FDA News 13th Annual Medical Device Quality Congress

Quality Metrics for Devices: Update on the Device Quality Measures Project

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Why FDA Launched Case For Quality?

- FDA found:
  - Repetitive quality issues among device manufacturers
  - Stagnant data regarding the quality issues

- Response:
  - FDA engaged McKinsey to analyze device quality issues. Findings published in the 2011 “Understanding Barriers to Quality” white paper
  - FDA Developed Case for Quality Forums
  - September 2014 FDA awarded contract to MDIC for CfQ project
  - MDIC: the first public-private partnership created with the sole objective of advancing medical device regulatory science.
  - Since 2014 MDIC has driven creation of models, methods and metrics to enable a new culture of quality across medical device ecosystem.

What Culture Change Looks Like

Reflecting its shared commitment with industry, the FDA made Case for Quality a strategic priority for 2016-2017.

- The FDA and medical technology companies, healthcare providers and other stakeholders should collaborate to inspire adoption of **quality practices** that, when present in **device design and production**, enhance patient safety and access to high quality medical devices.

- Elevate and shift the device sector focus from regulatory compliance to a state of **sustained product quality**.

- Create **continuous engagement** with a broad set of stakeholders to advance device product quality.

CDRH 2016/2017 Priorities

GOAL: STRENGTHEN PRODUCT AND MANUFACTURING QUALITY WITHIN THE MEDICAL DEVICE ECOSYSTEM

- By September 30, 2016 develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements

- By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.

- By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.

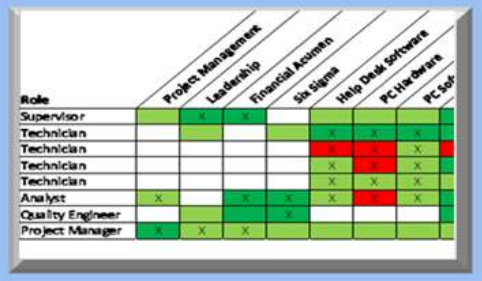
Case For Quality

Four Working Groups are building the Foundation

Device Quality Metrics

Maturity Model

Competency



Advanced Analytics

Focus of the Working Groups

- **Maturity Model**: Enable an organization to assess the capability of its quality system to reliably develop and manufacture high quality medical devices.
- **Advanced analytics**: Offer hospital providers information and analysis techniques to evaluate medical device quality and subsequent patient value.
- **Metrics**: Create well-defined, stakeholder-verified (FDA and industry) product quality metrics to predictively assess product quality.
- **Competencies**: Construct techniques that improve quality system competency and awareness among key stakeholders.

Device Quality Measures Project

Charge: to identify and/or develop predictive internal measures of product quality

- Submit to FDA and Medical Device Innovators Consortium (MDIC)
- Include assessment across three phases of production
- Potential to yield aggregated metrics to help FDA allocate resources based on risk

Participation:

- Championed by FDA
- Facilitated by Xavier University
- Conducted by Work Group members from 15 firms

Potential Model of Alignment with Case for Quality Framework

AdvaMed Successful Practices

FDA/Xavier MDIC Metrics

MDIC Maturity Model

MDIC Competency

MDIC Advanced Analytics

Could be used for

Risk-Based Resource Allocation Decisions

MDIC Metrics Project: Goals

Purpose:

To support the Case for Quality by increasing the assurance of product quality

Goals:

1. Identify, pilot, plan how to implement, and publicize predictive product quality system metrics
2. Improve assessment of the evolving state of product quality
3. Enable risk-based resource allocation decisions
4. Provide Payor visibility to product quality risk

MDIC Metrics Project: Purpose and Outcome

Purpose:

To provide a system of metrics across the Total Product Lifecycle that enables companies to assess and improve the robustness of their critical-to-quality practices, and therefore, risk to product quality.

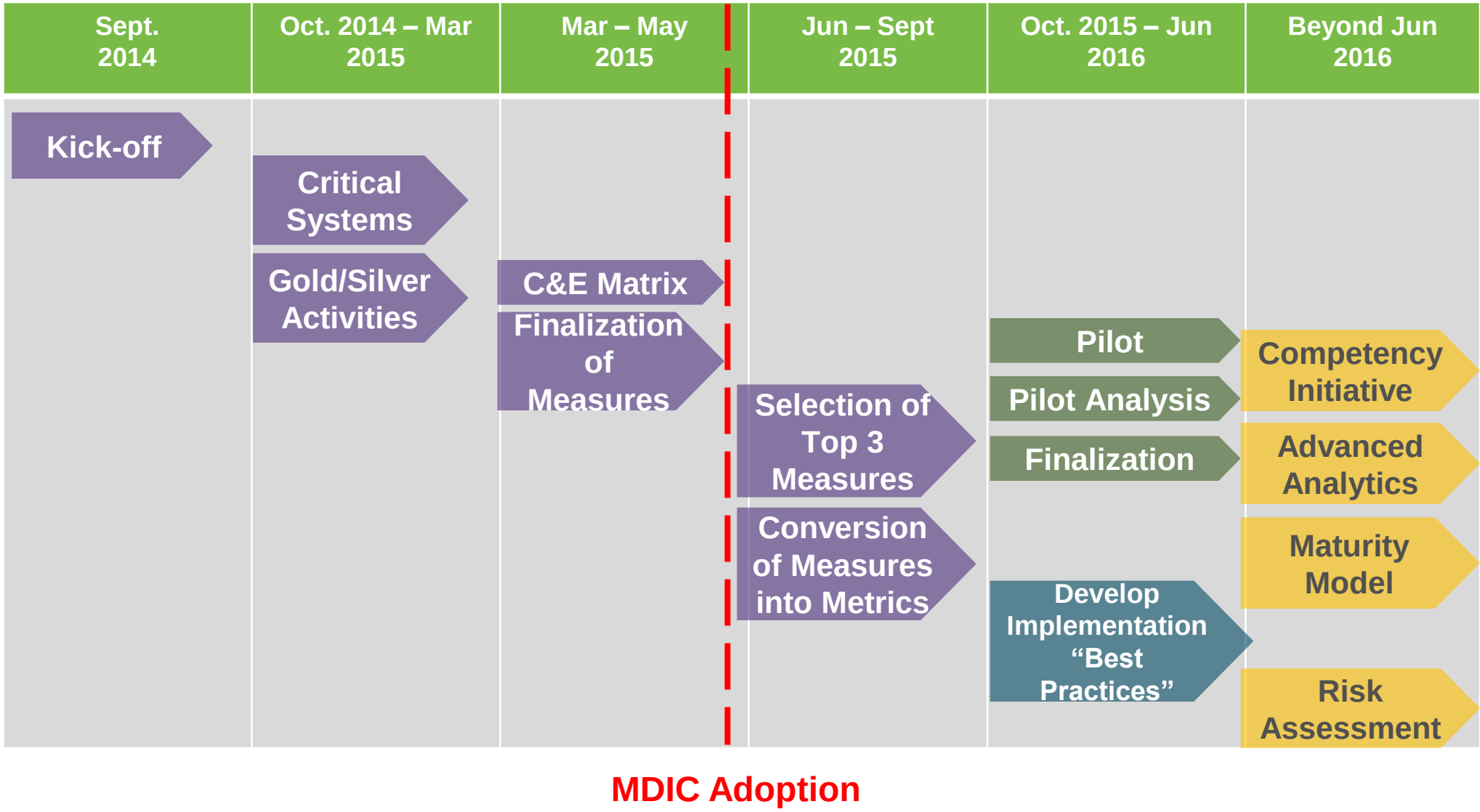
Outcome:

Identification of quality system metrics that will inform decisions and trigger action in a way that shifts the Right-First-Time mentality closer to the initial days of development.

How:

Diverse team of industry professionals and FDA officials through a rigorous methodical process with outcomes linked to patient safety, design robustness, process reliability, quality system robustness, and failure costs.

Timeline and Process



Team Members

Steering Committee			
Kathie Bardwell Steris	Gina Brackett FDA	Kristin McNamara FDA	Steve Niedelman King & Spalding
Marla Phillips Xavier University	Monica Wilkins Abbott		
Pre-Production Team			
Pat Baird Baxter Healthcare	Rafael Bonilla Scott Care	Tom Haueter Clinical Innovations	Pete Palermo CR Bard
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Bryan Knecht AtriCure	Brian Motter J&J MD&D	Rhonda Mecl FDA	
Post-Production Team			
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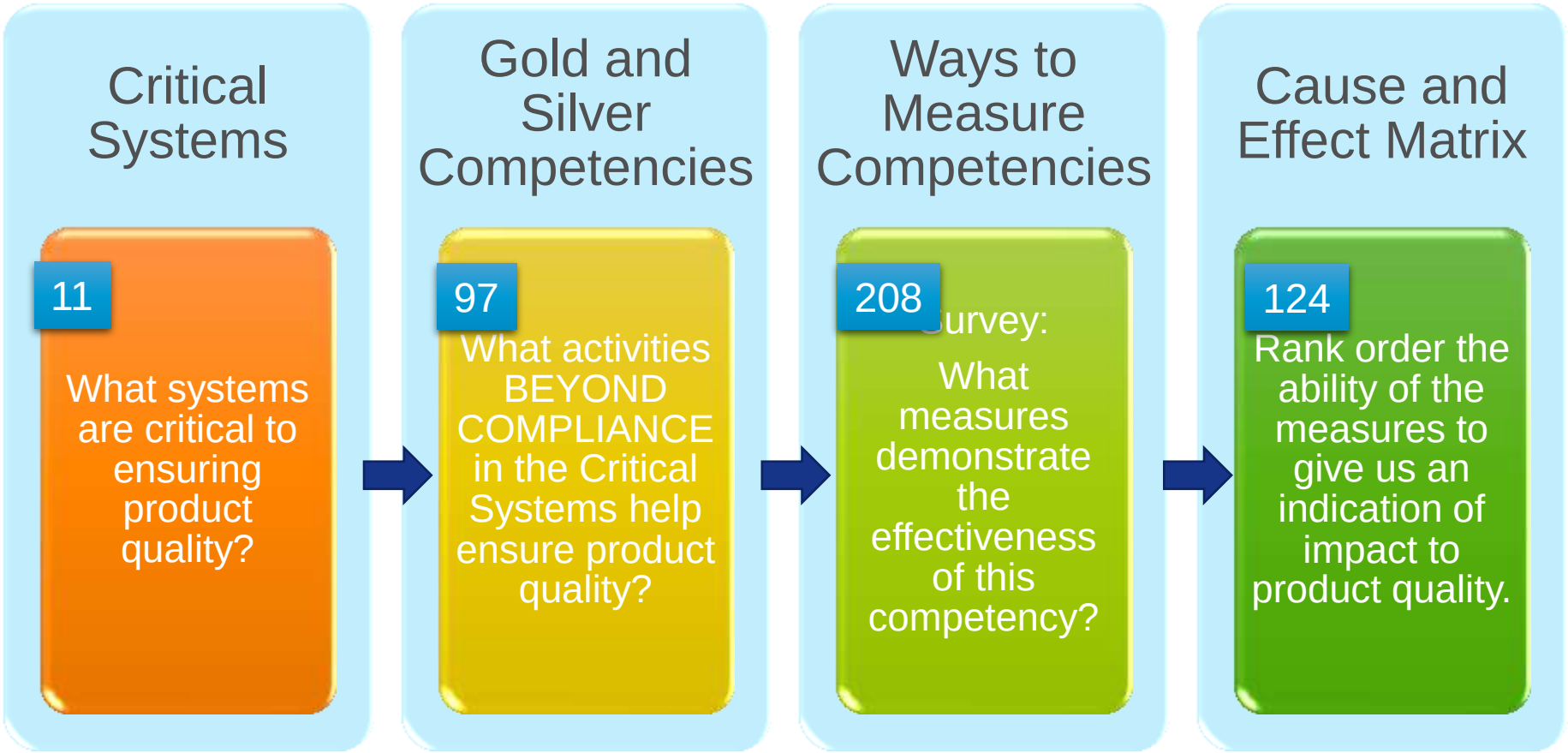
Jeff Ireland Medtronic	Scott Nichols Abbott	Luann Pendy Medtronic	

Methodology



13 Companies participated: Abbott, Baxter Healthcare, Boston Scientific, Carefusion, Clinical Innovations, CR Bard, Davol, Fisher & Paykel, Hospira, Medtronic, Meridian Bioscience, Philips, STERIS

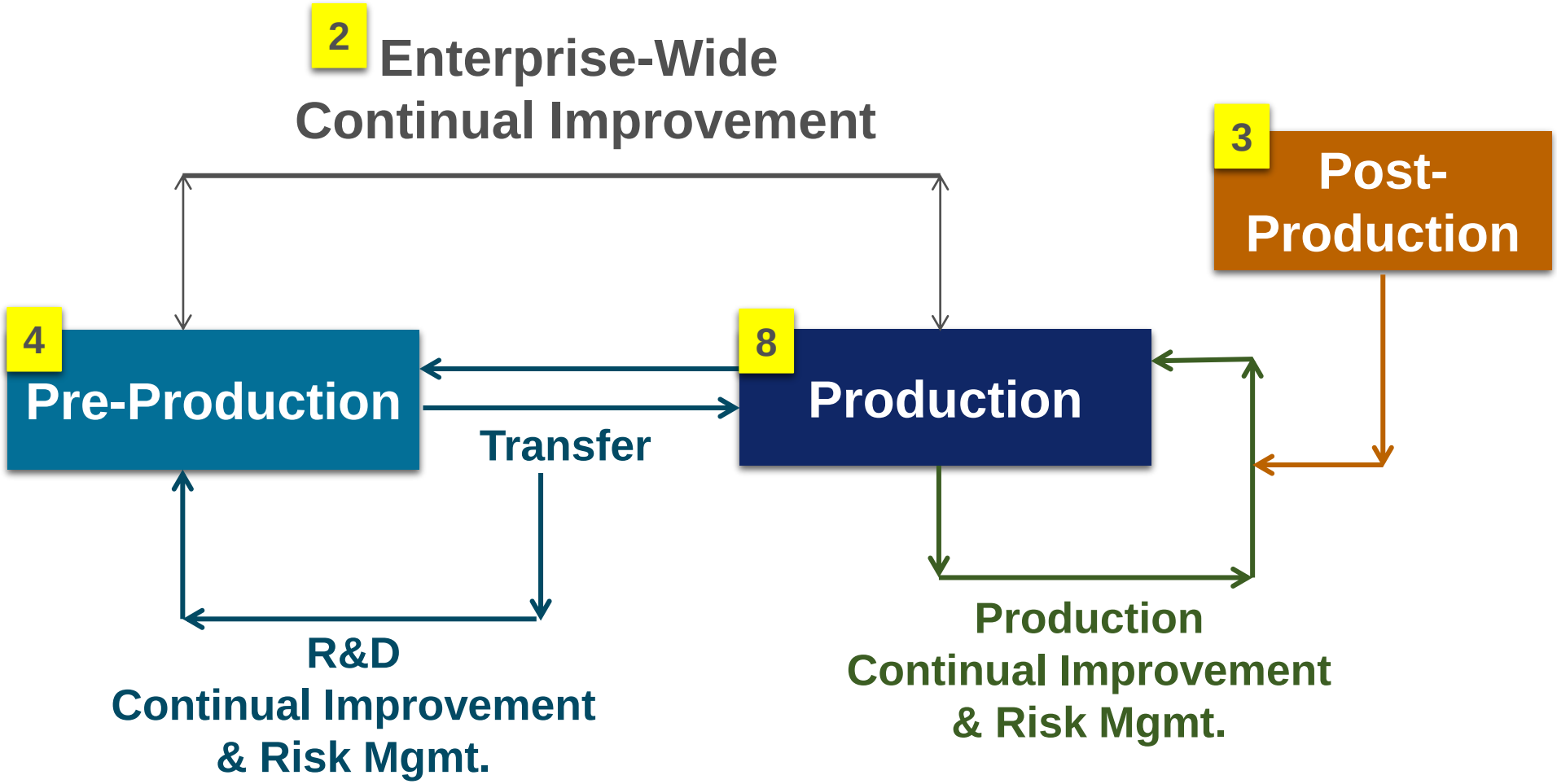
120 Survey participants – 18 Vice Presidents; 62 Directors; 30 Managers; 4 FDA Officials; 6 Other

Critical Systems

Identified 11 Critical Systems that would help ensure each system was assessed for predictive measures:

1. CAPA
2. Change Control
3. Complaint Handling
4. Customer-Related/VOC
5. Design Controls
6. Distribution
7. Management Controls
8. Post-Launch Surveillance
9. Production and Process Controls
10. Servicing
11. Supplier Controls

A Systems Approach



Final Metrics

Pre-Market

Design Robustness Indication

Identification of design elements that eliminate, reduce, and prevent design failures throughout the product lifecycle

Production

Right First Time Indication

Tracking and trending production-related right first time data to eliminate, reduce, and prevent repeat failures

Post-Market

Post-Market Indication

Analysis of key post market surveillance data to eliminate, reduce and prevent on-market failures

Pilot Study Design

Goal: Demonstrate that the metrics are sensitive enough to differentiate between varying levels of product quality

Pilot Companies:

- 8 companies participating with variability in company size, product type and product risk

Pilot Details:

- The study will only be retrospective, and participants have 6 months to complete the work
- Each company will choose products/work centers to include in the study that have differing levels of complexity and success
- Companies will not be compared to each other

Implementation Best Practices

Purpose: To help organizations understand how to best use the output from the metrics to inform decisions and trigger actions

- Output can be used to understand root causes
- Output can be combined with the output of other metrics to understand a more holistic picture, analyze trends, etc.
- Goal is to provide a feedback loop to improve systems that allowed the failure to occur originally
- Improve the systems from the earliest point possible

Power and Benefits of Measures

Linkage to Total Product Lifecycle

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Linkage to Critical Quality Systems

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Linkage to Critical Requirements (C&E Matrix)

Patient Safety	Design Robustness	Process Reliability	Quality System Robustness	Failure Costs

Next Steps - 2016

Quality metrics continues as a work in progress

- Through June 2016
  - Workgroups continue to develop the pilot and will analyze outputs to determine effectiveness of the top 3 measures
  - The workgroup shall develop and implementation “Best Practices” plan

- August: Working groups will complete pilots of their models and metrics with several medical device companies and will report the data.

- September 1: Present the Change Adoption Plan to the FDA.
  - The plan will propose a set of actions to help facilitate improved device quality.
  - Plan components include ways to: continue engaging key leaders across all stakeholders, develop the business case for quality, communicate the movement to all stakeholder groups, pilot potential product quality solutions, and assess the quality culture through organizational behaviors.

What is the Expected Outcome

Industry will be able to establish metrics to demonstrate they are performing above the baseline of conformance with the quality system regulation.

Expect FDA to ask industry to share these metrics voluntarily.

Despite assurances to the contrary this may raise some risk for industry

- Will each firm be measured against their competitors?
- Will the “Gold Level” become the expectation for all?
- Will FDA really not act on unfavorable data they have in their possession?

May reduce frequency of FDA inspection or depth of inspection

May be useful to build brand loyalty

Bottom Line

IF FDA agrees to adopt the premise of quality metrics and supporting data currently being piloted (there is currently no commitment by FDA to adopt the quality metrics initiative) the anticipated value to industry (and FDA) will be fewer inspections at those firms who can demonstrate they are operating at a higher level of performance than simply complying with the Quality System, and enabling FDA to expend its relatively sparse resources at firms more worthy of their attention and oversight.

Still a “work in progress” that may take some period of time to develop and implement.

Stay tuned….

Join The Movement….

- For more information about how you can join the Case for Quality movement, create a culture of quality in your organization and make a real difference in the lives of patients:
- Contact the MDIC at www.mdic.org/cfq
- Join our next Case for Quality Forum on March 8 in Washington D.C.

Acknowledgements

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Medical Device Industry Consortium

Questions?

Thank You!