respect to access to medical devices
- To optimize access to medical devices of public health importance
- To allow FDA and industry to arrive at same benefit/risk determinations to promote rapid assessment of and response to device safety and quality issues
  - Recalls
  - Shortages
- Facilitated by AAMI

Benefit Risk Framework- Plan

- Scope limited to Post Market Risk Management
  - Quality (Shortage Assessment)
  - Safety (Recalls)
- Draft White Paper (Comment until May 20th)
  - "Post-Market Risk Management of Medical Devices"
  - http://www.aami.org/productspublications/pressreleasedetail.aspx?ItemNumber=1786
- FDA Public Workshop held April 21st
- Four Subgroups to meet on hot items

Four Subgroups for Benefit Risk Framework

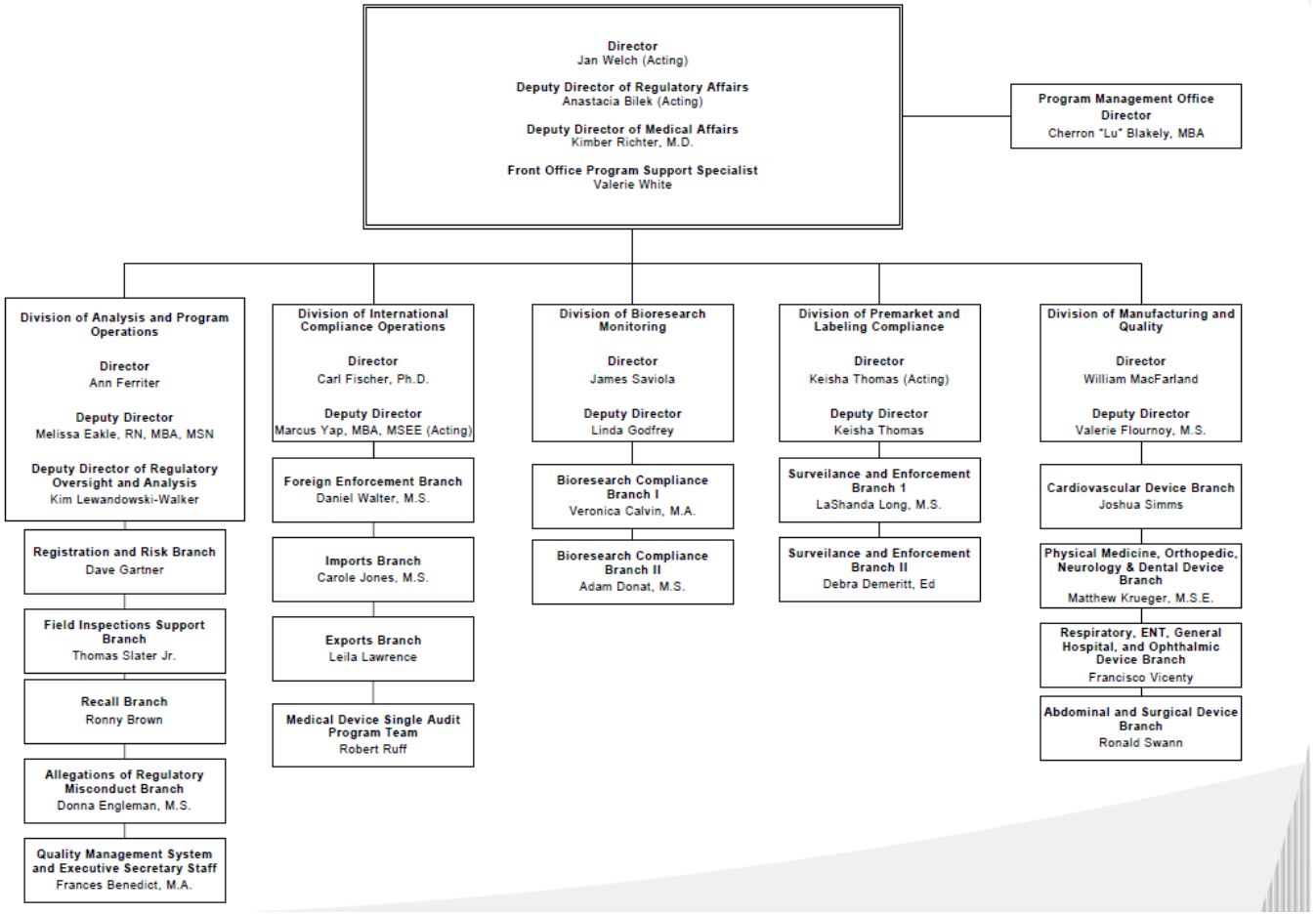
- HHE Processes, Threshold for Class III/II and Class II/I Recalls
- Recall Classification Policies
- Threshold for Recall - When would FDA take action?
- Guidance on Compliance Benefit/Risk

On the Fifth Day of Device Quality the FDA Gave to Me…

Divisions in CDRH's

Office of Compliance

OC – Organizational Structure



Division of Manufacturing and Quality (DMQ)

- Lead on device quality policy
- Reviews premarket approval application manufacturing sections, site change supplements, signals and complaints related to product quality
- Leads domestic activities related to device quality and safety

Division of Premarket and Labeling Compliance (DPLC)

- Explains premarket clearance and approval requirements
- Ensures labeling and promotion and advertising requirements are met for medical devices
- Engages in surveillance of industry practices
- Responds to urgent or high-priority public health concerns, such as fraudulent devices marketed during a pandemic

Division of International Compliance Operations (DICO)

- Assessment of foreign device manufacturers and importers
- Oversight of international audit program, compliance policy, and guidance development
- Responsible for export operations and policy
- Stakeholder communication and outreach

Division of Bioresearch Monitoring (DBM)

- Provides regulatory oversight of medical device clinical investigations, nonclinical good laboratory practice, and institutional review boards in support of the premarket review program
- Coordinates and reviews monitoring inspections of regulated parties and takes necessary action when appropriate
- Investigates and coordinates allegations of research misconduct

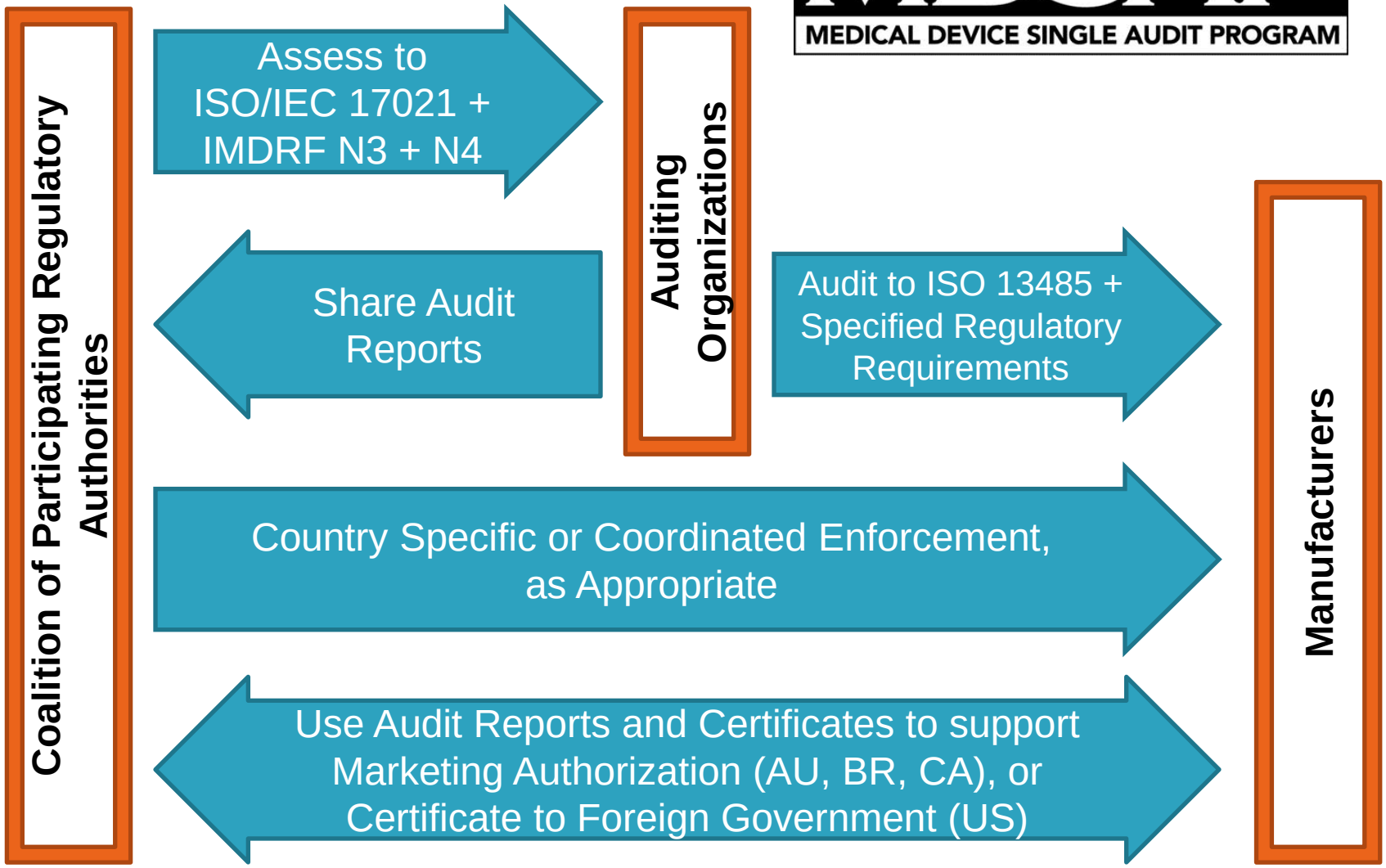
Division of Analysis and Program Operations (DAPO)

- Analyzes data, develops policy, drafts processes, and collaborates with FDA's Office of Regulatory Affairs (ORA) on inspection planning and assignments
- Responsible for establishment registration and listing program as well as the medical device tracking program
- Supports recall processing and establishment inspection reviews

On the Sixth Day of Device Quality the FDA Gave to Me…

Auditing Organizations (AOs) That Can Conduct MDSAP Audits

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

- Operational launch of the pilot on January 1, 2014
- 4 Participating Regulatory Authorities
  - Australia, Brazil, Canada, USA
  - 2 Observers (Japan, WHO)
- 6 Auditing Organizations ready to conduct MDSAP audits, out of 14 potential candidates
- 6 MDSAP audits witnessed by Regulatory Authority assessors (by end of May)
- Pilot to end on December 31, 2016
- Proof of Concept review

On the Seventh Day of Device Quality the FDA Gave to Me…

Program Alignment Workstreams

Specialization

- Establish device cadres – investigator cadre and compliance cadre
- ORA Medical Device Program Director
- Identify competency requirements
- Staffing and resource evaluation and transition

Training

- Develop training curriculum
- Harmonize training across individuals that perform inspectional and compliance activities for medical devices
- Novel training approaches, first in class
  - Opportunities for industry

Workplanning

- Multi-year outlook on future priorities and activities that allow FDA to adjust resources to meet future medical device program needs
  - Fine tuning site selection
  - Optimizing risk-based information
  - Planning for resources to support innovation, quality initiatives

Quality Policy and Strategy

- Improve access to high quality, innovative, safe and effective medical devices, which meet or exceed regulatory requirements
- Effectively communicated policies and strategies
  - New strategies and emphasis
- Improve consistency
- Streamline compliance activities

Imports

- Improve the execution of current import screening strategies
- Strategies for assessing device quality at the point of entry

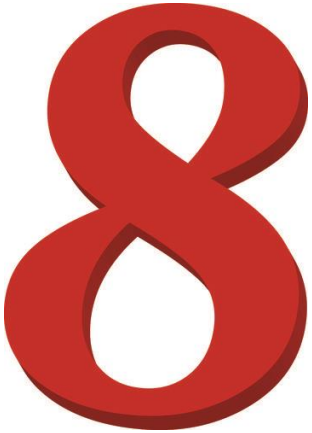
Lab Optimization

- integrate lab work planning and execution and program alignment goals
- Analyze current lab optimization plan and work to assess the need for further lab specialization

IT Development/Support

- Information exchange, visibility
- Sharing in requirements development

On the Eighth Day of Device Quality the FDA Gave to Me…



Case for Quality

High Priority Projects

Current High Priority Projects

CATEGORY / IN SCOPE	PROJECTS	STATUS	MILESTONES DATES	DELIVERABLE DATES	ISSUES	COMMENTS
I FoQ	Critical to Quality: Battery Pilot **Lead: Bill McFarland**		01/27/2015	12/15/2015		4 inspections completed; interviews with investigators and firms completed; analyzing data and drafting a summary by March 31, 2015.
II FoQ/DT/SE	Device Quality Measures Workgroup / Projects **Lead: Kristin McNamara**		01/27/2015	12/15/2015		Joint FDA-industry project, facilitated by Xavier, to identify measures of "Best" and "Good" activities (above compliance baseline level) within critical systems across TPLC by surveying firms, to be shared with and vetted through the broader MDIC stakeholder forum
I FoQ	ASQ Training **Lead: Kim Lewandowski-Walker**		01/27/2015	12/15/2015		FDA is considering whether ASQ has training material that would benefit FDA staff . FDA will also evaluate ASQ material to see whether a device "quality" and "compliance" course could be established. Kim Lewandowski-Walker is leading this effort.
III FoQ/DT/SE	MDIC Maturity Model R&D **Lead: Jan Welch**		01/27/2015	12/15/2015		Contract with MDIC in effect. MDIC CfQ Steering Committee selected Deloitte to conduct maturity model research. Literature search/research complete. Report out made to MDIC CfQ Steering Committee
III FoQ	Library of Quality Practices **Lead: Kim Lewandowski-Walker**		01/27/2015	12/15/2015		Team has proposed scope of this project but the 2015 deliverable and time frame is not defined. Need to revise scope/deliverable and meet with Steering Committee by March 1. Kim Lewandowski-Walker is evaluating ASQ material for potential inclusion in the Library of Successful Practices.
II DT	Device Purchasing Needs Assessment **Lead: Ann Ferriter**		01/27/2015	12/15/2015		Led by the Data Transparency efforts - Ongoing activity with purchasers and hospitals to understand the cost, value, and the quality needs in the market. Surveyed MedSun, Group purchasing organizations and AHA. Kim Lewandowski-Walker is finishing the analysis and write up.
II DT	CDRH Transparency **Lead: Ann Ferriter**		01/27/2015	12/15/2015		Published recall report in spring 2014. Released Recall and MDR APIs. R&L and device classification APIs are in process for 2015 release. 6 additional datasets have been identified for release. Cross CDRH team is working on training, documentation and testing.
	PMA Review **Lead: Bill McFarland**					

On the Ninth Day of Device Quality the FDA Gave to Me…

CDRH Office of Compliance Public Health Service Officers Deployed in Support of Ebola Efforts

Ebola Deployments

- 9 US Public Health Service officers from OC
- Monrovia, Liberia; Conakry, Guinea; Metro DC
- October 19, 2014- May 31, 2015
- An officer's perspective
  - Deployed for 54 days, during which 18 patients were seen with a 50% mortality rate, worked 16 hour days
  - Extensive training and expertise
- Recognized by President of Liberia, US Ambassador to Liberia and President Obama

On the Tenth Day of Device Quality the FDA Gave to Me...

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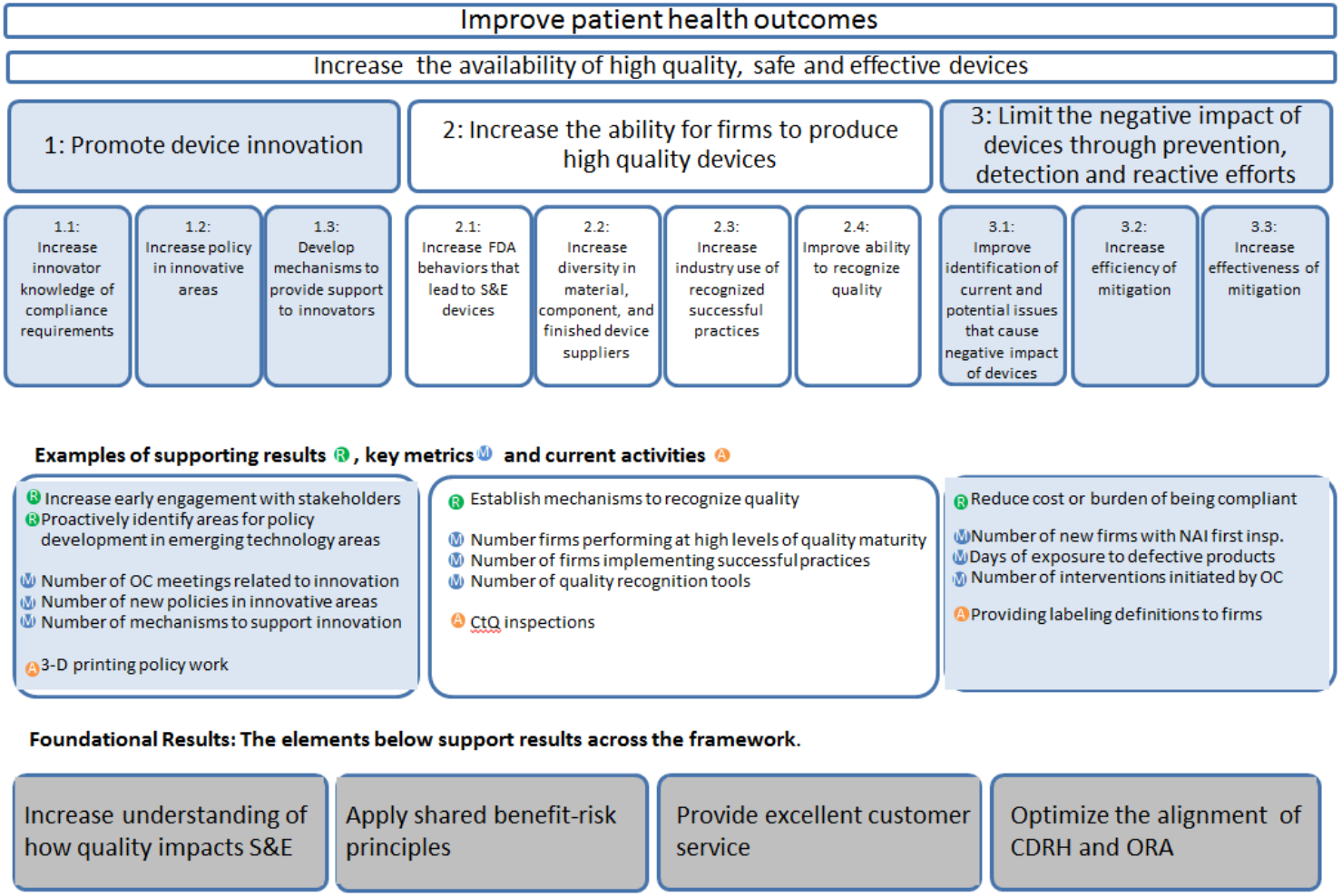
Office of Compliance Strategic Framework Elements

OC Strategic Framework Elements



On the Eleventh Day of Device Quality the FDA Gave to Me…

A year ago –

Foreign FDA Posts

FDA Foreign Posts

China	Europe	Latin America	South America	Africa	Middle East	India
Beijing	Brussels	Mexico City	Santiago	Pretoria	Amman	Delhi
Shanghai	London	San Jose, CR				Mumbai
Guangzhou	Parma					

On the Twelfth Day of Device Quality the FDA Gave to Me…

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Critical to Quality (CtQs) documents [2014]

12 CtQ Info Documents in 2014

CtQ Information Document	FDA Purpose?	Who was involved?
Implantable Devices with Batteries	FDA Pilot	CDRH WG, Battery Suppliers, OEMs
Implantable cervical disc	PMA post-approval	ODE/ASDB
Semi-constrained knee implants	RBWP	ODE/JFDB1
Abdominal surgical mesh	RBWP and 4 PMAs	ODE/GSDB1, ULDB, GEDB, RNDB and OGDB
Implantable cardioverter defibrillators	Routine inspections	ODE/IEDB, AdvaMed WG
Defibrillator leads	Routine inspections	ODE/IEDB, AdvaMed WG
Neuro-embolization devices	Routine inspections	ODE/NNDB, AdvaMed WG
Infusion pumps	Routine inspections	ODE/GHDB, AdvaMed WG
Ventilators	Routine inspections	ODE/RDB, AdvaMed WG

A Typical CtQ Indicator

Key characteristic → Sphericity and surface finish of the endplates are two key characteristics, because nonconformity of either one of these key characteristics can lead to excessive wear, which can ultimately lead to pain, metal debris inside the end-user's body, and need for revision surgery.

Impact of failure →

A. Sphericity is primarily an output of the CNC Turning, CNC Milling, and Deburring processes and verified through the Dimensional Inspection Process [21 CFR 820.80] [QSIT P&PC Objective #2]

Control →

Reference to 820 →

← Reference to QSIT

CtQ Inspection Pilot - Plan

- Use inspectional guidance to promote engagement on quality – inspectional pilot
  - "CtQs" generated via:
    - Internal CDRH and ORA experts
    - Technical stakeholder input
  - CtQs written into inspectional guidance
    - Shared with investigators
    - Shared with firms being inspected
  - 4 inspections completed in 2014

CtQ Inspection Pilot Feedback

Investigator Feedback:

- More upfront preparation work than normal
- Looked at documents they normally would not have seen
- Better understanding of the risk to patient if a failure occurred

Firm Feedback:

- Helped to have CtQ indicators ahead of time
- Drives quality before inspection, instead of after
- Engages both sides of the inspection more
- Drives quality before inspection, instead of after
- Helped increase firm’s confidence in their batteries

Let's Review! Sing Along!

On the 12th Day of Device Quality the FDA Gave to Me…….

12 CtQs [2014]
11 Foreign FDA Posts [a year ago]
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9 OC PHS Officers Deployed to support Ebola efforts
8 Case for Quality High Priority Projects
7 PAG Workstreams
6 AOs That Can Conduct MDSAP Audits
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2 Important Public Meetings
1 OC Director Vacancy