Case for Quality: Collaborating on quality for success

FDA Inspection Summit

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What is Case for Quality?

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

Case for Quality

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

2020 Current State: Collaborative effort to engage all stakeholders in the medical device ecosystem

Focus on Quality

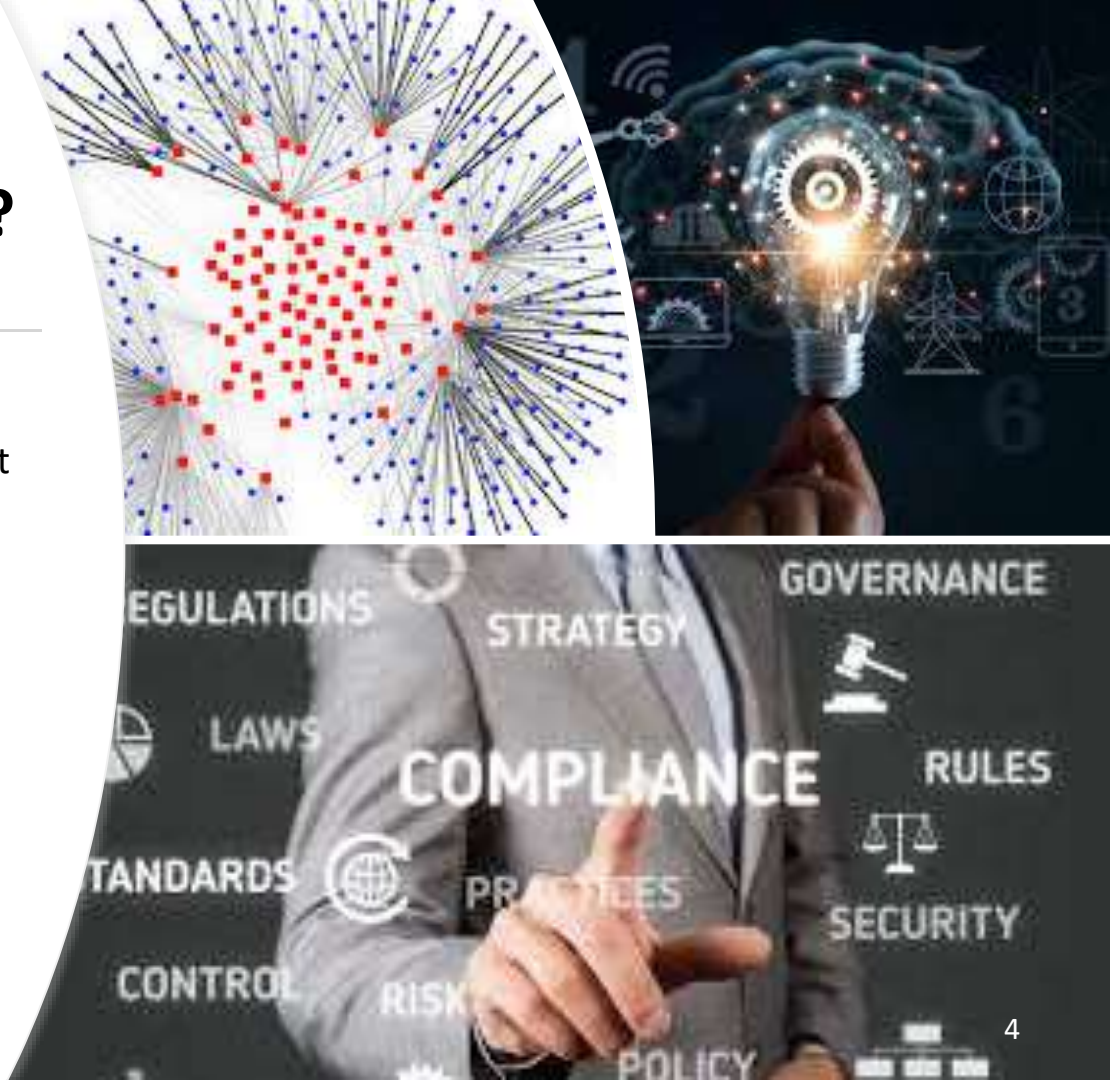
Enhance Data and Analytics

Adaptive Regulatory Framework

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

Why does all this matter?

- Compliance to regulations is still important and the legal requirement but not the goal
- Improving quality and safety is a complex and collective effort across all stakeholders
- FDA needs flexibility within the regulatory model.
- New tools and methods are needed to drive and reward continuous improvement and safety



Current CfQ Activities

Medical Device Information & Analysis Sharing

Advanced Manufacturing Efforts

Voluntary Improvement Program (VIP)

CAPA Improvement Pilot

Accelerate Sustainable Capability Pilot

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- Medical Device Information & Analysis Sharing
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VIP

Voluntary Improvement Program

VIP Participant Requirements

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

FDA Supporting Activities

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 Results

Safety and Availability

- 62% increase in daily production
- 20% Reduction in production defects
- 24 – 48% Reduction in Complaints

Value

- $250K – $650K Annual savings
- 7% Increase in net sales revenue
- Over $15M in net profit

CAPA Pilot (#makeCAPAcool)

Redesign CAPA

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

Today

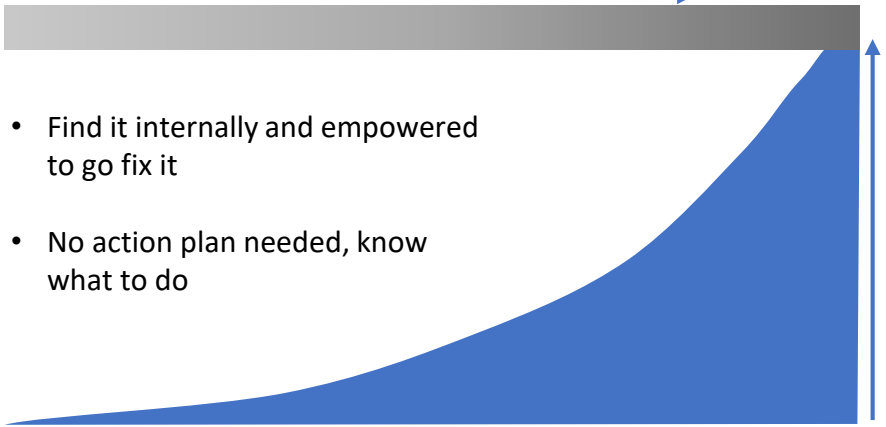
CAPA — Risk → CAPA

Fewer problems solved. Reduced improvement over time.

Future

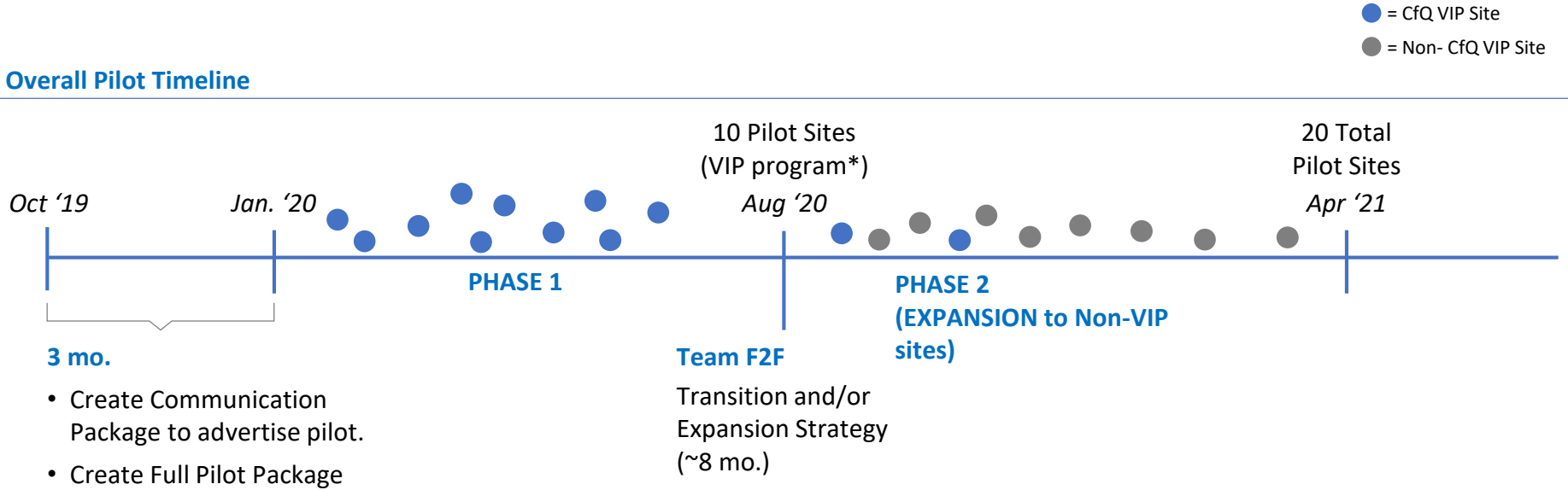
Find and fix — Risk → CAPA

- Find it internally and empowered to go fix it
- No action plan needed, know what to do



More problems solved. Greater improvement over time.

Pilot strategy



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)

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

Webinar: ASC Information Session [Link]
When: Wednesday, October 28 at 2pm EST

Where are we going?

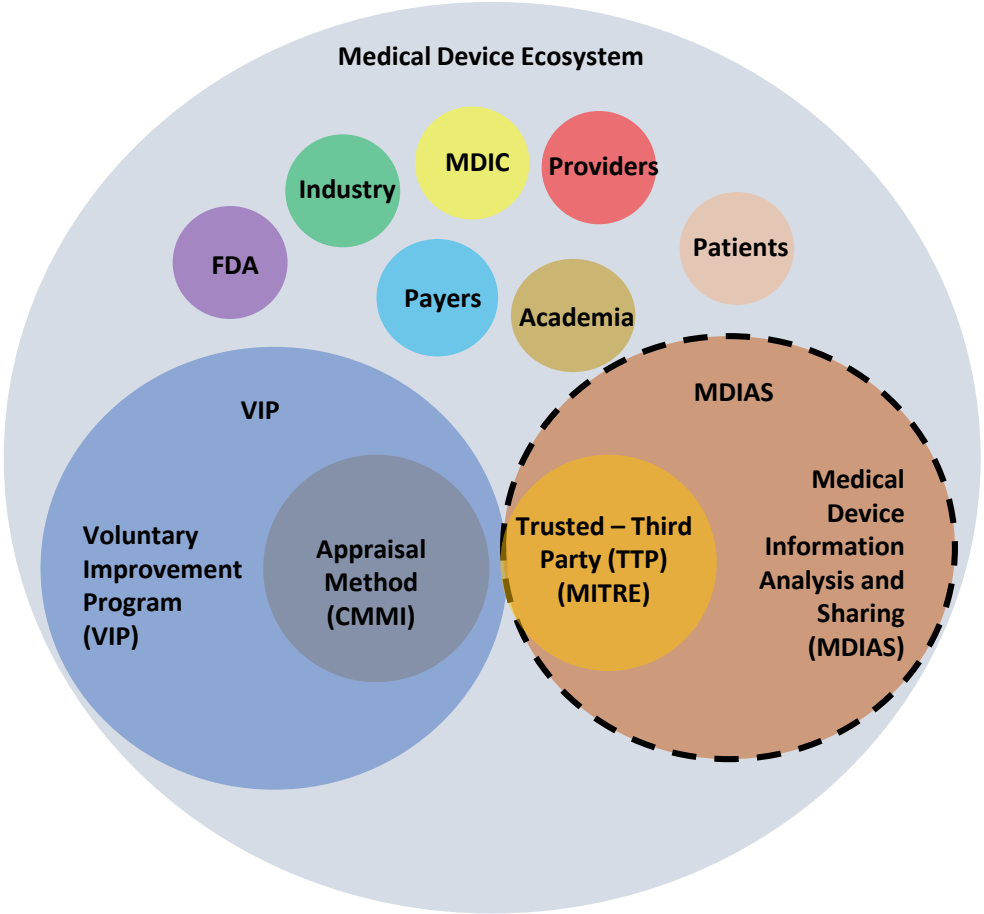
Trusted collaboration to improve quality and safety

Collaboration on quality and safety

More efficient and effective regulatory engagement

Rewarding high-quality product across the medical device ecosystem

Compliance becomes an outcome of continuous improvement



IMPACT WHERE IT MATTERS

Resources

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