CDRH Quality Metrics Project

October 26, 2016

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Agenda

- A review of our progress to date.
- Issues identified to date.
- What are the Agency's next steps?

Quality Metrics Concept

In the end, what are we trying to accomplish?

FDA Prioritizes Resources

Planned for a Pilot

- Utilize MDIC QS metrics and 4 specific device characteristics:
  - Would have selected one particular device type;
  - Evaluation criteria for QS and device specific quality information; and,
  - Would have used evaluation criteria to determine which firms get Level 1 and Level 2 Risk Based Work Plan inspections.
- Seeking industry feedback and engagement on approach and metrics.

Outline for Device Metrics

Metric Subcategory

Metric Category	A. Approach to Control •Factor 1: Risk Mgmt •Factor 2: Control •Factor 3: Monitoring	B. Trending
I. MDIC QS • Preproduction • Production • Postproduction	-	Table 1
II. Device Specific • Characteristic A • Characteristic B • Characteristic C • Characteristic D	Table 2 and 3	Table 4

Metrics: A Quick Review

- Draft metrics document:

Adobe Acrobat Document

What FDA would need to evaluate

Indicators of activity with increasing impact on quality

1. Essential activities
2. Proactive activities
3. Preventive activities

Table 1.
Category: I. QS
Subcategory: B. Trending

Information to Evaluate	Evaluation Criteria
Preproduction, production and postproduction information* as described by the Medical Device Innovation Consortium as it applies to product classification *abc.defg* for a *representative device*. Identify any goals established by your firm for these metrics. Describe any analysis conducted by your firm to identify increasing or decreasing trends. Describe any linkages established by your firm between the results of your preproduction, production and postproduction metrics and your firm's quality system and risk management system. The minimum reporting period is 6-months prior to the date of this notice.	1. Preproduction, production and postproduction information have been provided for the identified product classification for the prior 6-months. Increasing and decreasing trends have been identified. Any trends negatively impacting product and service quality are associated with actions taken by the applicant. 2. The reporting period is at least 12-months. Goals associated with preproduction, production and postproduction metrics have been established. The applicant's analysis includes an evaluation of factors that contributed to increasing and decreasing trends. 3. Tying QS trending analysis to the firm's risk management system in order to identify, control and contain emergent issues before product is released, or to promote prompt response once it is released.

Issues Identified to Date

- More stakeholder input is needed to ensure that these are the right evaluation criteria.

- Metrics need to have utility for FDA manufacturers and other stakeholders.

Issues Identified to Date

- FDA's approach to metrics needs to interface with the maturity model concept.

- We need to look at ways to pilot this approach that involves broad device community involvement.
  - Even if this means it is not an FDA run pilot.

An example of feedback received

- Which is more important?
  - a 99% right first time (RFT) rate with no ties to Risk Management (RM) or the Quality System (QS)?

Or

  - A 77% RFT, actively managed through the RM and QS?

An example of feedback received

- And to would this be more important?
  - A 77% RFT tied into the RM and QS, but more actively managed through a process improvement program?

Or

  - A 77% RFT tied into the RM and QS, but more actively managed through the program responsible for the given process area and achieving related business goals?

Next Steps

- In the coming months:
  - Obtaining more stakeholder input;
  - Refining metrics language/approach based on that input; and,
  - Redefining what a pilot would look like.

- We look forward to getting your feedback!

FDA Metrics Team Information

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