CDRH Quality Metrics Project

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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

<table>
<thead>
<tr>
<th>Metric Category</th>
<th>A. Approach to Control</th>
<th>B. Trending</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Factor 1: Risk Mgmt</td>
<td></td>
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<tr>
<td></td>
<td>• Factor 2: Control</td>
<td></td>
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<td>• Factor 3: Monitoring</td>
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</tbody>
</table>

### I. MDIC QS
- Preproduction
- Production
- Postproduction

<table>
<thead>
<tr>
<th>II. Device Specific</th>
<th>A. Approach to Control</th>
<th>B. Trending</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Table 2 and 3</td>
<td>Table 4</td>
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</tbody>
</table>

Table 1

Table 2 and 3

Table 4
Metrics: A Quick Review

• Draft metrics document:

What FDA would need to evaluate

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

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

Indicators of activity with increasing impact on quality
1. Essential activities
2. Proactive activities
3. Preventive activities
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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