Case for Quality Program Pilot

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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

- 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

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