CDRH 2019 Update

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May 1, 2019
Patients are at the Heart of What We Do

CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world
The Challenge

1,800 Dedicated “CDRHers”

190,000 Regulated Devices

18,000 Device Manufacturing Firms

21,000 Device Manufacturing Facilities Worldwide
The Misperception

Innovation and Safety

are not polar opposites but rather two sides of the same coin

Innovation

Safety
REALITY: CDRH has been advancing both safety and innovation for almost a decade

APPROACH: CDRH first enhances existing programs then advances innovative solutions and promotes global harmonization
For the device industry to successfully innovate and for the FDA to optimally safeguard the public, the FDA must be and must be supported to be innovative.
Outlines a vision for how CDRH can continue to enhance our programs and processes to assure:

- Safety of medical devices throughout the TPLC
- Timely identification and resolution of safety issues
- Advance innovative technologies that are safer, more effective and address unmet needs

Establish Medical Device Safety Net
Explore Regulatory Options
Spur Innovation
Advance Cybersecurity
Advance Use of TPLC Approach to Device Safety

Ensure that FDA is consistently first among the world’s regulatory agencies to identify and act upon safety signals related to medical devices
Firms are **8 times** more likely to report a recall after 21 CFR 806 violations.

Firms report **3 times** more adverse events following 21 CFR 803 violations.

FDA’s actions contributed to a **50% increase** in annual number of voluntary recalls reported and a **doubling in annual number of AERs** since 2009.
FDA Quality System Regulation and 13485

• FDA announced its intention to harmonize and modernize the Quality System regulation for medical devices

• The revisions will supplant the existing requirements with the specifications of ISO 13485:2016

• The revisions will help harmonize domestic and international requirements

• This approach is consistent with and complements MDSAP

See Spring 2018 Unified Agenda of Regulatory and Deregulatory Actions
Novel Approaches to Promoting Product Quality

Case for Quality 2011

MDIC Collaborative Forum 2014

Voluntary Quality Maturity Appraisal Pilot 2018

- Third-party certified by Capability Maturity Model Integration Institute (CMMI) conducts appraisal
- Collaboration and feedback on quality objectives
- Removal from the surveillance work plan
- Reduction in manufacturing submission requirements and faster approval for implementation
- Waive some pre-approval inspections

✓ 23 participating firms
✓ >35 appraisals
✓ 86% report appraisal had a positive impact on product quality
Device Safety 2019

- MDIC to develop a governance structure for Case for Quality Voluntary Improvement Program
- MDIC/NEST Coordinating Center task force to develop active surveillance roadmap
- CDRH to issue draft guidance on the Safer Technologies Program (STeP)
- CDRH to issue peer-reviewed white paper on hypersensitivity to metal implants and hold advisory panel
2019 Medical Device Cybersecurity Actions

• Finalize Updated Cybersecurity Premarket Guidance (released as DRAFT in 2018)
• Complete CVSS clinical rubric & submit for MDDT qualification (MITRE-led WG)
• Define and operationalize Software Bill of Materials through multi-stakeholder engagement and cross-agency collaboration (NTIA/Dept of Commerce)
• Complete new IMDRF work item - draft report on total product life cycle approach to medical device cybersecurity (FDA and Health Canada co-leads)
2019 Medical Device Cybersecurity Actions continued

• Expand x-stakeholder participation in DefCon Biohacking Village Device Hacking Lab, #Wehearthackers Challenge with the following goals:
  – Increase medical device manufacturer (MDM) presence
  – Introduce to clinical community
  – Engage HDOs

• Complete proof of concept on CYMSAB

• Convene PEAC public meeting on medical device cybersecurity
Novel Device Approvals

>4-fold Increase in # of Novel Device Approvals

* Novel devices include original PMAs, panel track supplement PMAs, de novos, HDEs and breakthrough 510(k)s
Clinical Trials (IDEs)*

>90% Reduction in Time to IDE Approval

Median number of days to full IDE approval

* IDE=Investigational Device Exemption
# Early Feasibility Studies: Perceptual Shifts in Ease of Conduct

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*Data provided by Aaron Kaplan/Dartmouth Device Development (3D) Symposium Annual Survey of 3D Participants*
Importance of Early Feasibility Studies

- Earliest patient access
- Close collaboration between developers & users
  - Clinical study continuity from early clinical use to post-approval
  - U.S. leadership and contributor to medical device innovation

U.S. Sites Re-engaging in Early Clinical Research

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<th>FDA Early Feasibility Study Program 2015-2018</th>
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<td>&gt;50 Company Participants</td>
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<td>&gt;180 Early Feasibility IDEs Approved</td>
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<td>121% Increase in Annual # of EFS IDEs Approved</td>
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MDIC to begin EFS Clinical Site Consortium Pilot
National Evaluation System for health Technology
FDA Has Taken Steps to Strengthen the 510(k) Program

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
Guidance for Industry and Food and Drug Administration Staff

2014 Foundational Guidance

• Established concept of primary predicate and reference devices
• Clarifies when a change in indication is a new intended use
• Addresses when technological differences raise different questions of safety and effectiveness
Modernized Approach to 510(k) Device Modifications
Final Guidance 2017

• Clarifies when device modifications require a new 510(k)
• Relies on Quality System regulation
• Leverages risk-based assessments and risk management principles
• Clarifies role of testing (i.e. verification and validation activities)
Published Guidance

• Published **>50** final cross-cutting and device-specific guidance documents impacting 510(k) devices since 2009

• **Topics include:**
  – Sterility
  – Biocompatibility
  – Use of Voluntary Consensus Standards
  – Design Considerations for Home Use Devices
  – Reprocessing
  – Acceptance of Clinical Data
  – Interoperable Medical Devices
  – Cybersecurity
  – And more!
Eliminated the Use of Some 510(k) Devices as Legal Predicates

1477 Number of 510(k) cleared devices eliminated for use as legal predicates since 2012

84% of devices eliminated for use as 510(k) predicates have been eliminated since 2012
More Information – More Thorough Review

1185 Average number of pages in a 510(k) in 2017

150% Increase in the number of pages per 510(k) since 2009

32% increase in the time spent by FDA review staff reviewing each 510(k) submission since 2009
Moderate Risk Devices - 510(k)

92% REDUCTION in Files that Miss Day 90

Decision within 90 FDA Days*

*Comparison of Receipt Cohorts 15 months After Start of FY
Introduced “SMART Template”

- Formatted guide/template for review staff
- Promotes consistency in review and documentation
- Includes links to help/advice to facilitate review
Quality 510(k) Review Pilot Program

- “Turbotax” for 510(k)
- Sponsor completes formatted eSubmission
- In return, CDRH will:
  - Skip RTA phase
  - Commit to interactive review without hold (where possible)
  - Strive to reduce FDA review time by 1/3 (goal: 60 days)

Launched Pilot (for ~ 40 product codes)
Fall 2018
Imagine: Single Submission

• Regulatory Submission with Common Data Elements
• Electronic Submission
• IMDRF Work Item to define common ‘Table of Contents’
Safety and Performance Based Pathway

- Moderate risk devices are evaluated through 510(k) Program
- Require demonstration of “substantial equivalence” to a predicate device
- Direct comparison to a predicate device may be burdensome and unnecessary
- Abbreviated 510(k) submission program relies on guidance documents, special controls, and FDA-recognized consensus standards to facilitate 510(k) review

Guidance Issued on February 1, 2019 Expands Abbreviated 510(k) Approach

- Optional approach for certain, well-understood device types
- Demonstrate new device meets FDA-identified performance criteria based on performance of modern predicates
- Transparency about device performance for health care providers and patients
- Provides opportunities for international harmonization and support the establishment of a Medical Device Single Review Program
Modern Predicates

• Nearly 20% of 510(k)s are cleared based on predicates that are > 10 years old
• That does not make them inherently unsafe
• The goal in focusing on older predicates is to drive sponsors to offer patients devices with the latest improvements and advances

CDRH is considering making public on its website those cleared devices that demonstrated substantial equivalence to older predicate devices.
Breakthrough Devices Pathway
(Formerly Expedited Access Pathway)

142 devices accepted into the program since April 2015
1st breakthrough device approved December 2017
11 breakthrough devices granted marketing authorization
Consideration of Uncertainty In Making Benefit-Risk Determinations in PMA, De Novo, and HDE Approvals

• Some degree of uncertainty generally exists around benefits and risks for regulatory decisions
• The regulatory standard is reasonable assurance – not absolute assurance
• Flexible regulatory paradigm

Clarified Through Draft Guidance Issued on September 5, 2018 the Circumstances Where FDA is More Likely to Accept More Uncertainty

• For example:
  – Breakthrough Devices
  – PMAs with small patient population
  – De Novos with minimal risk
  – Particularly if established postmarket data collection mechanism

• Provides opportunities for international harmonization, where appropriate, and supports the establishment of a Medical Device Single Review Program
ASCA Pilot

Accredits Testing Labs according to ISO/IEC 17025 and FDA specifications

Conducts testing and produces test reports of specific product characteristics per defined test method

Manufacturer contracts with testing lab for testing report to submit to FDA

Accreditation Body
ISO/IEC 17011 + FDA specifications

Testing Laboratory
ISO/IEC 17025 + FDA specifications

Medical Device Product Characteristics
Basic Safety and Essential Performance
Biocompatibility

FDA
- Defines and oversees pilot
- Establishes additional specific program specifications to clarify ISO/IEC conformity assessment standards
- Specifies rules and procedures for approvals at all levels of the program
Balancing Innovation and Patient Safety with Foundational Policies

- RF Wireless - guidance
- Mobile medical app (MMA)
- FDASIA Health IT report
- Premarket Cybersecurity
- MDDS/image storage and communication
- MMA update
- General wellness
- Accessories
- Postmarket cybersecurity
- Interoperability

2013
2014
2015
2016
2017

21st CCAct policies
Clinical and patient decision support, MMA revisions, multi-functionality

Draft
Digital Health Program

CENTER OF EXCELLENCE

Unified and collaborative environment; applying best practices, conducting research, support, training for software and digital health technologies.

Supplementing bench strength @ FDA

TECH POLICY SUPPORT

- Manage/Respond to Inquiries
  - Regulatory Submissions Support
  - Policy Implementation
  - Identify and develop staff training

STRATEGIC PARTNERSHIP

- Strategic Industry partnership
- Academic partnership
- Federal partnerships:
  - IMDRF
  - Harmonization through IMDRF

STRATEGIC INITIATIVES

- Explore tailored pathway: Software Precertification Pilot
  - Medical Device Interoperability
  - Cybersecurity

POLICY DEVELOPMENT

Cybersecurity Interoperability
- Artificial Intelligence / Machine Learning
- Software Policies under 21st Century Cures Act
- Policy Intelligence
Imagine: Single Review

The IMDRF Good Regulatory Review Practices (GRRP) working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.
IMDRF GRRP
Current Work Item

• Developing a conformity assessment/recognition program for medical device premarket review organizations
  – Models the Medical Device Single Audit Program (MDSAP) by leveraging existing documents where possible and making modifications as necessary to accommodate premarket review requirements
  – Utilize some requirements outlined in ISO/IEC standards (e.g. ISO/IEC 17065)
• Draft document to be submitted to IMDRF MC in June 2019 for public consultation
Opportunities To Obtain Payer and Health Technology Assessment Input

Public Payer Pre-submission Participation

Opportunity to Obtain Private Payer Input

- Voluntary Program
- Obtain input on clinical trial design or other plans for gathering clinical evidence

Current Participants:
- BlueCross BlueShield Association
- CareFirst BlueCross BlueShield
- CMS
- Cigna
- Duke Evidence Synthesis Group/DCRI
- ECRI Institute
- Humana
- Kaiser Permanente
- National Institute for Health and Care Excellence
- United Health Group

For more information: Google Search “CDRH Payer Program”
2018-2020 Strategic Priorities
Collaborative Communities

- Forum where public and private sector members work together on an ongoing basis to achieve shared outcomes and solve both shared problems and problems unique to other members
- In an environment of trust and openness, where participants feel safe and respected to communicate their concerns
- Where members share a collective responsibility to help each other obtain what they need to be successful
- And government has a seat at the table but does not run the forum
Establish the Office of Product Evaluation and Quality (OPEQ) - Combines the Offices of Compliance, Office of Device Evaluation, Office of Surveillance and Biometrics and the Office of In Vitro Diagnostics and Radiological Health into one “super office” focused on a Total Product Lifecycle approach to medical device oversight.

Establish the Office of Policy (OP) - Establishes two teams, the Guidance, Legislation and Special Projects Team and the Regulatory Documents and Special Projects Team. There are no changes in the functions for CDRH Policy.

Establish the Office of Strategic Partnerships and Technology Innovation (OST) - Combines the Science & Strategic Partnerships, Digital Health, Health Informatics and Innovation teams. There are no changes in functions within the different teams.
CDRH (Before Reorganization)

- Office of the Center Director (OCD)
  - Office of Compliance (OC)
  - Office of Communication and Education (OCE)
  - Office of Device Evaluation (ODE)
  - Office of In Vitro Diagnostics and Radiological Health (OIR)
  - Office of Management (OM)
  - Office of Surveillance and Biometrics (OSB)
  - Office of Science, and Engineering Laboratories (OSEL)
CDRH (After Reorganization)
For the device industry to successfully innovate and for the FDA to optimally safeguard the public, the FDA must be and must be supported to be innovative.

Do you believe the FDA has the right tools, authorities, and support to be optimally innovative?