Fostering Digital Health Innovation

Developing the Software Precertification Program
Day 1: Setting the Stage
KEYNOTE

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Digital Health

SOFTWARE PRECERTIFICATION PILOT

PROGRAM UPDATE

January 30-31, 2018
Overview

Pre-Cert Program Overview
• Need for re-imagining
• Program concept and scope
• Program goals and roadmap

Iterating for success
• Foundational excellence principles
• Other excellence models review
• Pilot participant and stakeholder input

Objectives of this workshop
• Activating the “10th Participant”
• Clarifying program questions
• Hearing perspectives
• Getting input

Workshop overview
PRE-CERT PROGRAM OVERVIEW
The rapidly evolving nature of digital health is sparking a paradigm shift

**Current Regulatory Paradigm**
- Pre-market timeline suited for **hardware** based products
- **Deterministic risks**, known responsibilities, physical products
- **Stable program volume**: ~3,500 510(k) submissions / 2200 pre-submissions

**Digital Health Paradigm Shift**
- **Software** development timelines, software development practices + rapid iterations
- **Evolving issues**: cybersecurity, distributed responsibilities, non-physical products
- Potential for **exponential** increase in volume of submissions
Opportunities

Regulatory Development Kit

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FDA Pre-Cert Program

An organization-based streamlined regulatory approach

for

Software as a Medical Device

that relies on a demonstrated Culture of Quality and Organizational Excellence
Software as a Medical Device (SaMD)

**Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.**

**SaMD Algorithm**

- **SaMD inputs**
  - Data
    - (Lab results, Image, Medical device data, Physiological info, Symptoms, etc.)
  - Reference data, Knowledge base, Rules, Criteria, etc.

- **SaMD Algorithm**
  - Algorithm, Inference engine, Equations, Analysis engine
  - Model based logic, AI/ML, etc.

- **SaMD outputs**
  - Defined Use (Significance + Context)

**SaMD Algorithm**

**SaMD inputs**

- Data
  - (Lab results, Image, Medical device data, Physiological info, Symptoms, etc.)

- Reference data, Knowledge base, Rules, Criteria, etc.

**SaMD Algorithm**

**SaMD outputs**

- Defined Use (Significance + Context)

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Concept: A reimagined approach using FDA Pre-Cert

Based on SaMD Risk + Pre-Cert level

Streamlined Pre-market Review

Commercial Distribution & Real World Use

Real World Data Collection

DH FEEDBACK

FDA Pre-Cert effectiveness feedback

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FDA Pre-Cert Goals

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. Is a program that learns and adapts (i.e., adjusts/tweaks/evolves scorecard elements and key dimensions and measures) based on the effectiveness of the program.

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Pre-Cert Program Roadmap

2018

Pre-Cert – Development

Public Input

Late Summer

Develop: Excellence Appraisal Model

Develop: Streamlined Review Approach

Develop: Real World Data (access, approach and analysis)

2019

Program – Iteration

Dec

Jan

Public Input

Late Fall

Public Input

Minimum Viable Program

2018 Roadmap

- Define excellence enablers and results
- Define KPIs, calculations, thresholds
- Define appraisal methodology, tools, and criteria to collect and analyze
- Define tiers, criteria and thresholds for program participation
- Id methods for visibility/transparency
- Id application process
- Id legal/regulatory
- Id IT Infrastructure

Excellence

Appraisal

- Define SaMD risk categorization (leverage IMDRF framework)
- Define variable approaches based on pre-cert status and risk categorization
- Id legal/regulatory impact
- Id IT Infrastructure

Streamlined

Review

- Define data elements
- Define RWD assessment methodology
- Define impact of RWD process on pre-cert status/review approach
- Id methods for visibility/transparency
- Id legal/regulatory
- Id IT Infrastructure

Real

World

Data

(RWD)

- Define SaMD risk categorization (leverage IMDRF framework)
- Define variable approaches based on pre-cert status and risk categorization
- Id legal/regulatory impact
- Id IT Infrastructure

MVP functionality
Building the first component of the program

Based on SaMD Risk + Pre-Cert level

e.g. lower-risk software, certain modifications

Commercial Distribution & Real-World Use

Streamlined Premarket Review

Real World Data Collection

DH FEEDBACK

FDA Pre-Cert level

DH FDA Pre-Cert

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Co-creating the program with stakeholders

- In July 2017, we announced the Pre-Cert Pilot Program
- In Sept, we selected nine organizations to help build the program
- Proposed a framework to understand excellence
- From Oct-Dec, we conducted 2-day site visits – in 7 weeks:
  - Understanding desired program benefits
  - Clarifying program questions
  - Identifying common traits
  - Understanding appraisal challenges/opportunities

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All of our work stems from five Excellence Principles

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>Demonstration of a commitment to providing a <strong>safe patient experience</strong>, and emphasizing patient safety as a critical factor in all decision-making processes.</td>
</tr>
<tr>
<td>Product Quality</td>
<td>Demonstration of a commitment to the development, testing, and maintenance necessary to deliver SaMD products at the <strong>highest level of quality</strong>.</td>
</tr>
<tr>
<td>Clinical Responsibility</td>
<td>Demonstration of a commitment to responsibly <strong>conduct clinical evaluation and ensure that patient-centric issues</strong> including labeling and human factors are appropriately addressed.</td>
</tr>
<tr>
<td>Cybersecurity Responsibility</td>
<td>Demonstration of a <strong>commitment to protect cybersecurity</strong>, and proactively address cybersecurity issues through active engagement with stakeholders and peers.</td>
</tr>
<tr>
<td>Proactive Culture</td>
<td>Demonstration of a commitment to a <strong>proactive approach</strong> to surveillance, assessment of user needs, and continuous learning.</td>
</tr>
</tbody>
</table>
EVOLVING THE PROGRAM THROUGH AN ITERATIVE APPROACH
From Concept to A Program: *An Iterative Approach*

A streamlined Regulatory Program for Software

In COLLABORATION with Pilot Participants + Stakeholders

Concept and framework
The evolution of identifying “Activities” and “Outcomes”

Our Foundation: Excellence Principles

Initial Approach
Common Validating Perspectives (CVP)

Inputs
• Review of Excellence Models
• Pilot Participant Site Visits

Today’s Construct
Enablers & Results *

Inputs
• Introducing The 10th Participant: You

MVP Framework
Collaboratively Created

Working this creative process during today’s Public Workshop

* Adapted from European Foundation for Quality Management (EFQM)
Aligning With Other National And International Excellence Models

**U.S. Baldrige Criteria for Performance Excellence**
- Model for the US Malcolm Baldrige National Quality Award
- Framework used as the basis for over 70 other national Business Excellence / Quality awards around the world
- Managed by the National Institute of Science and Technology (NIST)

**European Foundation for Quality Management (EFQM)**
- Model for the European Business Excellence Award
- Framework used as the basis for national business excellence and quality awards across Europe
- Managed by the European Foundation for Quality Management (EFQM)

**Singapore Quality Award Framework**
- Model for assessing Singapore’s organizations to the highest standards of quality and business excellence
- Framework used to establish Singapore as a country committed to world-class business excellence
- Managed by SPRING Singapore

**Canadian Framework for Business Excellence**
- Model used by Canadian organizations as a management model for organizational excellence
- Framework used for adjudication of the Canada Awards for Excellence
- Framework is administered by the National Quality Institute

**U.S. FDA Software Precertification Excellence Framework**
- The U.S. FDA’s software precertification program has identified – Patient Safety; Clinical Responsibility; Product Quality; Cybersecurity Responsibility and Proactive Culture – as "excellence principles" for companies to incorporate into their business objectives and for the USFDA to utilize for assessing a company’s eligibility to participate in the program.

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**CATEGORIES**

1. Leadership
2. Strategic Planning
3. Customer & Market Focus
4. Measurement, Analysis & Knowledge Management
5. Workforce Focus
6. Process Management
7. Business Results

1. Leadership
2. Policy & Strategy
3. People
4. Partnerships and Resources
5. Processes
6. Customer Results
7. People Results
8. Society Results
9. Business Performance Results

1. Leadership
2. Planning
3. Customer Focus
4. People Focus
5. Processes
6. Customers
7. Results

1. Leadership
2. Planning
3. Customer Focus
4. People Focus
5. Process Management
6. Supplier Partner Focus
7. Business Performance

1. Leadership
2. People
3. Strategy
4. Resources & Partnerships
5. Processes
6. Customer outcomes
7. People outcomes
8. Society outcomes
9. Business outcomes

**CORE VALUES AND CONCEPTS**

- Visionary leadership
- Customer-driven excellence
- Organizational and personal learning
- Valuing employees & partners
- Agility
- Focus on the future
- Managing for innovation
- Management by fact
- Social responsibility
- Focus on results & creating value
- Systems perspective

- Results orientation
- Customer focus
- Leadership and constancy of purpose
- Management by processes and facts
- People development and involvement
- Continuous learning, innovation and improvement
- Partnership development
- Corporate social responsibility

- Visionary leadership
- Customer-driven quality
- Innovation focus
- Valuing people and partners
- Agility
- Knowledge driven system
- Societal responsibility
- Results orientation
- Systems perspective

- Leadership through involvement
- Primary focus on stakeholders / customers and the market place
- Cooperation and teamwork
- Prevention-based process management
- Factual approach to decision-making
- Continuous learning and people involvement
- Focus on continuous improvement and breakthrough thinking
- Fulfill obligations to all stakeholders and society

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Consistent with core values and concepts

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Culture of Quality and Organizational Excellence (CQOE)

A framework for identifying CQOE aligned to business approaches

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**Excellence Principles**

**Integrating** appraisal with how an organization is managed to create and maintain products and services.

**Minimizing** translation needed for precertification appraisal.

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**Enablers**

- Leadership
- People
- Strategy
- Partnerships & Resources
- Process

**Organizational**

**Processes**

**Results**

- Customer
- People
- Society
- Business

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Lessons from Pre-cert Site visits

Inputs
• Review of Excellence Models
• Pilot Participant Site Visits

Today’s Construct
Inputs
• Introducing The 10th Participant: You

Future Construct
Collaboratively Created

Our Foundation: Excellence Principles

* Adapted from European Foundation for Quality Management (EFQM)
Pilot Participants shared their goals for the Pre-Cert program

Shared Vision
Deliver life-saving, high quality, patient-centered diagnostics and therapeutics to market faster, without undue delay or degradation of safety and effectiveness. Scalable, with process flexibility for small and large organizations.

Other Desired Objectives
- Create a faster **path to ship first product** (minimally viable S&E product);
  - Streamline process and reduce duplication
  - Identify low-risk SaMD products and bring them to market without pre-market review
  - Reduce number of submissions for software changes
- **Empower users** to make better decisions about their own data and care
- **Transparency** of program and participants to ensure confidence and credibility of both
- **Automated** precertification tracking and monitoring

We are grateful for the time the nine Pilot organizations are spending co-creating the Pre-Cert program.

We are looking forward to learning from you, The 10th Participant, to shape our program.
Excellence Principles

Excellence principles **affirmed** by Pilot Participants and through input from other stakeholders.
Common questions from pilot participant questions

**On certification and scoring**
- Will the program include hardware?
- Will updates to software be launched more easily for a precertified organization?
- Would FDA use third party certification for software precertification?
- How will FDA evaluate companies that have a wide range of business arms?

**On data and evidence**
- What types of real world post market data would FDA expect from organizations that are precertified?
- Would organizations get credit for compliance with other industry standards and accreditations (e.g., security certifications)?
- How will FDA ensure the KPIs it selects are applicable to the variation in processes and metrics across companies?

**On timing and product roadmap**
- When do you expect to announce which companies have received precertification?
- How will inspections and audits be conducted for precertified companies?

Today, we’ll go through some of these questions, and open the room up for more.

Today is all about activating the 10th Participant, you.

Answers to FAQs

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Across the nine Pre-Cert pilot organizations, we saw some shared themes ...

**Leadership**
- Promoting a culture of learning and empowerment
- Values demonstrated across the organization
- Engaged leadership and empowered staff

**People**
- Cross-disciplinary product teams inclusive of medical expertise
- Engrained culture of accountability for product quality,
  - Right skills, expertise and capacity

**Strategy**
- Staying at cutting edge in clinical / scientific / technology

**Partnership & Resources**
- Know their product’s users and the use environment
- Actively engage with stakeholders

**Processes**
- Transparency in communicating issues to users
- Continual monitoring of products
- Agile processes
- Highly effective, open, internal communications
- New product launches are intensively monitored and managed
- Leverage connectivity, social media and user feedback to monitor product performance and safety
- Have vigilant cybersecurity processes and practices, and treat user data responsibly

The shared themes indicate commonality and alignment to the Enablers and Results

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PUBLIC WORKSHOP OVERVIEW
The Evolution of the Pre-Cert Model

Paradigm Shift

Initial Hypothesis
Common Validating Perspectives (CVP)

Inputs
• Industry Review of Excellence Models
• Pilot Participant Site Visits

Today’s Construct
Enablers & Results *

Inputs
• Introducing The 10th Participant: You

Future Construct
Collaboratively Created

Working this creative process during today’s Public Workshop

Our Foundation: Excellence Principles

* Adapted from European Foundation for Quality Management (EFQM)
Day 1 (Tuesday) – Setting the Stage

- **Panel 1:** Pilot Participants Experience
- **Panel 2:** Q&A with the FDA Pre-Cert Core Team
- **Panel 3:** Perspective from Healthcare Stakeholders
- **Panel 4:** Input from other Digital Health Industry Trade Groups and Associations
- **Panel 5:** Learning from Excellence Models used in other Sector

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Day 2 (Wednesday) – Co-creating the Program

**Workshop Focus:** Precertification

**Breakout 1: Enablers & Drivers**
- Leadership
- People
- Strategy
- Partnerships & Resources
- Processes

**Breakout 2: Measuring Results**
- People
- Society & Public Health
- Business
- Customers
- Leading & Lagging Indicators

**Breakout 3: Weighting & Evaluation**
- Tiers of Precertification
- Variability in KPIs
- Aggregation and Scoring
- Reducing Regulatory Burden

**Upcoming Discussion Topics (not for today)**
- Product-level risk categorization framework
- Risk-informed streamlined pre-market review
- Post market surveillance and Real World Evidence

Provide input

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To discuss in breakout 3: aggregating, weighting, and scorecards

Sub-Dashboards by Principles

- Excellence Principles differ in complexity and overall value
  - Principles comprised of components
    - Quality and Safety could be weighted more and have more components (e.g. n=5)
    - Culture is generally more static and may have less components (e.g. n=3)
  - Component comprised of an attribute/process and metric/KPI
  - Thresholds (< 100%) for “passing” need to be determined

Product Quality  Product Safety  Cybersecurity  Clinical  Culture

Draft Pre-Cert Scorecard

Step 1: Assess SaMD Risk

Step 2: Complete Pre-Cert Scorecard

Step 3: Identify Pre-Cert Grade (example)

What does a Pre-Cert Grade of “B” Mean? (Brainstorming)

- FDA WILL REQUIRE PRE-MARKET REVIEW FOR...
- FDA WILL REVIEW YOUR PRE-CERT GRADE FOR...
- YOU WILL SUBMIT RUST DATA SET (REGULARLY)...
- THE CLINICAL DATA REQUIRED IS...
- FDA WILL INSPECT YOUR ORGANIZATION...

Example SaMD Product Health Dashboard

- Feature Utilization
- Feature Results
- Survey Results

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Engage

- **bit.ly/Precertupdates**: Look for ongoing Program updates
- **FDAPre-CertPilot@fda.hhs.gov**: Ask Questions about the Program
- **bit.ly/docketjan18**: Provide ongoing input through the Public Docket
Panelists will share their experiences engaging with the FDA, and mapping their processes and metrics to the excellence principles.

- **David Amor**, VP, Quality & Regulatory Affairs, Pear Therapeutics
- **Alex Bisignano**, CEO, Phosphorus
- **Larry Carrier**, Head of Global Regulatory Affairs, Verily
- **Diane Johnson**, Digital Health Policy Lead, J&J
- **Yong Jin Lee**, Senior VP, Samsung
- **Howard Look**, CEO, Tidepool
- **Danelle Miller**, VP Global Regulatory Policy, Roche
- **Jennifer Newberger**, Senior Legal Counsel, Apple
- **Adam Pellegrini**, General Manager, Fitbit

**Moderator:**
Bakul Patel, Associate Center Director for Digital Health
Break
10:45 – 10:55 AM

Next
10:55-11:30 AM
Panel 2: Q&A with the FDA Pre-Cert Core Team
Moderator: Bakul Patel
Associate Center Director for Digital Health

Get Involved

Need More Info?
• FAQs [http://bit.ly/FAQjan18]

Have Specific Questions?
• FDAPre-CertPilot@fda.hhs.gov

Have Formal Comments?

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Panelists will discuss goals for the Pre-Cert program and lessons learned from site visits with Pilot Participants.

- Catherine Bahr, Digital Health Expert Advisor, OCD
- Adam Berger, Personalized Medicine Staff, OIR
- Esther Bleicher, Senior Policy Advisor, OCD
- Marisa Cruz, Senior Medical Advisor, OCD
- Martin Ho, Assoc Dir for Quantitative Innovation, OSB
- John Murray, Expert Reg Review Scientist, OCD
- Linda Ricci, Assoc Dir For Digital Health, ODE
- Francisco Vicenty, Program Manager, OC

Moderator:
Bakul Patel, Associate Center Director for Digital Health
Open Public Comment

**Moderator:**
Marisa Cruz, Senior Medical Advisor
Lunch
12:00 – 1:00 PM

Next
1:00–2:00 PM
Panel 3: Perspectives from Healthcare Stakeholders
Moderator: Cara Tenenbaum
CDRH Policy Advisor

Get Involved

Need More Info?
• FAQs http://bit.ly/FAQjan18
• Bios http://bit.ly/biosjan18

Have Specific Questions?
• FDAPre-CertPilot@fda.hhs.gov

Have Formal Comments?
• http://bit.ly/docketjan18

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