The FDA's Case for Quality:
Voluntary Pilot Program Update

Case for Quality

Why

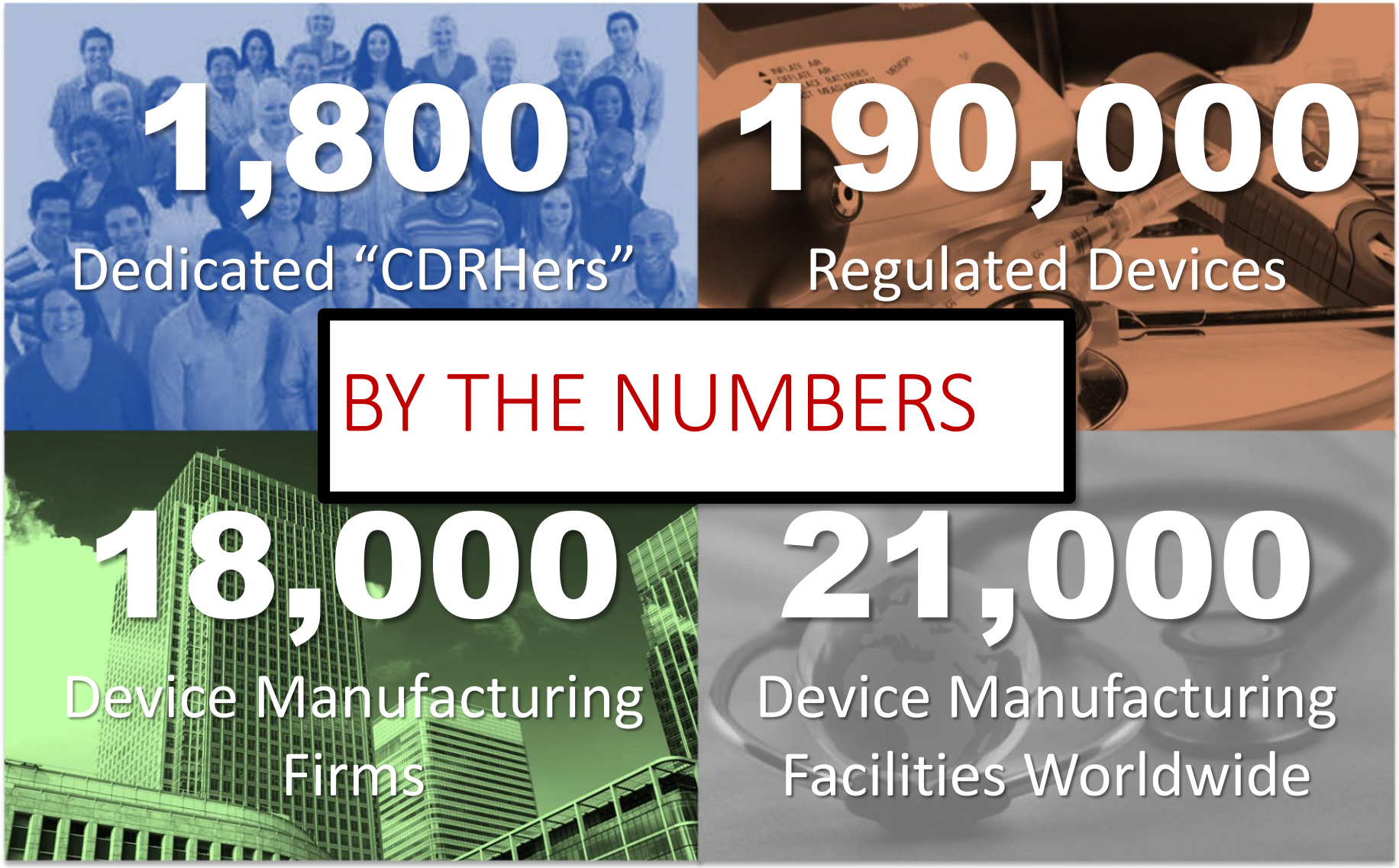
Risk to patients from quality issues and hampered innovation in manufacturing and product development practices

- High industry focus on meeting regulatory requirements versus adopting best quality practices
- Low investment in automation and digital technologies
- No competitive market around medical device quality

What

Collaborative effort that focuses on organizational excellence and product quality

- New ways to assess organizational performance, focusing on quality, shifting from inspection
- Adapt regulatory oversight to increase agility, responsiveness, simplification, error-proofing, and enable continuous rapid improvement
- Drive connections within systems, increase visibility into product quality to enable market drivers


1,800
Dedicated "CDRHers"
190,000
Regulated Devices
BY THE NUMBERS
18,000
Device Manufacturing Firms
21,000
Device Manufacturing Facilities Worldwide

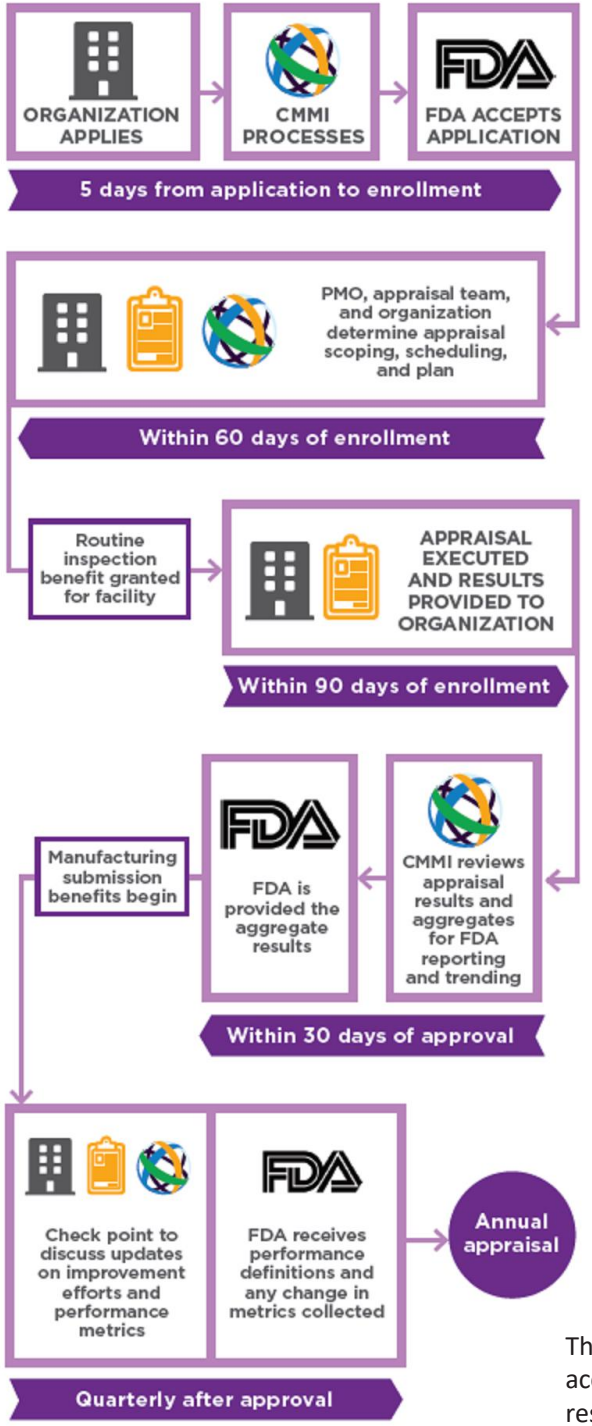
www.fda.gov

A new paradigm

Voluntary Medical Device Manufacturing and Product Quality Pilot

Pilot program

- 3rd-party maturity appraisal that leverages the Capability Maturity Model Integration (CMMI) framework to assess a medical device organization's capability to produce high-quality devices and increase patient safety
  - Quarterly progress check with lead appraiser
  - Quarterly metrics/KPI submission to FDA
- Pilot was announced on December 28, 2017 and will continue through December 28, 2019



FDA adjustments

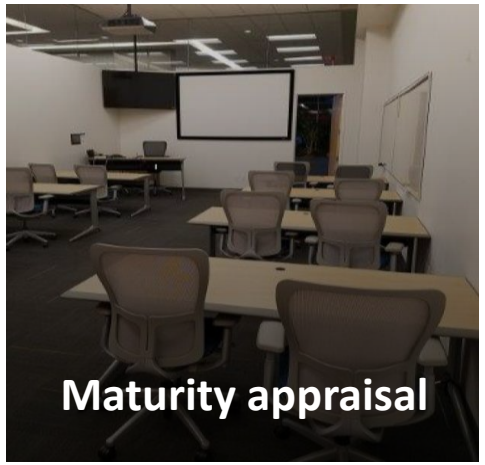
- Forgo surveillance, post-approval, and risk-based inspections
- Manufacturing change notice submissions
  - Streamlined submission
  - Accelerated acceptance 5 business days vs. 30 days
- Manufacturing site changes
  - Streamlined submission
  - Accelerated approval – 10 business days
- Original PMA manufacturing section
  - Streamlined submission
  - Forgo preapproval inspection

These changes reduce the burden and disruption of inspections, accelerate the review and approval process for changes, and shift resources to innovation and improvement


13

Changing the status quo

FDA Inspections



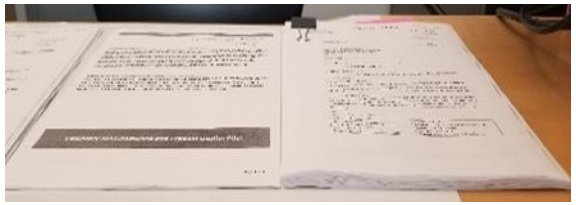
Defense **Value**

Learn

Apply

Pre-Approval Inspections

30 Day PMA - Least burdensome



13 Hours is the Benchmark!

- **Changes per PMA**
- **Documentation**
- **Time (88% ≤ 5 days)**

- Hesitancy → Engagement
- Problem solving mindset
- New opportunities, collaborative learning, and ideas
- Assumptions and reactiveness → Understanding and insight

CDRH Pilot metrics to date

Current Pilot Statistics

- 49 Enrolled sites
  - 45 Active Sites/22 Companies
  - 5 Multi-site appraisals
  - 14% are FDA recognized small businesses
  - Class I Only Sites: 2
  - Class II Only Sites: 6
  - Class III Only Sites: 3
  - Class I and Class II Sites: 6
  - Class I and Class III Sites: 0
  - Class II and Class III Sites: 16
  - All Class Products at Site: 12

Inspection Metrics

- Routine Inspections Waived: 45
- Pre-Approval Inspections Waived: 4
- For causes that occurred: 3
  - No observations
- Foreign sites: 14

CDRH Metrics

- 45+ Modified change notices reviewed
- 88% Reviewed in 5 days or less
  - Average review time (2.8 days)
- 1 Reviewed in 10 days with 7 changes in one submission
- 3 required the 30-days to complete
  - 1 had drug-component change that required CDER consult
  - 1 site was not yet approved for the modifications
  - 1 Required additional subject matter consults

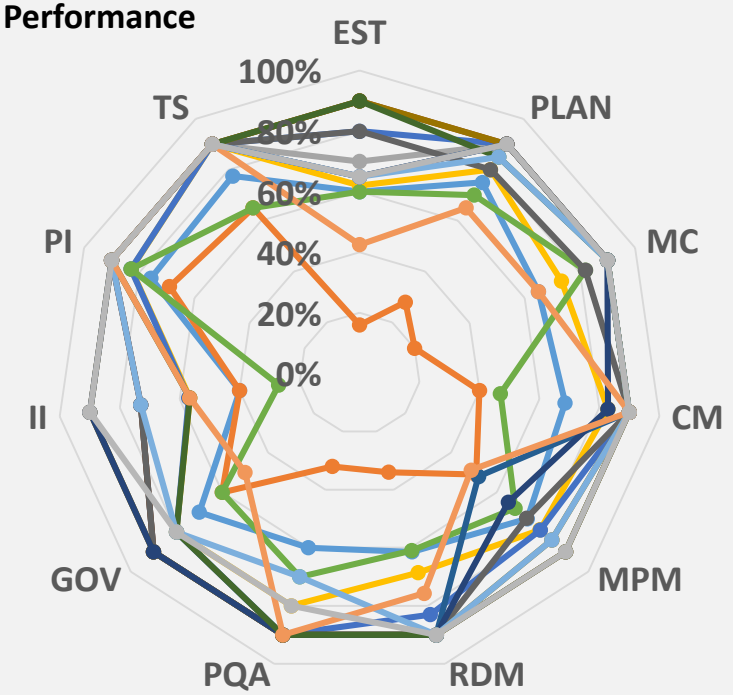
Site transfer

Streamlined site transfer submission developed by ODE reviewers

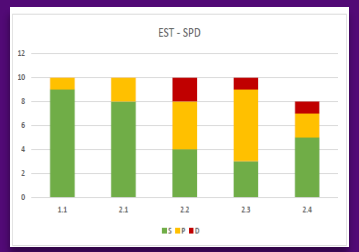
- 3 participants to testing in Q1 of 2019
- Target 10 business day review

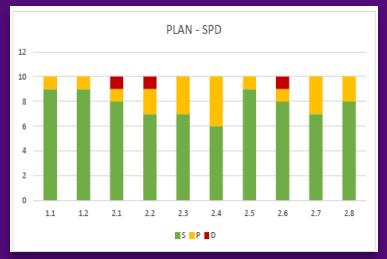
What is FDA learning?

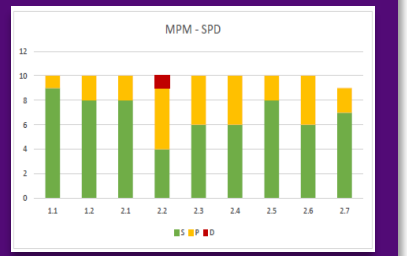
Practice Area Performance



Aggregated Results







Pilot data observations

Appraisal process provides more insight and granularity into organizational performance than compliance audit

- Participants sites all have good compliance history
- Wide range of organizational performance

Aggregated performance details provide data-driven opportunities for systemic improvement across manufacturers and in regulatory interactions

- Improve performance measurement and management capabilities and systems
- Systems considered “business operations” are not considered part delivering quality and significantly impact functions typically audited for compliance
- CAPA System has shifted from issue resolution and continuous improvement system to high-burden documentation system for regulatory use (Not driving problem-solving and continuous improvement)

Pilot experience results

Post-Appraisal Survey Results:
(194 respondents)

Experience with appraisal
positive: 91.2%
neutral: 8.8%
negative: 0%

Value to product quality
yes: 86.3%

Conflict with compliance
no: 97.9%

Appraisal has value add
yes: 93.7%

Would recommend pilot
NPS +49 **(n=41)**

Comments:

- The objectives were clearly defined and the meetings and line of questions were **well-organized**.
- CMMI Consultants were **knowledgeable** and **great to work with**.
- Every effort was made to **put me at ease** and help me **understand the process**.
- I felt **90% of the appraisal results resonated** with me and what I know about our organization. That's a pretty good success rate for such a short time with us.
- The majority of weaknesses identified during the process highlight **legitimate areas for improvement**.
- A **huge leap forward in identifying the issues** that hold back a compliant, high-performing company.
- The overall approach, if supported, genuinely will be **more effective** than the reactionary approach to traditional inspections.

Experience:

"The maturity assessment provided us with an evaluation of the health of our operations, engaging individuals most familiar with our day-to-day work. The assessment helped us identify strengths and weaknesses and opportunities for further consideration.

As important, the assessment helped us develop operational excellence metrics that will measure the continuous execution and quality oversight of our processes. Now, a cross-functional team is exploring how we can capitalize on what we learned to further advance our processes and our ability to provide world-class products and services to our customers."

Kathie Bardwell
SVP & Chief Compliance Officer
STERIS Corporation

Effectiveness

Pilot impact metrics

Value analysis was based on data provided based on comparison to traditional compliance audits and an average manufacturing change implementation improvement of 21 days for pilot sites as compared to non-pilot sites

Patients/Providers

- 37% of manufacturing changes were to improve product quality and were implemented 21 days faster
- Increase in manufacturer improvement submissions, including changes to reduce manufacturing defects
- 882 High-risk patients received treatment due the 21 day difference → Greater than $10 Million dollar savings in annual healthcare costs
- Increase implementation of manufacturing automation to improve traceability and error-proofing (18%) of changes

FDA

- Increase in submissions to improve product quality
- Increased engagement on process improvement
- Improved submission decision consistency
- Increased sponsor engagement
- Increased resource visibility and allocation for inspections and reviews
- Improved impact traceability
- Improved data-analytics on changes, products, and sites
- Best practice sharing among manufacturers
- 11 – 46% Improvement in performance over 1 year

Manufacturers

- Assessment costs
  - FDA/ MDSAP: $140-350K – Site operations disrupted
  - Pilot appraisal: Less than $80K – No operation disruptions
- Reported change notice value examples
  - $286 K Annual savings
  - 10 Dedicated inspection employees reallocated to higher value operations due to improvement
  - 11% Production capacity increase → Greater than $15 million in product sales
- Strategic/systemic improvement implementation vs compliance resolution

Disclaimer:

All efforts are being done in the current systems and structures

As pilot continues we may encounter system or resource limits

Need to continue to build on success and think differently

Next Steps

Acting on learning

#makeCAPACool	"Neutral Zone" for Safety	Leadership Engagement	Quality as a Career
• Resetting CAPA to continuous improvement framework • CAPA system has evolved into a compliance-centric regulatory process as opposed to continuous improvement/problem solving cycle.	• Non-competitive, collaborative, sanction-free environment • Enable a significantly improved environment for identifying safety signals, proactive industry improvement strategies, and performance analytics	• Influence leadership in medical device companies to participate in quality initiatives • Remove the perspective of "quality" being owned by the quality function which results in quality being synonymous with compliance.	• Establish "Quality" as a fundamental discipline at the College/University level as a foundation in the MedTech industry • Quality is not viewed as a positive first step for undergraduates and young professionals. Quality theory and principles are not part of undergraduate curricula.

Improving Pilot Program

- **Expanding Regulatory Modifications**
  Objective: To identify, develop, test, and finalize any additional regulatory modifications that can enhance safety and improve efficiency for participants of the Program.

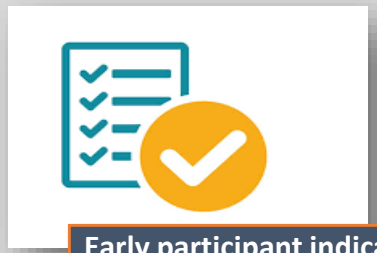
- **Performance Measures**
  Objective: To reduce reappraisal scope and/or increase the length of time to reappraisal via data transparency, by identifying additional information needs and outcomes, considering improvement opportunities to the methodology, and discussing potential synergies for continuous monitoring.

- **Reappraisals**
  Objective: To define and develop the standards and exceptions for conducting reappraisals. Increase the value of follow-up appraisals.

- **Multi-Site Appraisals**
  Objective: To define and develop the standards and exceptions for conducting multi-site appraisals.

- **Program Features**
  Objective: To identify, develop, test, and finalize new desired features of the Program, as well as identify, analyze, and resolve any undesirable features of the Program.

Enhance Performance Metrics



Move from compliance indicators to quality indicators

Early participant indicators

- NCR
  - NCR trends
  - NCR resolution timelines
- CAPAs
  - Counts open vs. closed vs. overdue
- Field actions open per site
- ECO#/turn time
- Scrap rate trends (positive vs. negative trend events)
- Projects exceeding planned timeline
- Yield trends (positive vs. negative trend events)

Recent performance indictors submitted

Quality Indicators	Details Submitted
First Pass Yield Financial Damages CAPA Management Operational Effectiveness	• Details of what is monitored • Three year trends • Annual quality target • Quarterly trend
Quality Domains	
Safety	• Device and procedure related adverse events in commercial and clinical compared to literature search meta- analysis for similar products and procedures • Quarterly comparison rates
Effectiveness	• Clinical and registry data compared to hypotheses identified in study plans • Procedure related adverse events compared to literature search meta-analysis for similar products and procedures for training and IFU effectiveness • At least annually
Reliability	• Accelerated voltage life test • Run down testing on devices returned with remaining battery life • Device adverse events benchmarked against similar product
Availability	• Inventory and sales volume by geography • Quarterly with management review

Why quality indicators, KPIs, and metrics?

FDA

CDRH

Visibility

- Direct observation – new way to demonstrate control
- Problem solving
- Make abnormal conditions stand out

Least burdensome

- Simplification
- Reduce error
- Improve information exchange
- Increase value

Safety & Innovation

- Address problems immediately
- Predict and prevent issues
- Accelerate improvement
- Accelerate new technologies
- Improve patient outcomes

Ongoing work

Finalizing pilot summary and assessment report

CDRH has received budget authority to support effort

Developing operationalization proposal and strategy for 2020

Continuing current pilot efforts and improvements and engagements as long as capacity allows

Questions?

Information, Engagement, and Collaboration

21

- For additional information, enrollment, or feedback
  - http://mdic.org/cfq/
  - http://mdic.org/cfq/enroll/
  - caseforquality@fda.hhs.gov
- Program Updates
  - http://mdic.org/mdicx/
- Public Workshop
  - https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm568069.htm
- Pilot FR Notice
  - https://www.federalregister.gov/documents/2017/12/28/2017-28044/fostering-medical-innovation-case-for-quality-voluntary-medical-device-manufacturing-and-product
- For any issues or concerns contact
  - Francisco.vicenty@fda.hhs.gov or Jennifer.Kelly@fda.hhs.gov.

Thank you

www.fda.gov