The FDA’s Case for Quality: Voluntary Pilot Program Update
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Cisco Vicenty
Program Manager, Case for Quality
Strategic Initiatives Staff
Office of Product Evaluation and Quality, CDRH
How are we progressing?
## CDRH Pilot Details To Date

**Current Pilot Statistics**

- 51 Accepted sites
  - 45 Active Sites/23 Companies
  - 5 Multi-site appraisals
  - FDA recognized small businesses
- All types of product risk classifications at site
- Additional enrollments
  - Non-regulated site
  - Pharmaceutical only sites

**Inspection Metrics**

- Routine Inspections Waived: 46
- Pre-Approval Inspections Waived: 5
- For causes that occurred: 4
  - No observations
  - Foreign sites: 16

**Observations**

- Increased industry investment
- Cross-training and collaboration
  - Practice sharing
- Focus on culture
- Issue resolution and patient safety focus
CDRH Pilot metrics to date

**CDRH Metrics**
- 60+ Modified change notices reviewed
- 73% Reviewed in 5 days or less
  - Average review time (3.2 days)
- Issues observed
  - Some submissions needed extra expert consults
  - Expanding product areas
  - Submission tracking/visibility
  - Variability in review focus
  - Training
  - Communication

**Site transfer**
Streamlined site transfer submission developed by CDRH reviewers
- Target: 180 days → 10 business day review
- First site change
  - 95 Days
    - Internal communication
    - Resource
    - Training
- Second site change
  - 13 Days

**Improvement Activities at CDRH**
- Improving training on pilot
- Improve clarity and expectations
- Increasing engagement with review teams
- Improving incoming submission tracking/communication
- Improving results sharing across review teams

Communicate: CaseforQuality@fda.hhs.gov
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.
Next Steps
Ongoing work

Operational program proposal and strategy for 2020

• CfQ VIP Charter Development
• Establishing trusted operational structure

Continuing current pilot efforts and improvements

• Expanding areas of focus in development
• Improving data and information sharing
• Improving regulatory review capability for other submission types.

Evaluating program applicability for manufacturers struggling with compliance

Improving systemic barriers identified
Questions?
Thank you