Case for Quality: Establishing Quality for Success

FDA Small Business Regulatory Education for Industry (REdI)

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U.S. Food and Drug Administration

Compliance ≠ Quality

"…one device manufacturer can meet FDA requirements

and *still* make a poor quality device whereas

a second manufacturer may not comply with all FDA requirements

and yet make a high-quality device"

Jeff Shuren, M.D., J.D.,
Director CDRH

Learning Objectives

- Identify and describe the various Case for Quality activities
- Describe value of engaging and how to determine if participation is right for you
- Describe the direction FDA wants to go and how to engage

What is Case for Quality?

www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality

WHY?

***NOTE: Compliance to regulations is still important, as it is required – a high quality product is not a substitute for a compliant product under our current statutory situation

Case for Quality

2011 Initial Launch: CDRH CfQ campaign to transition from compliance to a culture that prioritizes product quality and patient outcomes

2020 Current State: MDIC CfQ collaborative effort to engage all stakeholders in the medical device ecosystem

Focus on Quality

Enhance Data and Analytics

Adaptive Regulatory Framework

https://mdic.org/program/case-for-quality/

Current CfQ Activities

- Voluntary Improvement Program (VIP)
- Medical Device Information & Analysis Sharing
- makeCAPACool Pilot
- Advanced Manufacturing
- Accelerate Sustainable Capability Pilot

VIP

Voluntary Improvement Program

VIP Summary

High Level Operating Parameters

US manufacturers with a successful compliance inspection (FDA or MDSAP) within 5 years (No OAI)

Activities building a quality culture

- Manufacturer undergoes 3rd-party appraisal to assess the facility's quality system capability
- Manufacturer has quarterly check points with appraiser
- Manufacturer submits quarterly quality performance metrics

FDA receives data set from appraisal and quarterly metrics

VIP Summary

FDA Activities Accelerating Innovative Changes:

- FDA forgoes certain inspections (such as surveillance, post-approval, risk-based inspections, preapproval)

- FDA streamlines content and review timeframes
  - Manufacturing change notice submissions
  - Manufacturing site changes
  - Original PMA manufacturing, streamlined, waiver of preapproval inspection

VIP has been in operation for over 2.5 years

- 73 Facilities are currently enrolled

Effectiveness Metrics (462 Respondents)

- Experience with appraisal – 91.6% Positive, 0.4% Negative
- Appraisal identified improvements to increase product quality – 85.8% Yes
- Conflict with compliance – 96.8% No
- Appraisal added value – 96.2% Yes
- NPS (n=309) = +56

Program Updates

CDRH has received over 250 CfQ 30-Day Submissions to date:

- 72% completed in less than 10 days with an average of 4.5 days
- 46% completed in less than 5 days with an average of 3 days

180-Day Site Change Supplements

- Three to date
  - 63 Days
  - 26 Days
  - 13 Days

PMA Original

- No submission yet

CDRH Performance

MDIAS

Medical Device Analysis & Information Sharing

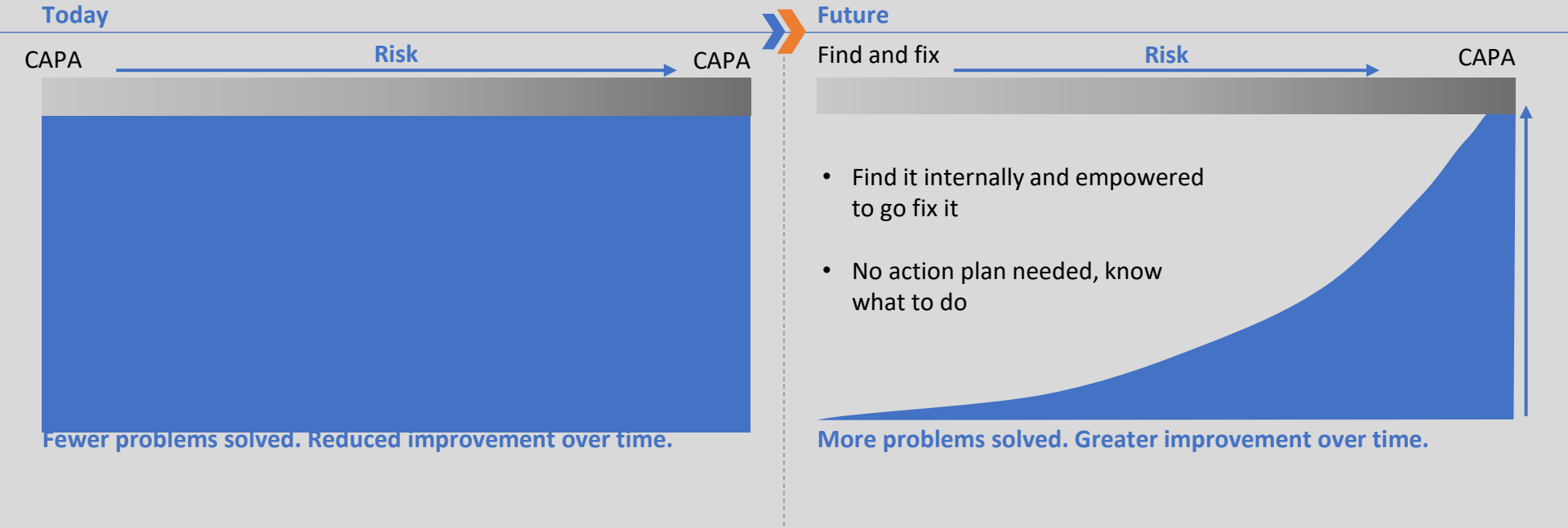
Enhance performance and analytics

- MDIAS
  - Medical Device Information and Analysis Sharing Platform
- Collaboration with MITRE
  - Development and Trusted-Third Party
- Protected partnership for data sharing across all stakeholders
- System for sharing and analyzing organization and product data for safety and improvement

Make CAPACool

Redesign CAPA

Improve CAPA effectiveness and the decrease burden to drive product quality improvements, reducing patient risk.



Pilot strategy

= CfQ VIP Site
= Non- CfQ VIP Site

Overall Pilot Timeline

3 mo.

- Create Communication Package to advertise pilot.
- Create Full Pilot Package

Team F2F

Transition and/or Expansion Strategy (~8 mo.)

Advanced Manufacturing

Supporting Activities

- Software assurance guidance
- MDIC BAA – Advanced manufacturing landscape analysis
- Establish an independent clearing house for advanced manufacturing technologies

Initial Clearinghouse Proof-of-Concept

- Digital twin of a medical device through the total product lifecycle

- Apply the digital twin to challenges highlighted by the COVID19 public health emergency

ASC Pilot

Accelerate
Sustainable
Capability
Pilot

- Apply a quality system maturity and integration approach
- Focus and accelerate the improvement efforts
- Structure participant's quality systems for continuous improvement.
- Develop objective data and metrics regarding product residual risk

ASC Pilot

Pilot Detail Summary

- **Operating Timeline** – July 29, 2020 and will be active for 12 – 18 months from final enrollment
- **Participants** – Pilot open to 9 sites that meet the following scenarios on a first come basis
  - Voluntary Self-Reporting Firms
  - Firms with Findings
  - Firms with unresolved agency actions
- **Enrollment** – https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/

Knowledge Check

Which Case for Quality Activity is intended to decrease the burden on driving quality improvements ?

a. Voluntary Improvement Program (VIP)

b. makeCAPACool Pilot

c. Accelerate Sustainable Capability Pilot

Value of Engaging:
Why Should I Participate?

Who can participate in CfQ?

- **All Case for Quality activities are open to medical device manufacturers independent of product or size who meet the identified criteria**

VIP Participant Breakdown	
73 Active sites	2 Class I Only Sites
7 Small Business	11 Class II Only Sites
26 Foreign Sites	9 Class III Only Sites

- What are your business objectives?
- Where are the challenges in your operation?
- How is quality and safety integrated throughout the organization?
- How does your organization measure and gain value from quality?
- How does your organization assure its voice is heard?

Things to consider

VIP Value Achieved

62% increase in daily production

20% Reduction in production defects

Over 1000% reduction in Complaint Incidents Per Million

$250K – $650K Annual savings

7% Increase in net sales revenue

Over $15M in net profit

makeCAPACool Pilot

- Review of 156 CAPAs
- 70% of CAPAs opened could have been resolved with no additional effort or action required under pilot process
- 8% needed formal CAPA
- International compliance audit showed no issues with pilot process
- Reduction of 10,900 hours in effort (5 FTE Engineers)

Knowledge Check

FDA is not interested in business value.

a. True

b. False

Where is this all going and how do I engage?

Least Burdensome

Enhance Toolbox

Enabling Change

A new, collaborative, and data-driven regulatory model

FDA CDRH

Visibility

Least burdensome

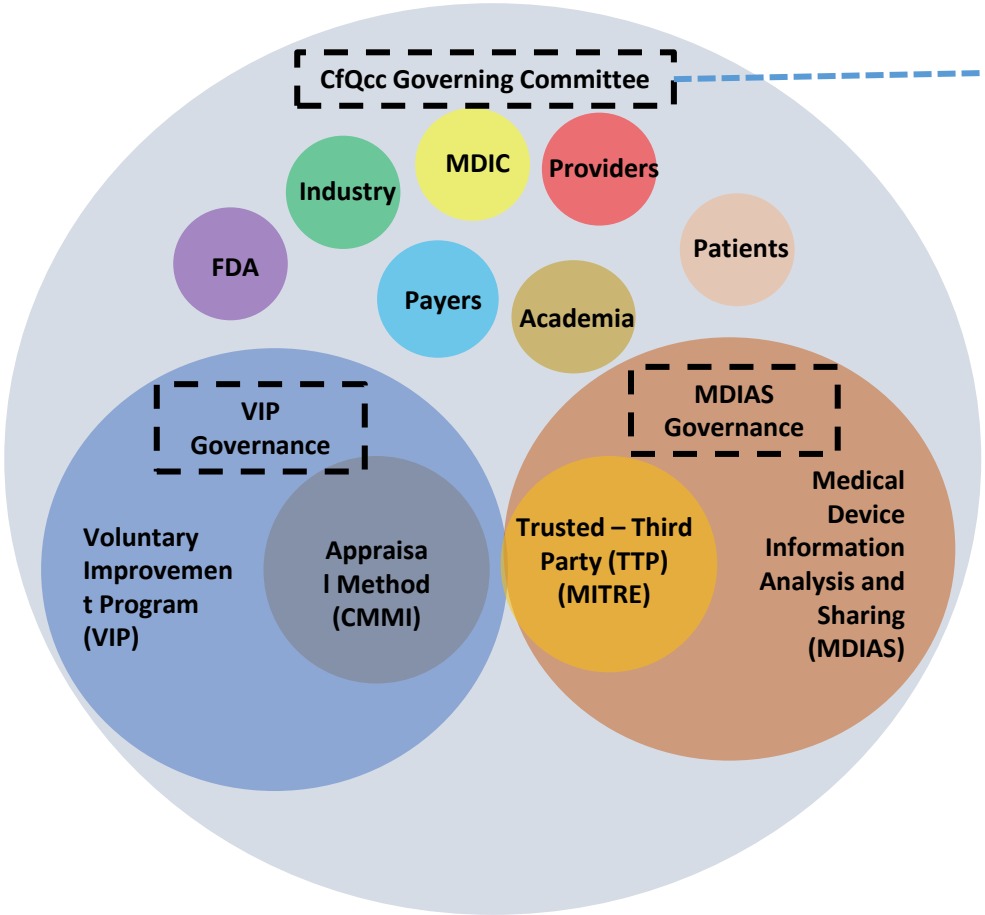
Safety & Innovation

Future for the Case for Quality: A Collaborative Community

Collaboration on quality and safety

Rewarding high-quality product across the medical device ecosystem

Compliance is an outcome of continuous improvement



TAKE PART IN THE COMMUNITY

CaseforQuality@fda.hhs.gov

Summary

- Case for Quality is not a one time project or activity. It is a collective shift towards improving quality and safety
- Case for Quality activities help develop new tools and ways to engage that are focused on value for all participants across the ecosystem
- FDA is working towards developing an agile regulatory model that is suited to best achieving its mission

Resources

Slide Number	Cited Resource	URL
5	FDA Case for Quality Site	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality
7	MDIC Case for Quality Site	mdic.org/program/case-for-quality/
16	makeCAPACool Whitepaper	mdic.org/news/mdic-releases-case-for-quality-capa-process-improvement-whitepaper/
22	Enrollment in the accelerating sustainable capability pilot	mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/
33	Case for Quality Mailbox	CaseForQuality@fda.hhs.gov

Questions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