Compliance Central: CDRH 2017 Trends and 2018 Priorities

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Assessing Benefit-Risk

Benefit	Risk	Other Factors
• Type of Benefit • Magnitude of benefit(s) • Likelihood patients experience one or more benefits • Duration of effects • Patient preference on benefit • Benefits for healthcare professionals or caregivers • Medical necessity	• Risk Severity • Nonconforming product risks • Duration of exposure to population • False positive or false negative results • Patience tolerance of risk • Risk factors for healthcare professionals or caregivers	• Uncertainty • Mitigations • Detectability • Failure mode • Scope of the device issue • Patient impact • Preference for availability • Nature of violations/ • Nonconforming product • Firm compliance history

Goals: arrive at the same risk determination, weigh options while minimizing disruption of care and protecting public health

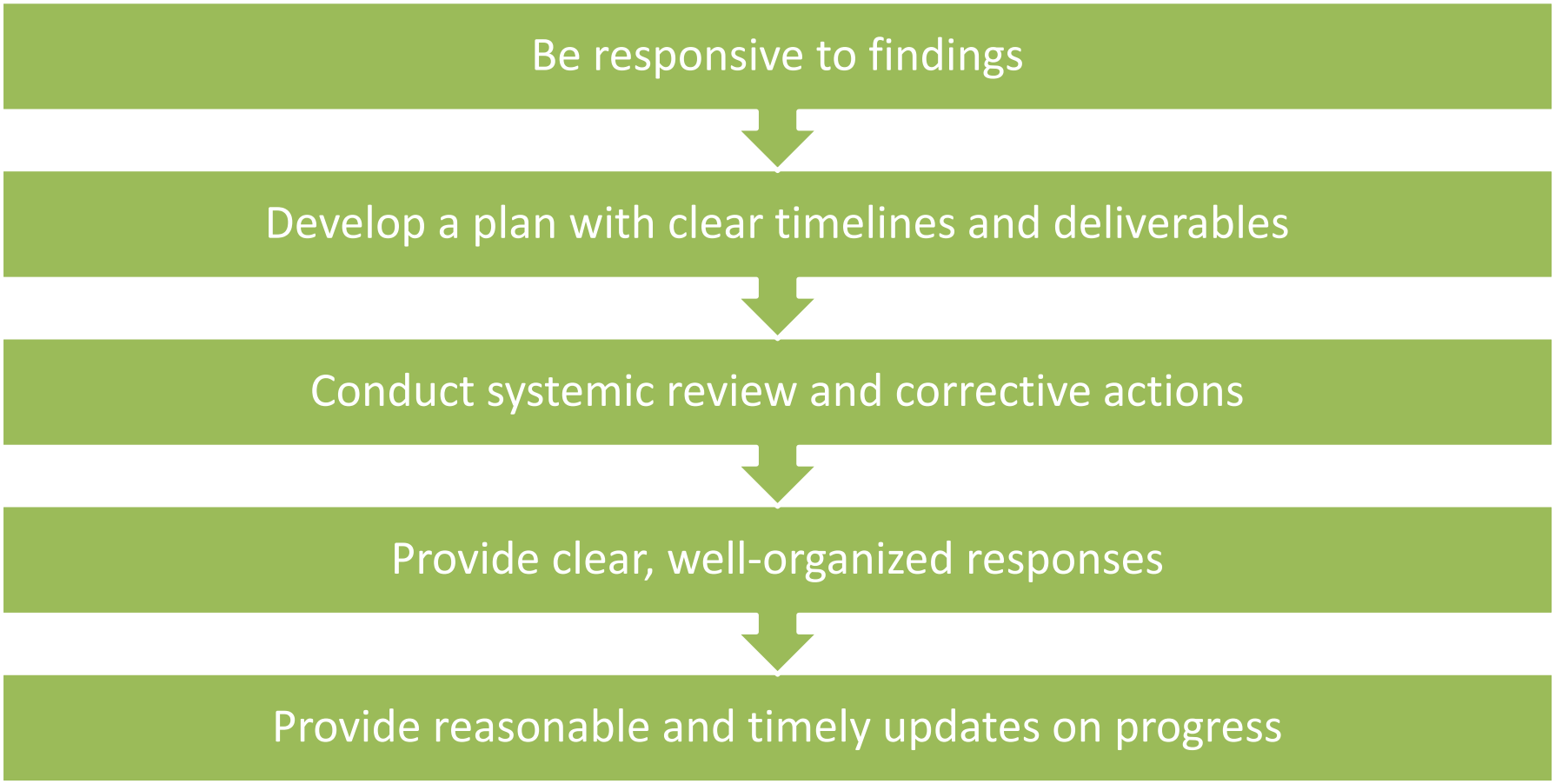
Inspections and Site Selection

A risk-based approach for routine surveillance and targeted inspections

- Novel devices
- Rapidly evolving technology
- Compliance history
- Adverse event trends
- Experience from reviews and interactions

3

Post-Inspection Follow-up



FDARA

Flexibility to inspect medical device facilities based on risk

Greater predictability and transparency to the inspection process

Ability to recognize international auditing organizations for inspection purposes

Least Burdensome Approach

Expanded Application Incorporates Benefit-Risk Tradeoffs

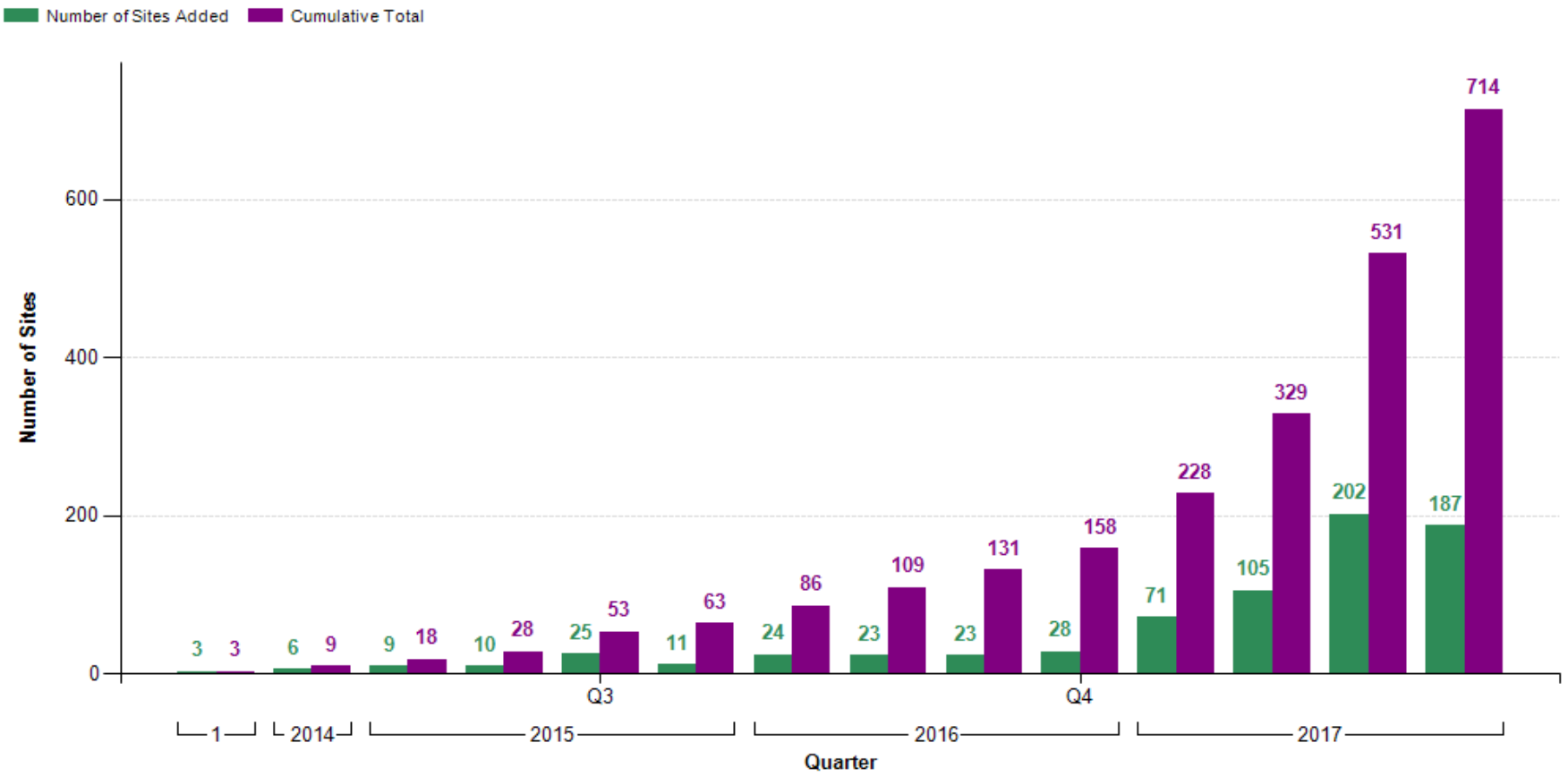
- FDA should request the minimum information necessary to adequately address the right regulatory question or issue
- Industry should submit material to FDA, including premarket submissions, that are least burdensome for FDA to review
- The most efficient means should be used to resolve regulatory questions and issues

Least Burdensome Approach

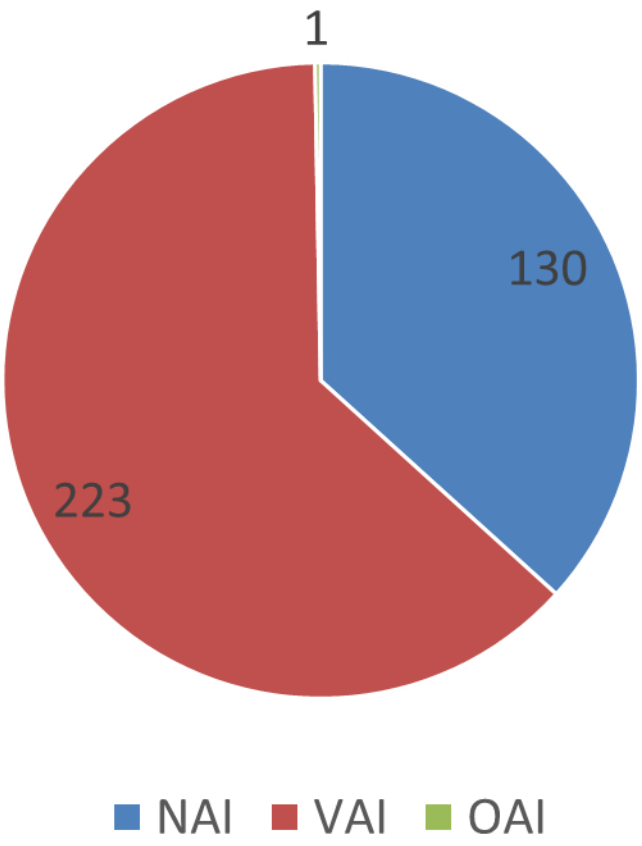
Expanded Application Incorporates Benefit-Risk Tradeoffs

- Provide the right information at the right time
- Regulatory paradigms should be designed to fit the technology
- Leverage data from other countries and decisions by national medical device regulatory authorities to the extent appropriate and feasible
- Apply least burdensome principles in international medical device convergence and harmonization efforts

MDSAP Audits



MDSAP Audit Outcomes



Voluntary Program Pilot

What is the pilot?	What Does FDA get?	What changes?
• The pilot involves voluntary participation in a third-party maturity appraisal performed by CMMI. • A baseline set of effectiveness metrics is collected • There will be pulse checks of those metrics at 90 – 180 day intervals	• FDA receives a progress report from CMMI of how the quality system is performing at the appraisal • FDA receives a better set of objective metrics as a baseline to monitor progression and benchmark • More engagement and feedback on quality objectives	• Support and guidance from appraisers on improvement • Collaboration on driving improvements and issue resolution • Removal from the surveillance work plan • Reduction in manufacturing submission requirements and faster approval for implementation • Waive some pre-approval inspections

FR for the October 10, 2017 Public Meeting
https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm568069.htm

PMA CtQ Pilot

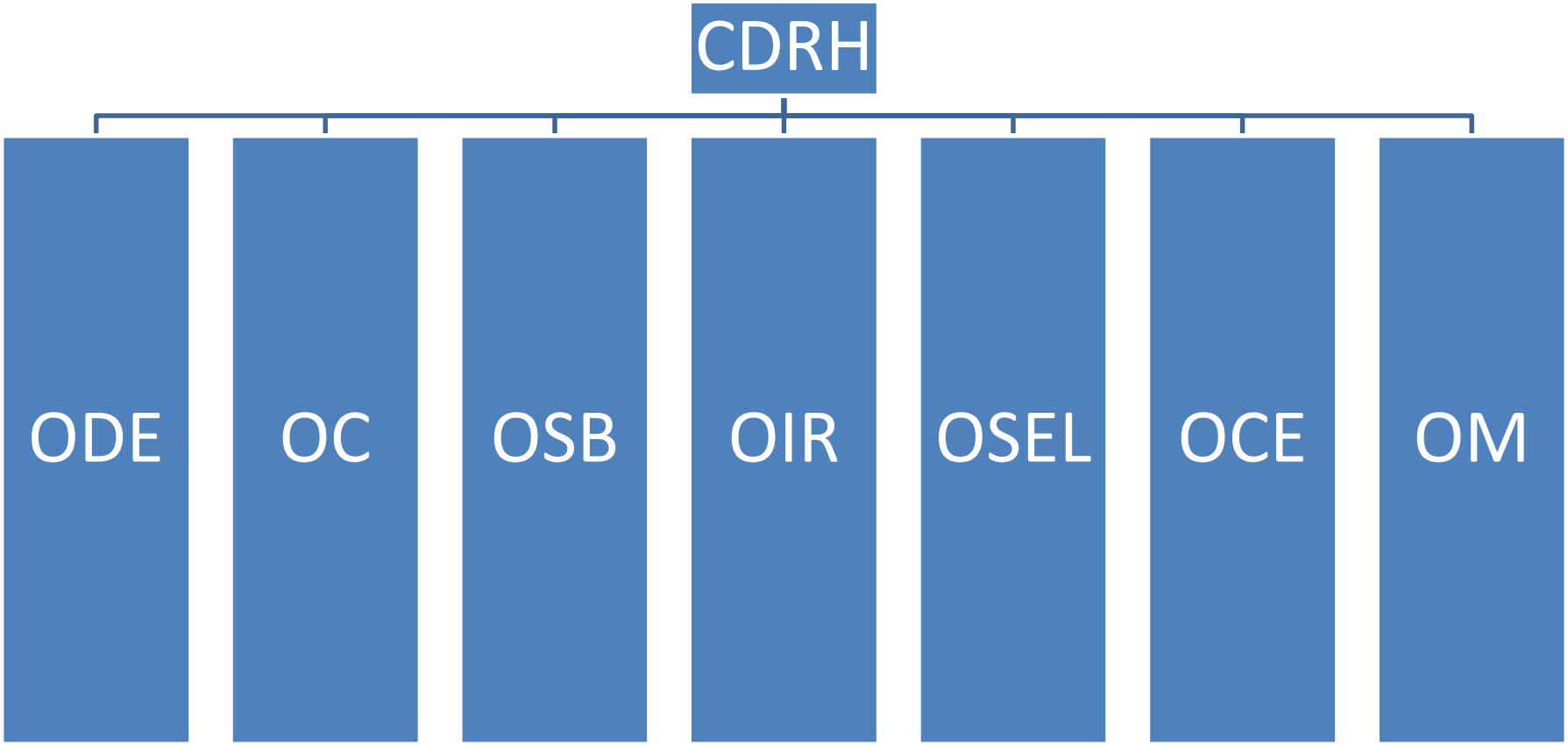
What is the pilot?	What Does FDA get?	What changes?
• Early interaction with FDA through pre-submission process on device characteristics that are critical to quality and how they are controlled	• Earlier engagement on manufacturing reviews • Improved understanding of essential device features and manufacturing processes	• Waive preapproval inspection prior to PMA decision • Conduct a focused inspection after PMA approval decision

FR for the PMA CtQ Pilot
https://www.federalregister.gov/documents/2017/09/12/2017-19258/center-for-devices-and-radiological-health-premarket-approval-application-critical-to-quality-pilot

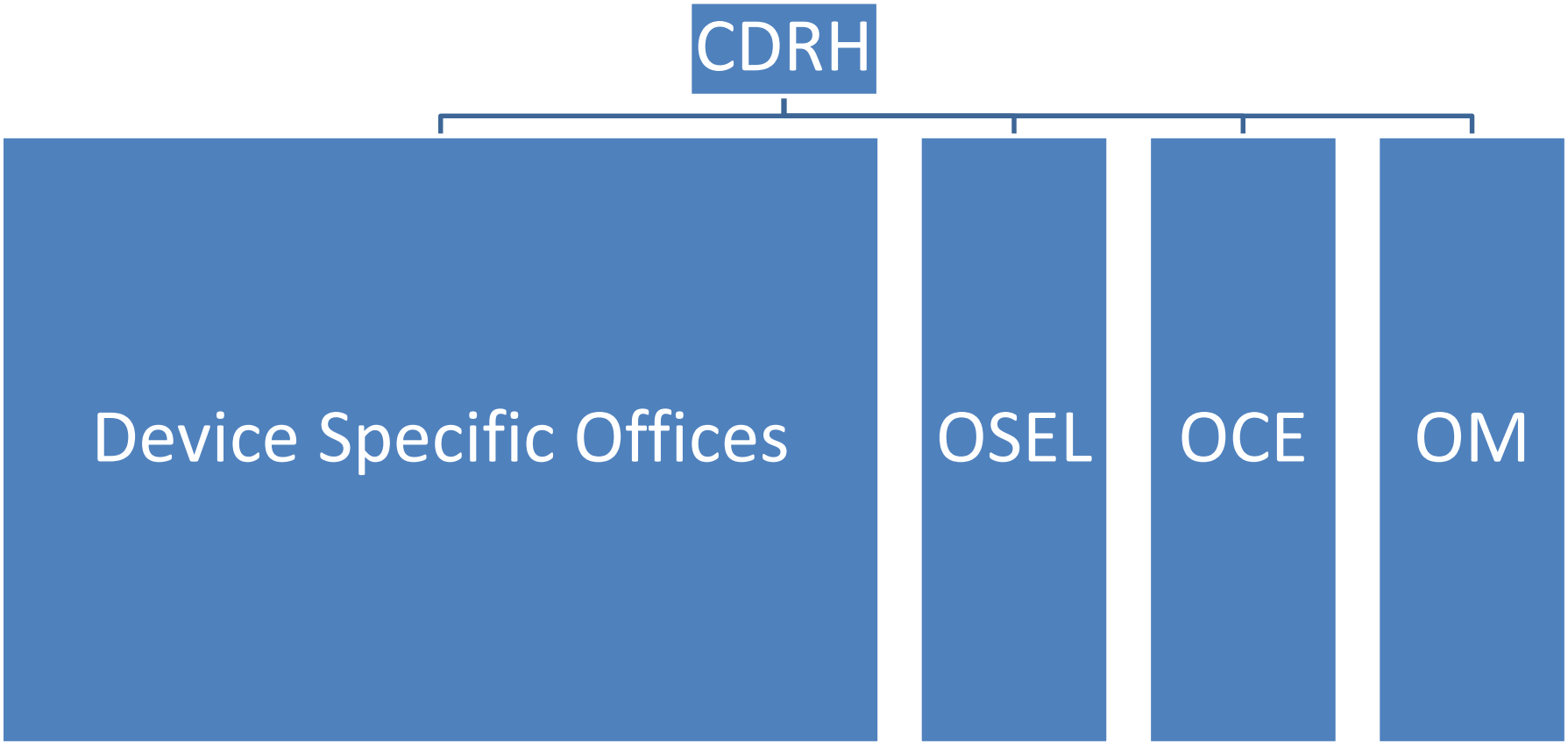
Novel Approaches

MDSAP	PMA CtQ	Voluntary Program
• Compliance audit meeting multiple international jurisdictions • Replaces routine FDA surveillance inspection	• Engagement with FDA on key device characteristics, manufacturing controls • Faster PMA decision, targeted inspection following approval	• Maturity appraisal identifying value provided to customers and business • Replaces routine surveillance inspection, streamlines PMA 30 day notice and site change reviews, fosters interactive approach with FDA

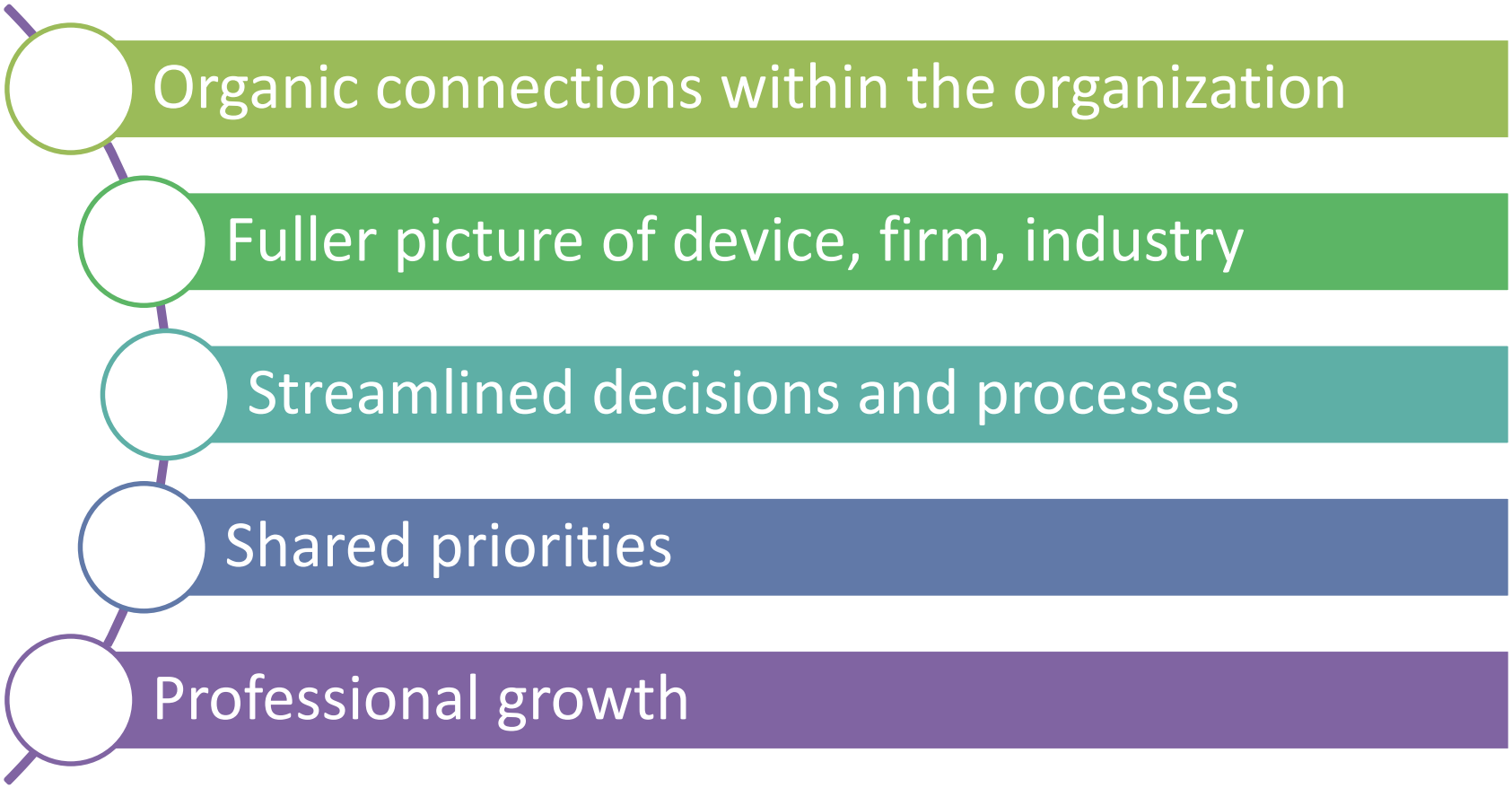
CDRH Total Product Life Cycle



CDRH Total Product Life Cycle



TPLC Goals


Organic connections within the organization
Fuller picture of device, firm, industry
Streamlined decisions and processes
Shared priorities
Professional growth


FDA
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