Case for Quality Program Pilot

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For Discussion

Experiences to date

Comments on the program

Upcoming pilot announcement

For the future

Experiences to date from the pilot

- Scoping of appraisal is complex and varies significantly
- CDRH system and process constraints
- Rethink proposed approach to sites with combination products and 30-Day Notice submissions
- Need to coordinate with MDSAP program
- Increase visibility for non-participants

Early thoughts and insights

- Collaboration is critical
- Need to think differently
- Need to be open to “hard to hear” realities

Comments on the program

- One comment to the docket so far
  - Comment period extended until December 14, 2017
  - https://www.regulations.gov/docket?D=FDA-2017-N-4180

- Unofficial feedback
  - Skepticism on FDA actually moving this way to the extreme of it is about time
  - Lots of concerns regarding scalability and applicability to new innovators
  - Positive feedback on the openness, collaboration, and shift
  - “It looks like I need to find a new job”

Upcoming pilot announcement

- Still in final review and clearance

- What to expect
  - Details on how program operates and what can be expected
  - Details for submissions under pilot
  - Details on the data to be collected
  - Location for information updates and frequency

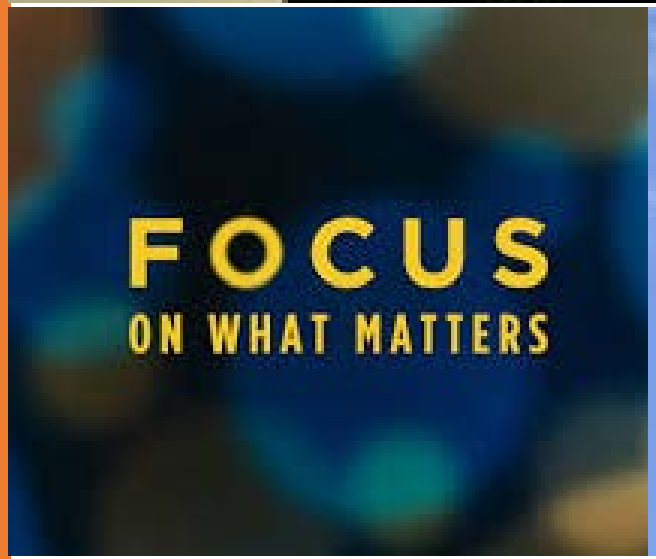
- Challenges
  - Need to work through PRA concerns and process. Includes another comment period.
  - Information updates may require collaboration with MDIC and CMMI

Where we could be?

Goals moving forward

Continue	Continue to increase focus on manufacturing and product quality, improve value of the review, speed-up innovation and access to new products
Focus on	Focus on organizational excellence and system execution instead of individual products and review
Create	Create a regulatory approach that can rapidly adjust and focuses on driving excellence not compliance
Leverage	Leverage a continuous method for organization and product performance which enables faster clearance or approval of medical devices and quality improvements

What does it take?



How can we do this?

- Continue collaboration
- Reducing regulatory barriers and simplifying capability to improve
- Benchmarking and learning from other industries
- Developing visibility

Product Quality Dashboard

- What is the solution?
  - A comprehensive picture of product quality and risk management that allows leaders to get a view of quality across metrics representing the development, manufacturing and post-production processes in conjunction with financial and cultural metrics.
- Who benefits?
  - Quality, Manufacturing and Product leadership
- What is value?
  - Establish an entry point into enterprise quality and risk analytics that is in-line with the Medical Device Innovation Consortium's (MDIC) leading practices
  - Develop confidence in metric results through embedded adjudication process that confirms data and metrics are complete and accurate
  - Provide real-time visibility into metrics that cross disconnected systems
  - Determine focus areas for quality improvement initiatives patterns across manufacturing sites and products
  - Enable metric configurability to fit within a dynamic environment

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Thinking about next steps

- Do not be constrained by how we do it now!
- How do we demonstrate that the rights are being done?
- How do we change the regulatory system to accommodate?
- How do the next steps in Case for Quality help move us closer?

Questions?

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Thank You!


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