Welcome to Today's FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

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Digital Health

SOFTWARE PRE-CERT PILOT PROGRAM STATUS UPDATE WEBINAR

Topics covered at Kickoff Meetings

- Pre-Cert Pilot Goals and Objectives
- FDA Perspective
- Pre-Cert Pilot Program Logistics
  - Points of Contact
  - Engagement Plan and Schedule
- Site Visits and Data Collection: Excellence Principles and Common Validating Perspectives
- Questions and Discussions

FDA Pre-Cert Pilot Overview

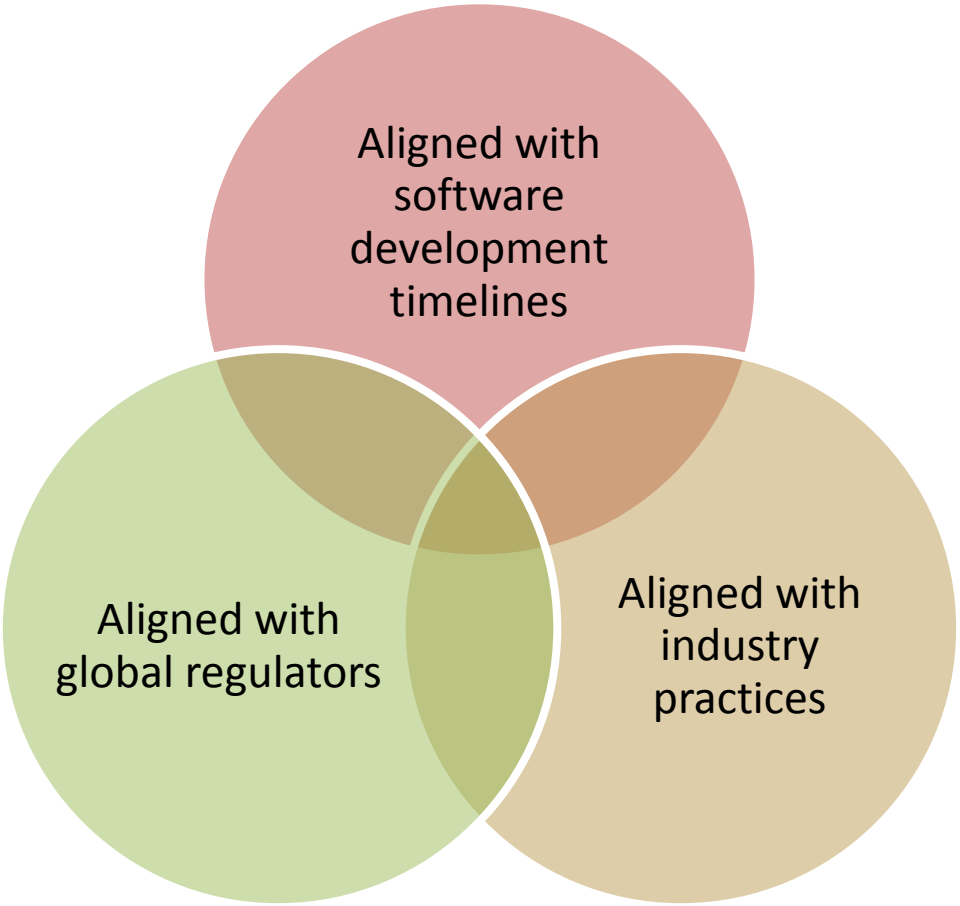
A company-based, streamlined regulatory approach for Software as a Medical Device that relies on a demonstrated Culture of Quality and Organizational Excellence

CDRH Objectives

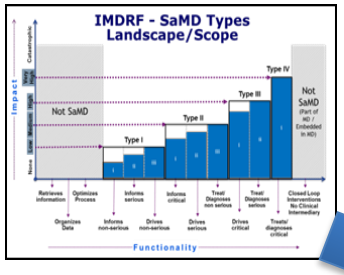
- Enable “**patient centered**” public health as digitization touches every aspect of healthcare.
- Foster **trust in innovative technologies** as an enabler of a new healthcare paradigm.
- **Partner with customers** to be "digital-future ready”.

CDRH: Envisioning a New DH Paradigm

An agile and learning regulatory paradigm that is:



FDA Pre-Cert Concept



Based on
SaMD Risk +
Pre-Cert level

e.g. lower-risk software, certain modifications

Commercial Distribution & Real-World Use

FDA Pre-Cert level

Streamlined Premarket Review

DH
FDA Pre-Cert

Real World Data Collection

FDA Pre-Cert effectiveness feedback

Assessment effectiveness feedback

DH
FEEDBACK

Regulatory Science

Real-World Evidence

Clinical Trials

Patient Preference

Outcomes research

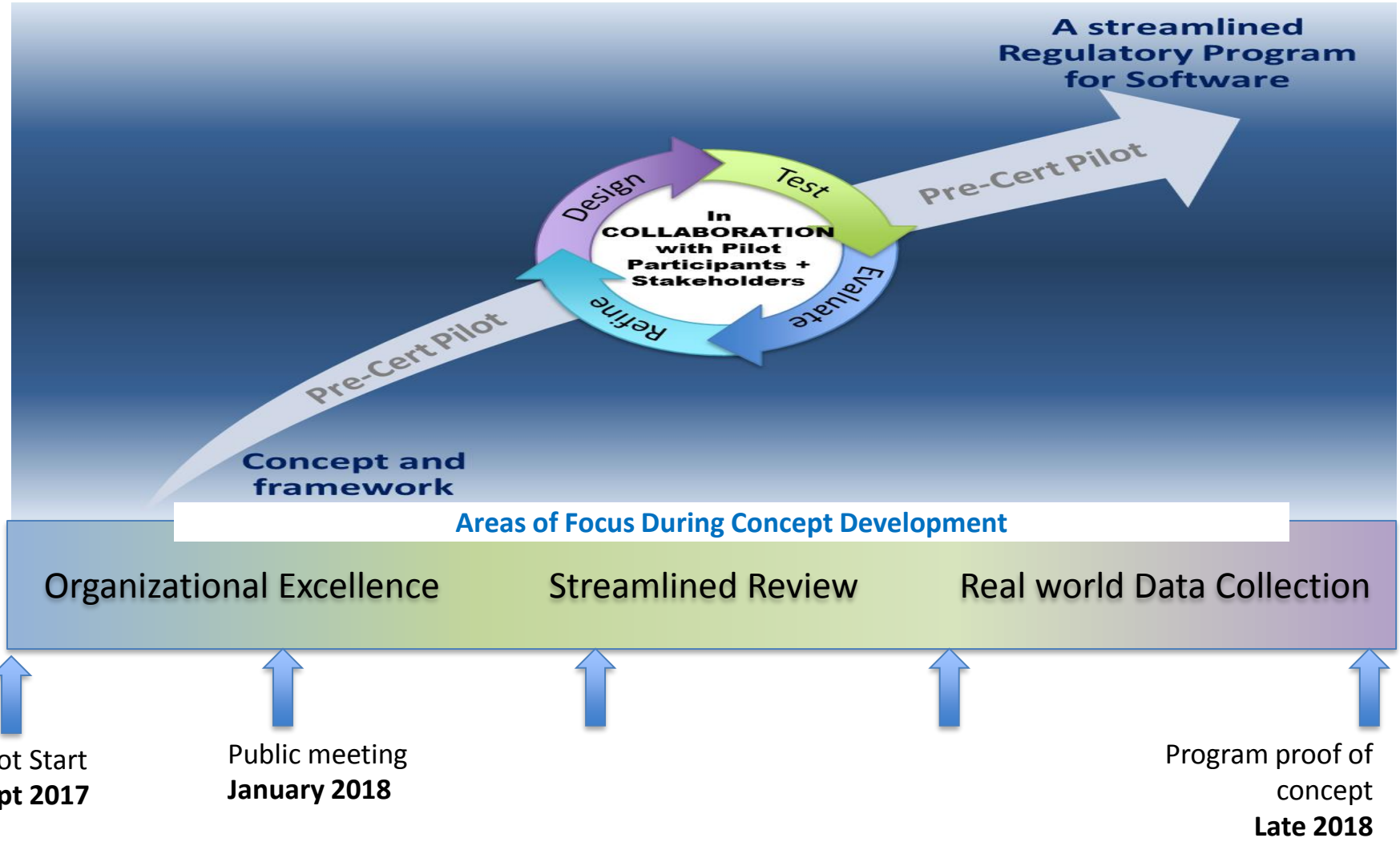
Pre-Cert Program Objectives

1. Enables a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion;
2. Is an easy to follow process for obtaining FDA Pre-Cert and is easily maintained by the FDA and industry;
3. Ensures high quality and safe and effective software throughout the life of the product by enabling companies to demonstrate their embedded culture of quality and organization excellence (CQOE);
4. Enables measurement of “Key Performance Indicators” (KPI) independent of organization size, deployment strategies, or computing platforms and provides credit for what a company is doing “right”;
5. Enables for scalability, variation and evolution of software development and management processes in use today or others that may exist in the future; and
6. Not static -- a program that learns and adapts (i.e., adjusts/tweaks/evolves scorecard elements, key dimensions, and measures) based on the effectiveness of the program.

FDA: Key Deliverables

Program component	Deliverable/Outcomes of Pilot
Pre-certification Framework	Measures to benchmark CQOE elements
	Criteria to evaluate measures
	Levels of certification correlated to SaMD risk type
	Prototype mechanism for companies to collect measures for pre-certification as part of their business operations
	Mechanics for obtaining and maintaining certification
Regulatory Pathway Decision Criteria	Develop criteria using IMDRF SaMD risk framework and levels of certification
	Develop and test mechanism/tools for pathway determination
Processes for Streamlined Regulatory Review	Explore optimal review method and content
	Explore options for review method content to Pre-Cert status
Post-Market Evidence Collection	Identify use scenarios and collection scope and methods
Program Feedback and Evaluation	Identify appropriate Pre-Cert program metrics and KPIs to measure effectiveness of the program

From Concept to A Program: *An Iterative Approach*

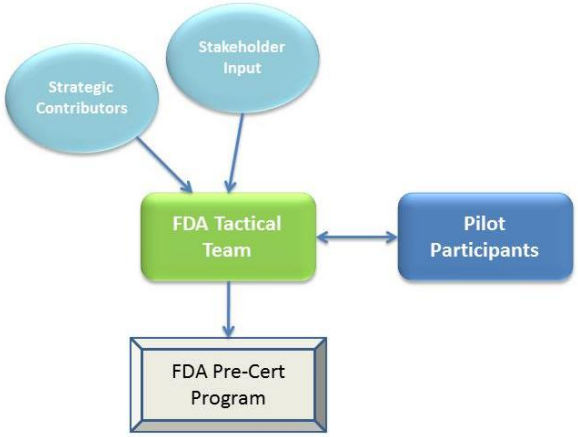


FDA Pre-Cert Pilot Engagement

FDA Team Structure & Governance

FDA Site Visit Team
(5-7 Members)

1. Bakul Patel, *Associate Director, Digital Health*
2. *Point of Contact - Marisa Cruz/ Cathy Bahr/John Murray*
3. *Pre-Market office*
4. *Post-Market Surveillance*
5. *Compliance*
6. *Entrepreneur-in-Residence*



POC Key Responsibilities:

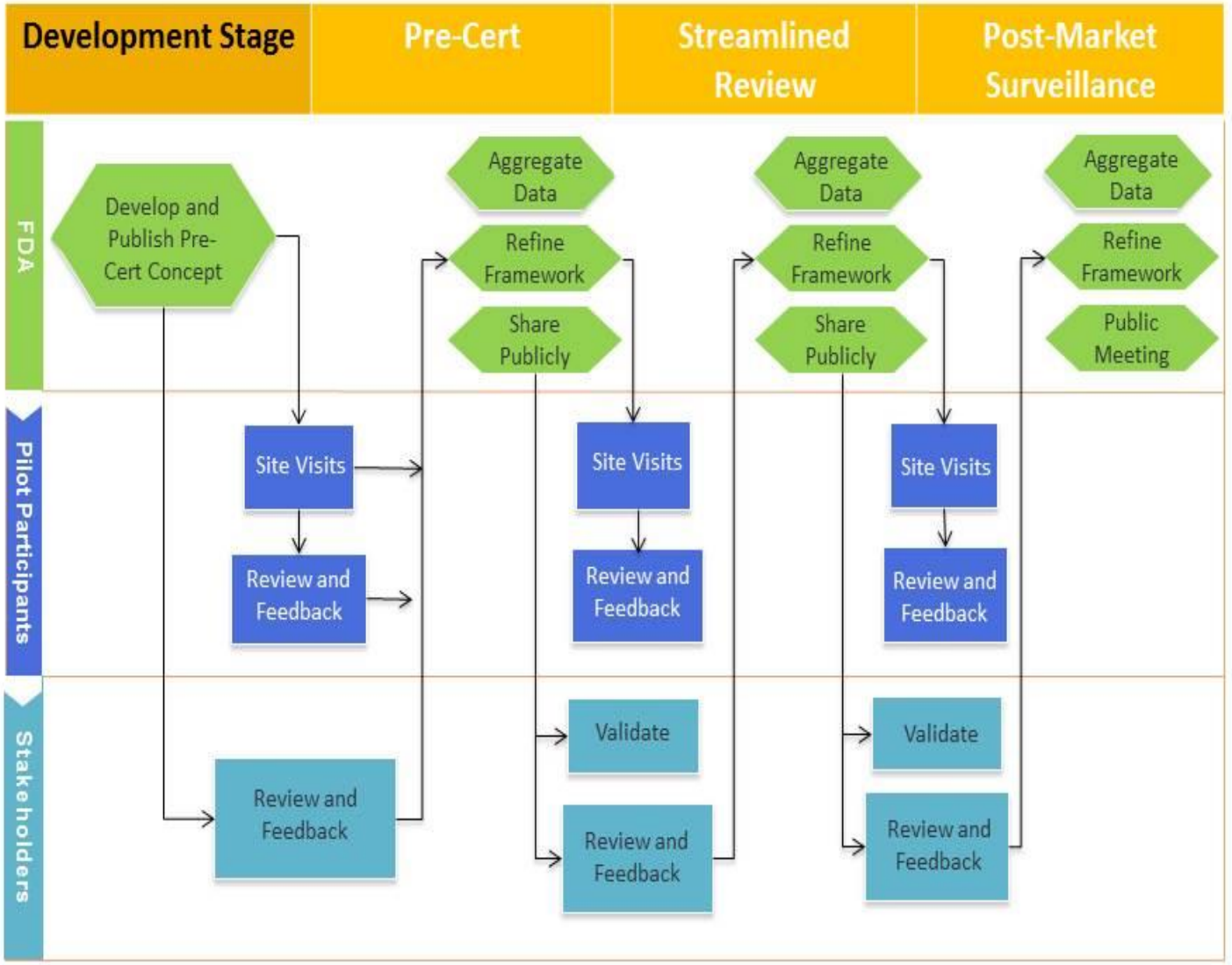
- Serves as primary liaison between Pilot Participants and FDA Tactical Team
- Facilitates site visit, including exchange of information prior to and following visit
- Leads review and analysis of company-provided data, including synthesis and aggregation for purposes of public presentation or disclosure

Pilot Participant Engagement Plan

Activity Topic	Lead	Outcomes
Kick-Off Meeting	FDA	• Set frequency of engagement • Review product roadmap • Assign FDA POC for PP
CQOE Collection Plan	FDA + PP	• Review of PP CQOE measures • Set agenda for site visit
CQOE Collection	PP	• Collect CQOE measures • Establish mechanism for data sharing
Consolidate CQOE Measures	FDA + PP	• Aggregate and normalize CQOE measures across PP **
Update CQOE / KPI	FDA + PP	• Update Pre-Certification Framework **
Determine Pre-Cert Status	FDA	• Establish Pre-Cert status
Public Meeting	FDA + PP	• Set agenda for public meeting • Determine findings to be shared at public meeting **
Product Review Plan	FDA + PP	• Product categorization • Set post-market data collection plan **
Product Review	FDA + PP	• Product review
Pilot Participant Debrief	FDA + PP	• Aggregate lessons learned ** • Refine CQOE measures ** • Refine product review pathway

** opportunities to share publicly

Staged Area of Focus



Pre-Certification Framework: Principles of Excellence

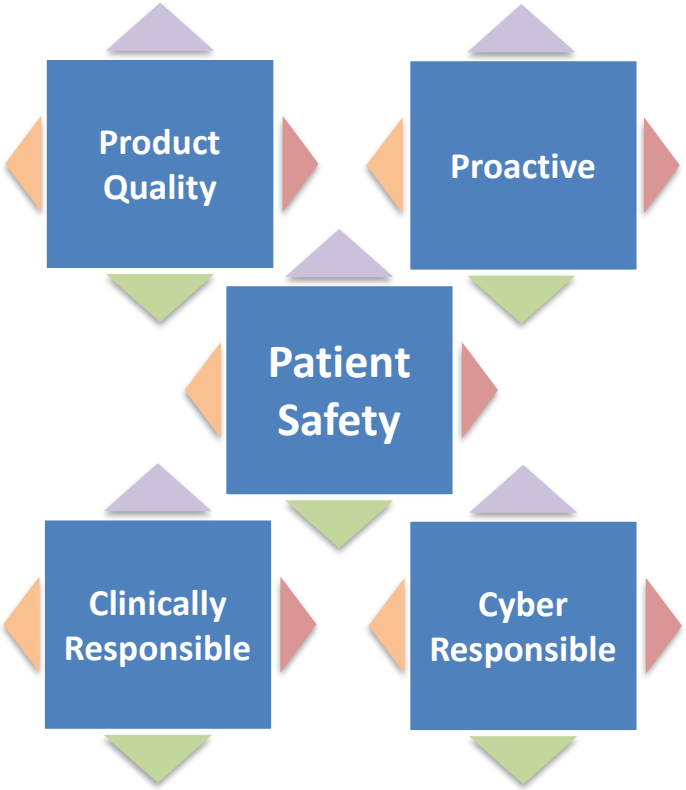
Excellence Principles

Patient Safety	Demonstration of a commitment to providing a safe patient experience, and to emphasizing patient safety as a critical factor in all decision-making processes.
Product Quality	Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the highest level of quality.
Clinical Responsibility	Demonstration of a commitment to responsibly conduct clinical evaluation and to ensure that patient-centric issues including labeling and human factors are appropriately addressed.
Cybersecurity Responsibility	Demonstration of a commitment to protect cybersecurity, and to proactively address cybersecurity issues through active engagement with stakeholders and peers.
Proactive Culture	Demonstration of a commitment to a proactive approach to surveillance, assessment of user needs, and continuous learning.

Company Specific –
Common Validating Perspectives

Scorecard Framework

Excellence Principles



Common Validating Perspectives

Process Perspective

Organizational Resource Perspective

Customer Perspective

Learning and Growth Perspective

How will we employ continuous learning and improvement to support our commitment to the excellence principle?

Objectives Measures Initiatives

Key Performance Indicators

Library of qualitative and quantitative measures that evaluate excellence

Bridging to KPIs: Appraisal Questions

EP	CVP	Appraisal Questions	KPI
Patient Safety	Organizational Resource	How do employees identify, report, and act on patient safety issues?	
	Customer	Does your organization contact your customers regarding patient safety issues?	
	Learning and Growth	How does your organization identify future development or skills needs with regards to patient safety?	
	Process	How does your organization validate corrective actions to prevent patient safety issues and inform patients/customers about potential issues?	

Bridging to KPIs: Appraisal Questions

EP	CVP	Appraisal Questions	KPI
Product Quality	Organizational Resource	What tools do employees have available to identify and track product quality issues?	
	Customer	How does your organization monitor customer reports of product quality issues?	
	Learning and Growth	How do you leverage real-world evidence in improving product quality?	
	Process	How are quality risks in marketed products identified and managed?	

Bridging to KPIs: Appraisal Questions

EP	CVP	Appraisal Questions	KPI
Clinical Responsibility	Organizational Resource	How do you ensure that employees responsible for clinical evaluation have the knowledge, skills, and experience to understand clinical benefits and risks?	
	Customer	How does your organization incorporate customer perspectives into product development and modification?	
	Learning and Growth	How does your organization utilize learning from external sources regarding clinical risks and benefits relevant to product design or process improvements?	
	Process	How does your organization identify weaknesses or gaps in the process of clinical evaluation?	

Bridging to KPIs: Appraisal Questions

EP	CVP	Appraisal Questions	KPI
Cybersecurity Responsibility	Organizational Resource	How is leadership made aware of cybersecurity issues that arise in product design, development, and validation?	
	Customer	How does your organization assess customer needs and concerns related to cybersecurity?	
	Learning and Growth	How do employees throughout the organization learn about cybersecurity issues?	
	Process	How does your organization monitor process optimization and improvement activities for cybersecurity?	

Bridging to KPIs: Appraisal Questions

EP	CVP	Appraisal Questions	KPI
Proactive Culture	Organizational Resource	How is the value of operational and product improvement efforts measured?	
	Customer	How does your organization communicate with customers about new or emerging issues?	
	Learning and Growth	How often are employees rewarded for proactively identifying and taking action on opportunities for improvement?	
	Process	How are the goals and vision for a proactive corporate culture communicated to the organization?	

Questions and Considerations

- How would you refine the excellence principles and/or common validating perspectives to better reflect your understanding of excellence in an organization? How?

- How do you use the common validating perspectives to demonstrate commitment to the excellence principles?

- How does your organization use metrics to evaluate your performance against these excellence principles?

FDA Pre-Cert Pilot Site Visits

Pre-Cert Site Visit: Objectives

- To experience and understand methods and processes for establishing and demonstrating a culture of quality and organizational excellence.
- Understand current practices.
- Have a clear understanding of how your organization approaches and tracks progress towards each excellence principle.
- Identify items to enhance the excellence framework.

Key Points

- The site visit is NOT an audit or inspection.
- FDA and company will collaborate and be in a learning mode to refine the framework.

Pre-Cert Site Visit: Inputs

- Modifications and/or additions to excellence principles and common validating perspectives.

- Processes and measures used within the organization that align to business needs, rather than to traditional regulatory requirements.

- Mapping of processes and measures to CQOE (excellence) principles and perspectives.

Measuring Excellence in Your Organization

EP	CVP	Appraisal Questions	Rationale/Added Value	Key Performance Indicators/Measures
Patient Safety	Organizational Resource Perspective			
	Customer Perspective			
	Learning and Growth Perspective			
	Process Perspective			
Product Quality	Organizational Resource Perspective			
	Customer Perspective			
	Learning and Growth Perspective			
	Process Perspective			
Clinical Responsibility	Organizational Resource Perspective			
	Customer Perspective			
	Learning and Growth Perspective			
	Process Perspective			
Cybersecurity Responsibility	Organizational Resource Perspective			
	Customer Perspective			
	Learning and Growth Perspective			
	Process Perspective			
Proactive Culture	Organizational Resource Perspective			
	Customer Perspective			
	Learning and Growth Perspective			
	Process Perspective			

Inviting All Stakeholders To Provide Input

Building the Program Together

What FDA is doing

- Providing regular status updates on web site
- Holding regular discussion webinars
- Hosting public meetings (first meeting to be held at end of January)
- Supporting a docket to receive public input

What all stakeholders can do

- Associations, coalitions, alliances, and other common interest groups are encouraged to engage interested parties
- Groups should monitor the Pre-Cert status webpage
- Groups should stay engaged and collectively provide input to the docket
- All stakeholders should participate in webinars and public meetings

Questions ?

For questions related to Digital Health, please contact the Digital Health Team:
fdapre-certpilot@fda.hhs.gov

For general question, please contact the Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under the Heading: Specialty Technical Topics; Subheading: IT and Software

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