14th Annual Medical Device Quality Congress

Case For Quality
CDRH Quality Metrics Project

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Agenda

- Background
  - CDRH Vision and the Case for Quality
- Getting to today's Case for Quality
  - Barriers to Quality
  - FDA's role in the Case for Quality (CfQ)
- Metrics to date and feedback received
- Moving towards a 3rd party program
- Questions & feedback throughout

CDRH Vision

- Patients have access to high quality, safe, effective medical devices, of public health importance, first in the world.
- Case for Quality promotes that vision through a shared FDA-industry goal to provide patient access to high-quality medical devices. In 2016 it matured into a CDRH Strategic Priority.

What is the Case for Quality?

- The Case for Quality is collaborative effort within the medical device ecosystem to shift the primary focus of the medical device sector from regulatory compliance to a state of sustained product quality in order to enhance patient safety and access to high quality medical devices.

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Barriers to Quality

- The focus of the relationship between FDA and industry may have been on managing compliance rather than on a shared goal for continuously improving quality.

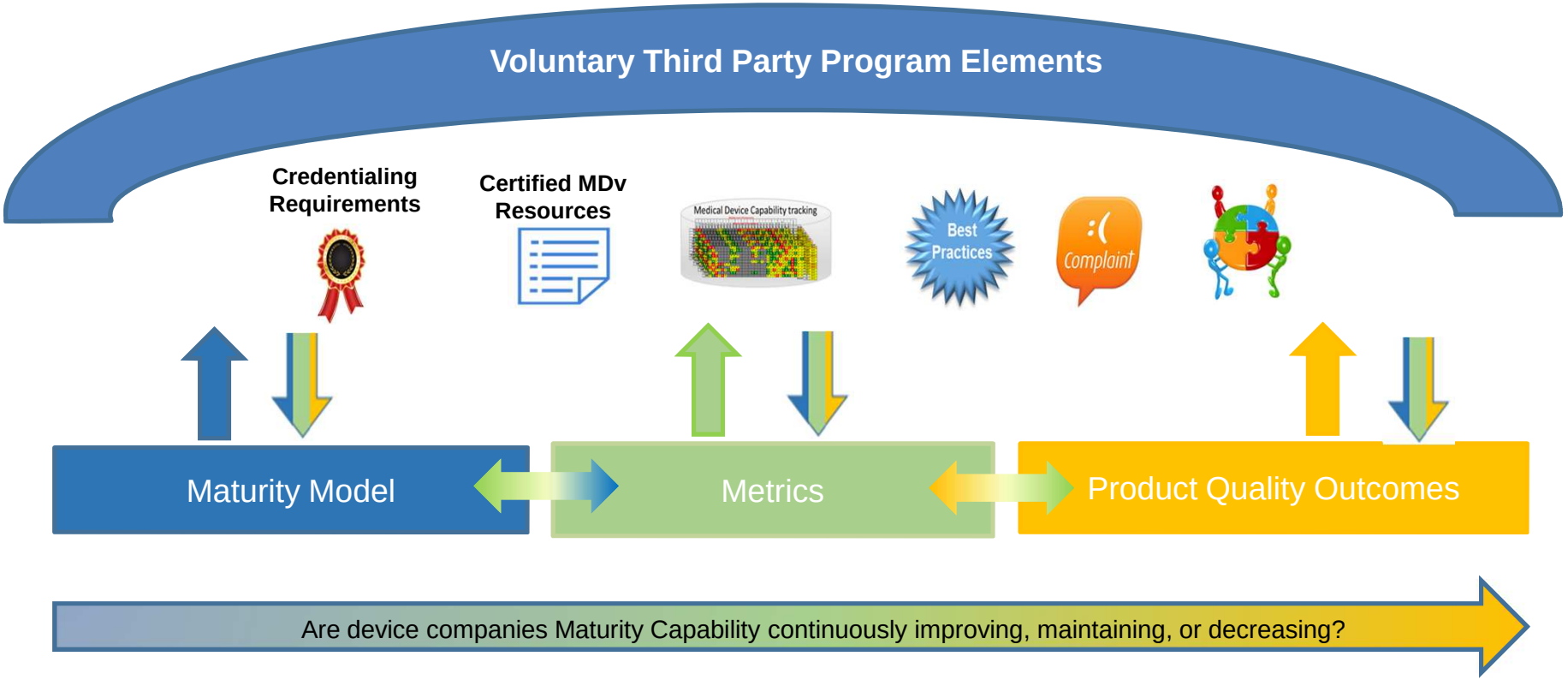
- A perceived and real lack of transparency and comparative data hampers informed decision making by users, purchasers, and the FDA, and thwarts rewarding good performers.

Note[1]
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm277272.htm

FDA's role in the Case for Quality

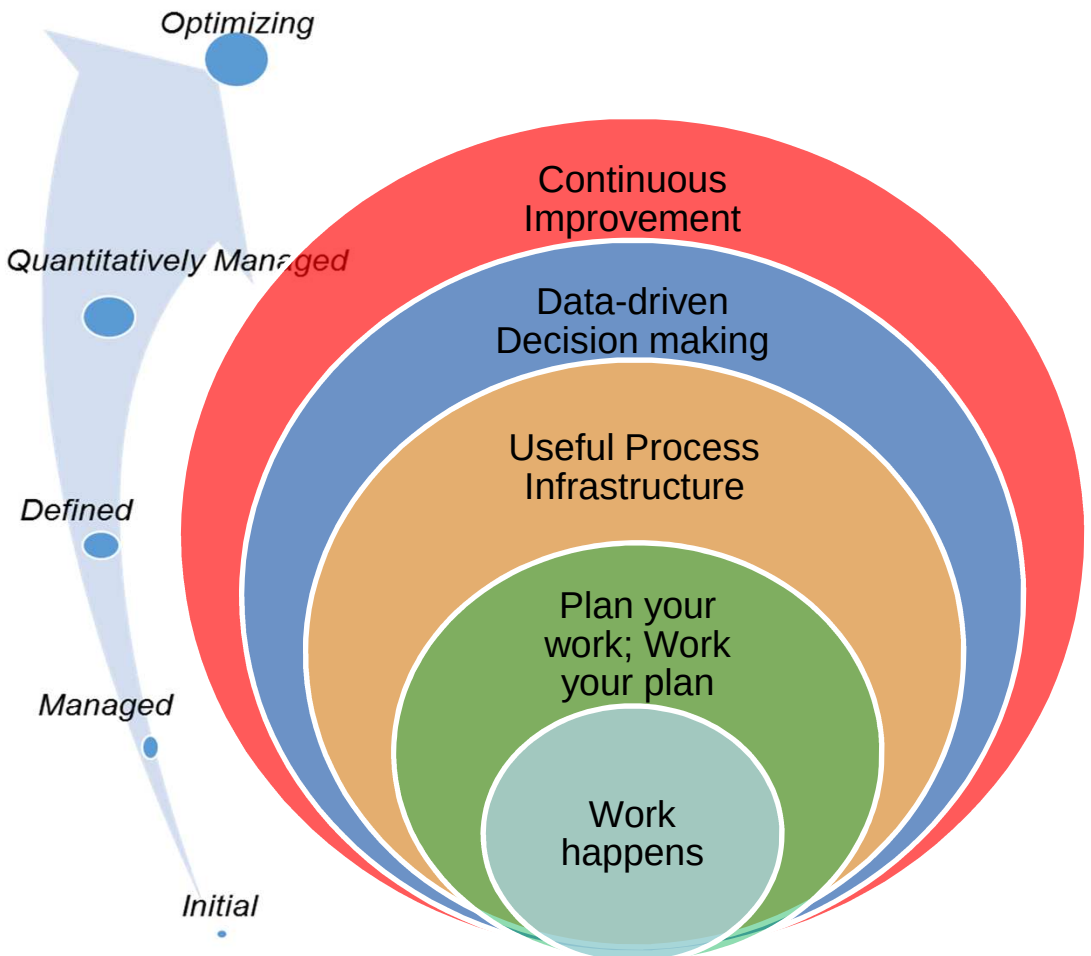
- CDRH Strategic Priority Goal: Strengthen Product and Manufacturing Quality within The Medical Device Ecosystem
  - Develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements
  - Pilot voluntary use of product and manufacturing quality metrics and evaluation tools
  - Propose a voluntary program to recognize independent evaluation of product and manufacturing quality

Today: The Case for Quality



Today: the Case for Quality

- **Maturity Model:**
  - Strengthen Product and Manufacturing Quality within The Medical Device Ecosystem and focus on quality execution beyond compliance



Today: the Case for Quality

- Value Analysis Teams: "What is quality?"

1. **Safety**: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.
2. **Effectiveness:** Device produces the effect intended by the manufacturer relative to the medical condition(s).
3. **Reliability:** Device system or component is able to function under stated conditions for a specified period of time.
4. **Patient Satisfaction:** Device was perceived to meet or exceed patient expectations of usability and outcome.
5. **Usability:** Device minimizes the risk of user errors by patients or clinicians.
6. **Availability**: Device is available to fill first request orders.
7. **Compatibility:** Device is compatible with related devices or drugs, the use environment or relevant standards.

Categories for Draft CDRH Device Metrics

Metric Category	What is evaluated
I. Quality System (capability) • Preproduction • Production • Postproduction Index	Trending
II. Critical Device Specific Characteristics •Factor 1: Risk Mgmt •Factor 2: Control •Factor 3: Monitoring	Approach to Control Trending

QS Metrics for Pilot Study

Phase/Metric Name	Metric Calculation
Pre- Production: Design Robustness Indicator Assess the number of product changes that are related to product or process inadequacies or failures	total # of product changes ——————— total # of products with initial sales in the period
Production: Right First Time Rate Assess the number of production failures related to product and process inadequacies or failures	# of units mfg. without non-conformances ——————— # of units started
Post- Production: Post-Market Index Assess an aggregate of post-market indicators with root causes of product or process inadequacies or failures	Index: Complaints * (0.20) + Service Records * (0.10) + Installation Failures * (0.20) + MDRs * (0.20) + Recalls (units) * (0.20) + Recalls (total) * (0.10)

CDRH Draft Metrics – High Level View

What FDA would need to evaluate

Indicators of activity with increasing impact on quality

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

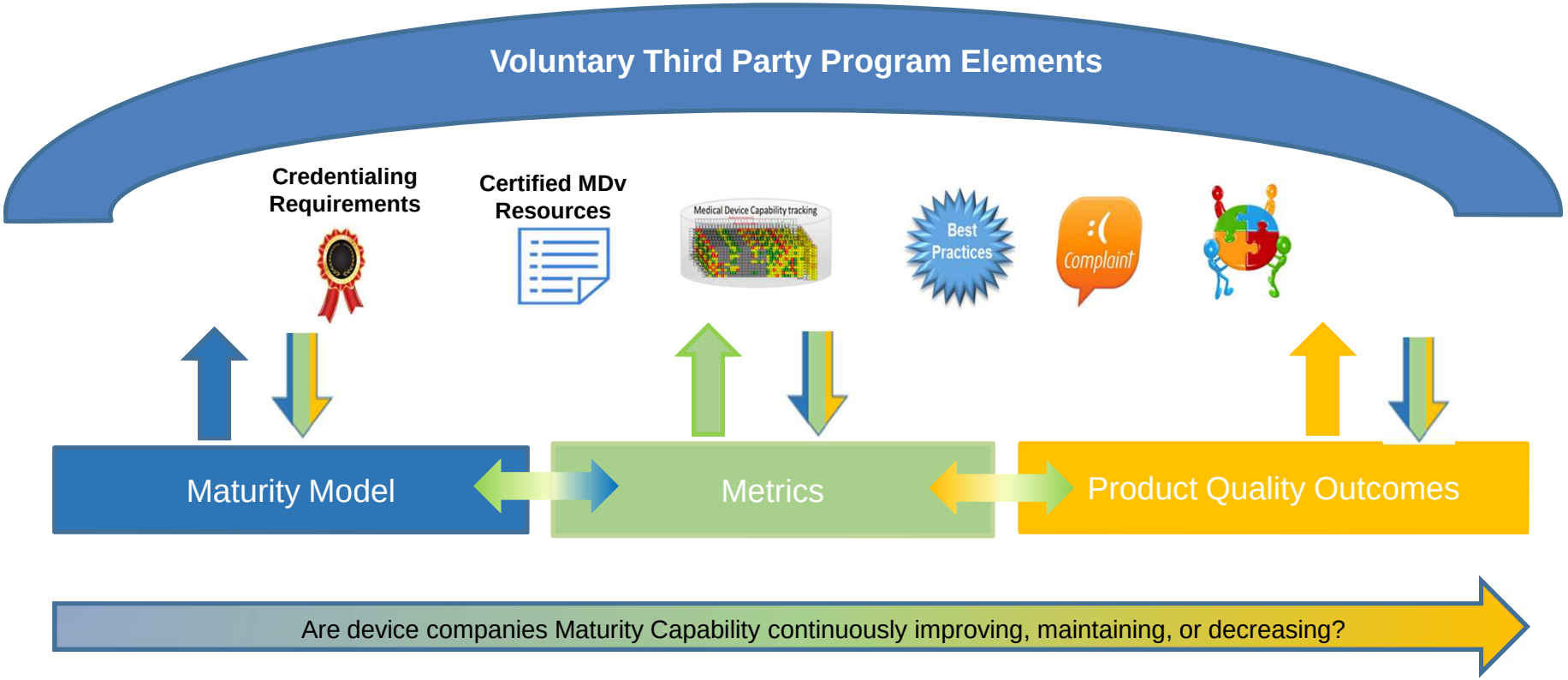
Table 1.
Category: I. QS
Subcategory: B. Trending

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.

Feedback Received

- There is a tradeoff between a generalized metrics approach and the value of the metrics themselves
- Value in integrating into maturity model assessments
- Where outcomes data/analytics data is available, that tends to be preferred over leading indicators of quality.

Today: The Case for Quality



Seeking More Feedback

- Promoting interest in participation in this approach?
- Metrics/tools to prepare for maturity model assessment?
- Standardized metrics – the line on cost/benefit?
- Incentive(s) for feeding outcome/analytics?

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