



MDIC Open Forum

FDA Quality Metrics Project

June 28, 2016

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FDA/CDRH/OC/Division of Manufacturing and Quality

Agenda

- Why is FDA interested in quality metrics?
- What are the Agency's expectations for its quality project?
- What is FDA's thinking so far?
- What are the Agency's next steps?

Quality Metrics: A Priority for FDA

U.S. Food and Drug Administration

2016-2017

Strategic Priorities

Center for Devices and Radiological Health

GOAL: STRENGTHEN PRODUCT AND MANUFACTURING QUALITY WITHIN THE MEDICAL DEVICE ECOSYSTEM

- By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.
- By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.
- By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.

To accomplish these goals, CDRH will take several steps including the following:

- Resources permitting, continue to implement the [CDRH Quality Management Framework](#).
- Develop education and training for CDRH staff to facilitate adoption of practices characteristic of a culture of quality and organizational excellence.

Quality Metrics: A Priority for FDA

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Quality Metrics Project

- Purpose:
 - To develop a mechanism whereby device manufacturer quality metrics can be used to prioritize how FDA uses its resources
 - To propose how this approach would utilize third parties

Today We Are in a Listening Mode

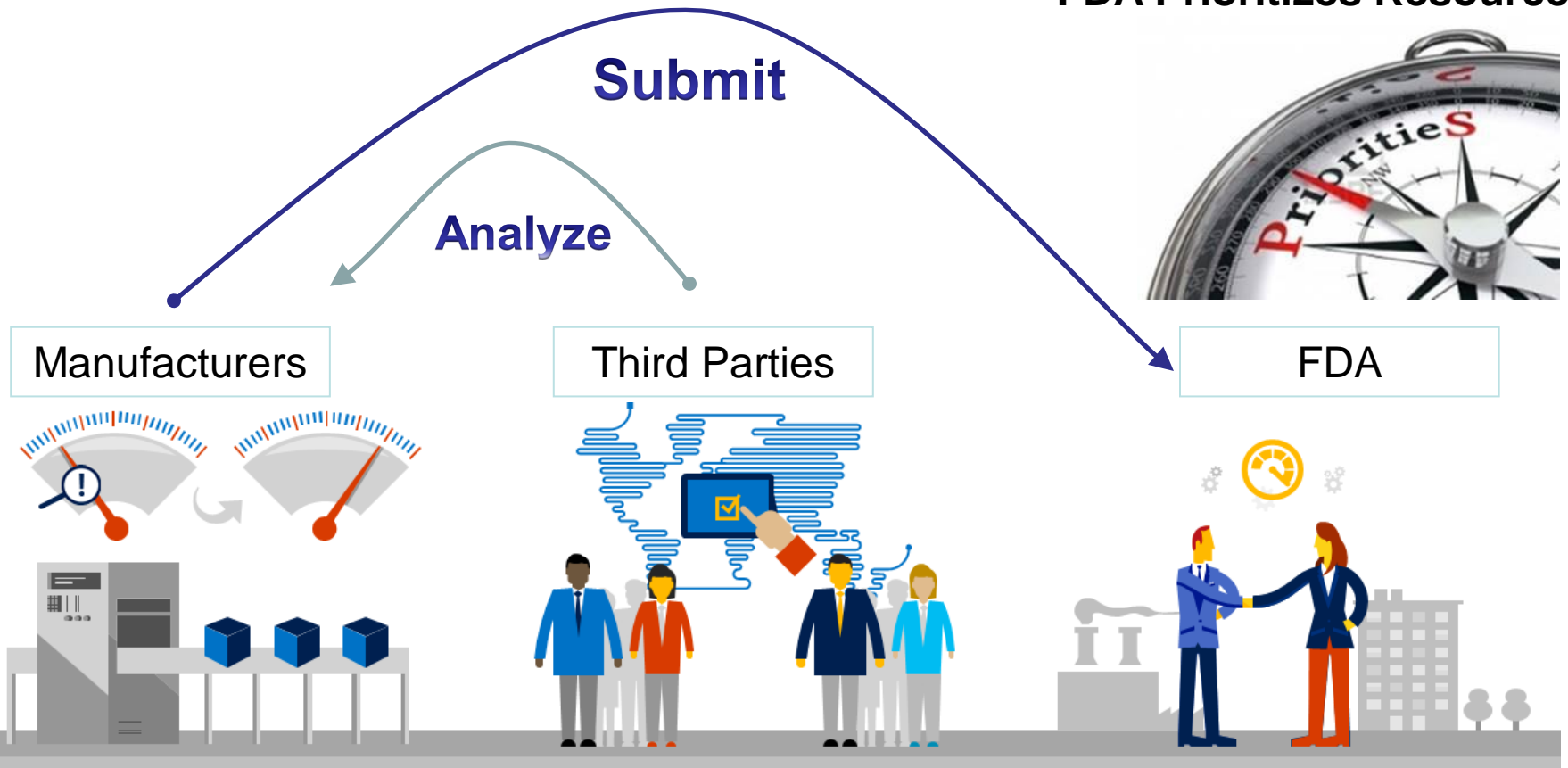
We are here to engage stakeholders on:

- FDA's interest in further developing quality metrics
- Hear organizations' preliminary experiences/ lessons learned with the MDIC metrics pilot, and concepts for path forward
- Develop an understanding of how quality metrics are utilized
- Discuss options for handling challenging issues, e.g.:
 - Ensuring metrics have utility for FDA and firms
 - Aggregating metrics from firms with different approaches

Quality Metrics Concept

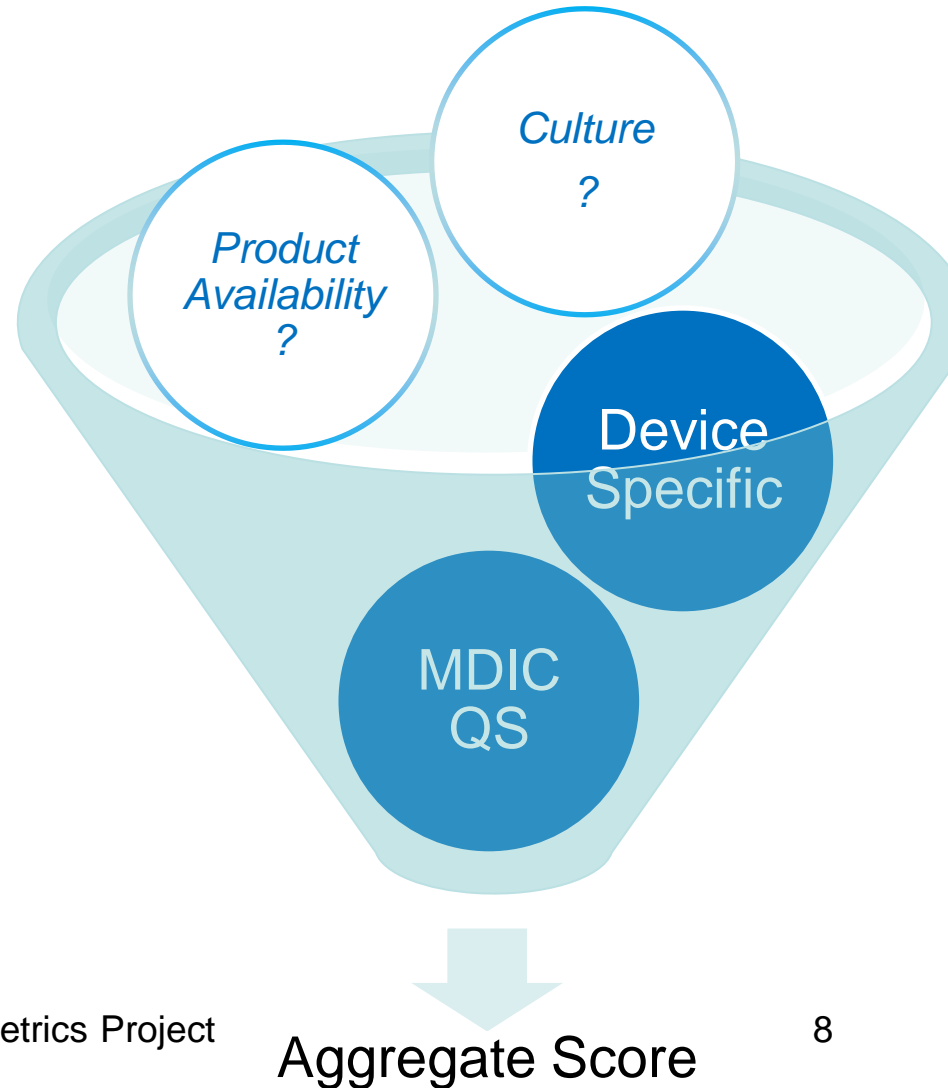
What are we trying to accomplish?

FDA Prioritizes Resources



The metrics—what’s being discussed?

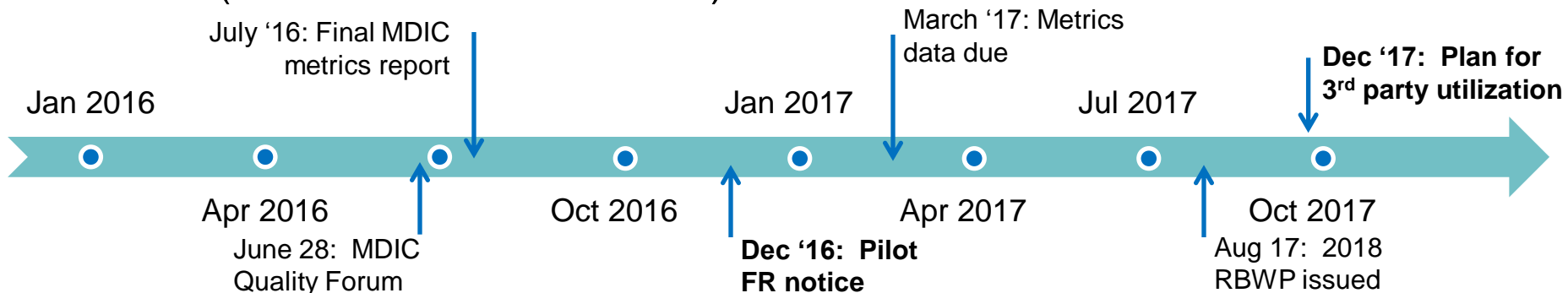
- Plan to pilot the use of MDIC quality system metrics
- Developing device specific metrics based on CtQ guidance work
- Discussing potential for product availability and culture metrics



Project Requirements & Boundary Conditions

Project Requirements:

1. The metrics need to provide insights on quality within a device segment and across device segments
2. Although plan to utilize the Risk Based Work Plan (RBWP) in a pilot, the applicability of the metrics tool needs to be capable of being extended to other FDA programs
3. The quality metrics tool needs to interface with the maturity model
4. The project must address the '16-'17 CDRH strategic priorities. The timeline associated with these priorities dictates activities by certain points in time (**bolded in timeline below**)

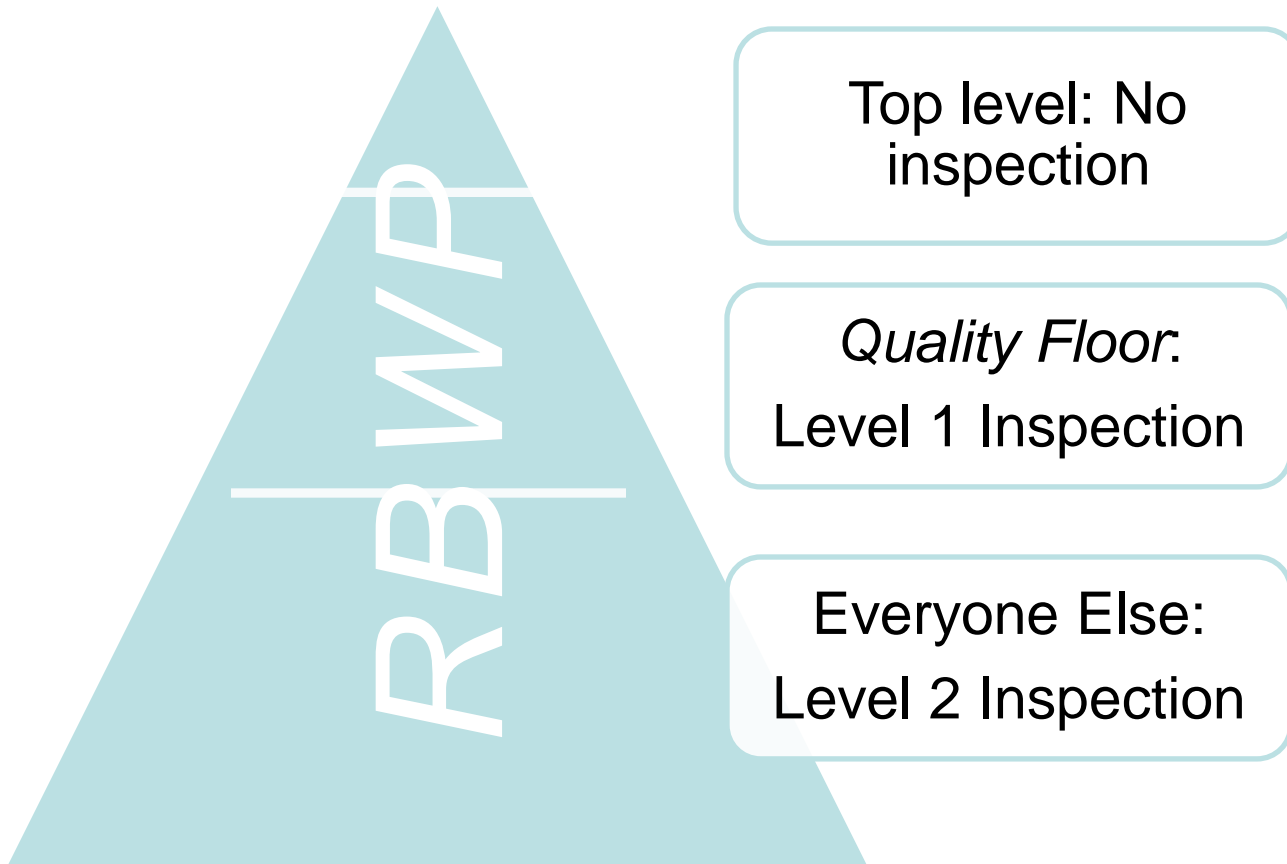


Project Requirements & Boundary Conditions

Boundary Conditions – factors to be considered

- A. The current focus is leading indicators of product quality
- B. We need to establish an aggregate scoring system that has relevance despite different quality characteristics, quality control methods and levels of quality assurance
- C. For the 2018 RBWP, we need to give firms as much time as possible to gather this quality information and submit it to FDA
- D. We do not want the metrics methodology to steer firms' approach. We want the results of the metrics evaluation to influence their approach.
- E. For the 2018 RBWP assignment, meeting a *quality floor* level should count for something
- F. We should consider making public the list of firms that fall into the highest scoring category

Concept for Score Levels – for Pilot



Third Party Utilization

- In 2017 we plan to focus more on how to utilize third parties:
 - What role can they play?
 - Studying benchmarks for third party utilization.
 - Defining approaches that have utility for stakeholders and FDA.
 - Proposing a plan for third party utilization by December 2017.

Next Steps

- Define a quality metric methodology utilizing the input obtained at the June 28 MDIC Open Forum.
- For a given device characteristic, different firms have different:
 - Quality controls (Receiving acceptance, full verification, process validation, process monitoring, etc.)
 - Device specifications
 - Levels of assurance (with 90% confidence, 90% of the time, component shall meet specifications)

Next Steps

- Continued:
 - Select the device area subject of the pilot
 - Define how we would analyze the data and train FDA staff
 - Request metric information via FR Notice by the end of 2016



QUESTIONS & DISCUSSION



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