Voluntary Medical Device Manufacturing and Product Quality Program

Participation Criteria and Rules of Engagement

Public Workshop

October 10, 2017

Overview

- Criteria for enrollment and participation
- Pilot Logistics
- Engagement and interactions
- Commitments

Enrollment Criteria

- Enrollment is site specific

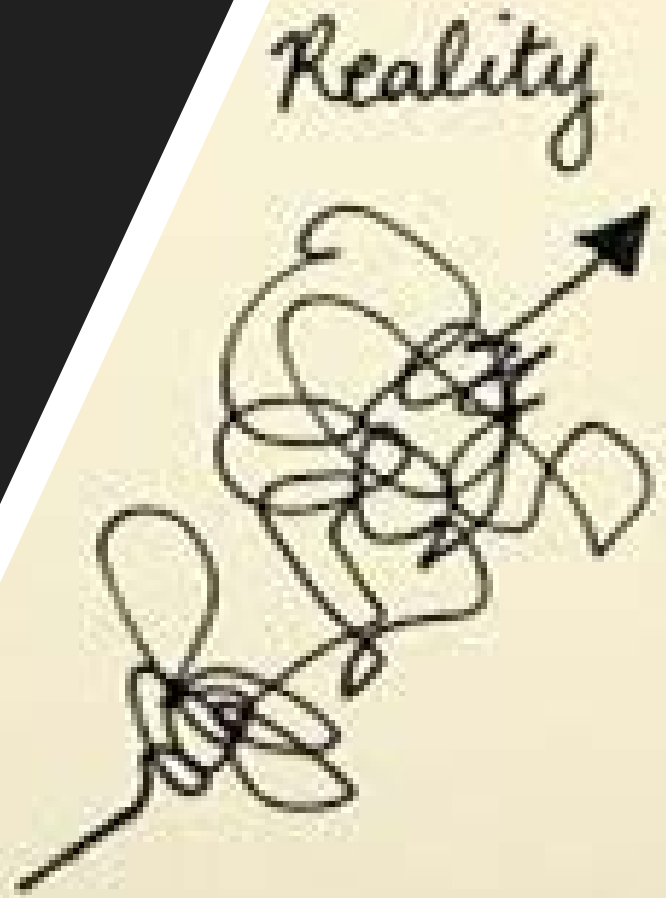
- Most recent FDA or MDSAP site audit in the last 5 Years must have been found compliant
  - NAI or VAI →FDA
  - Minor Non-Conformances →MDSAP

- Enrollment
  - http://www.cmmiinstitute.com/MedicalDevice

- Contact
  - medicaldevice@cmmiinstitute.com
  - CaseForQuality@fda.hhs.gov

Participation Expectations

- Appraisal occurs within 90 days of acceptance (unless there is agreement with FDA for a reasonable extension)
- Participant will provide the baseline set of effectiveness metrics during appraisal and participate in program surveys
- Participant will provide updates to metrics and the process area checks at the established intervals
- Participant agrees to early engagement and candid feedback on pilot, process, metrics, value…..

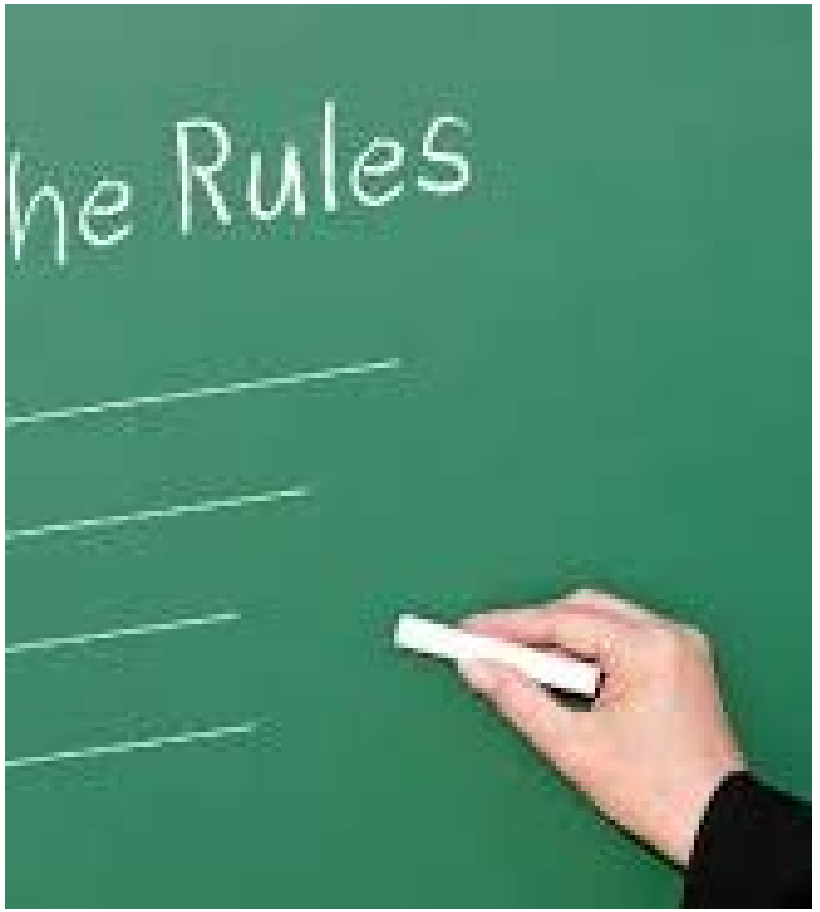


Pilot Program Logistics

- Minimum of 30 sites
  - Various sizes, product categories, maturity levels, manufacturing
- Pilot will run from January 2018 through December 2018
- New enrollment will close at the end of September 2018
- Details, templates, modifications, and learning will be made available on the FDA Case for Quality and through MDIC.
- Feedback will be collected through the open docket prior to December 2017 and can be submitted through the Case for Quality email through out the pilot.
  - CaseForQuality@fda.hhs.gov

Engagement and Interactions

- Product quality issues
- Public health or safety issues
- Interaction from FDA
- “Rules of Engagement”
  - Early interaction when safety issue arises
  - FDA will meet and work on solutions with participant
  - Action plan and periodic check-ins for visibility into progress
    - Timeline for action plan and progress checks will be established at initial meeting
  - No communication or action to resolve issue or engage with FDA may result in removal from the pilot and additional compliance actions



Commitments

- We are developing a learning system and will be open to feedback and engagement
- We are focused on product quality and patient outcomes. The best path towards assuring those is what we will pursue
- We will adapt from feedback quickly
- We will incorporate least burdensome principles into the pilot activities
- The metrics and data gathered will be used for learning not creating enforcement actions
- We will commitment to solution-focused approaches when engaged early and with transparency

Questions?

U.S. FOOD & DRUG ADMINISTRATION

Thank You!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