

# CDRH's New Direction in Product Clearance and Compliance: Four New Initiatives That Will Affect Industry

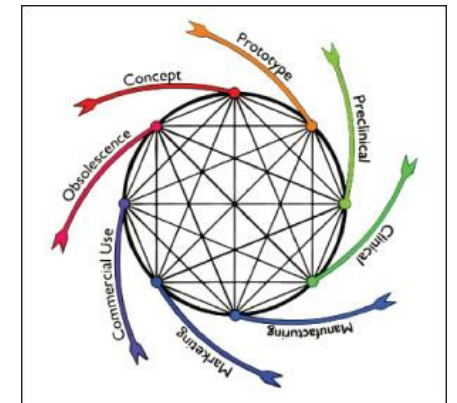
Adam E. Saltman, M.D., Ph.D.

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# Topics

1. Streamlining & Simplifying
2. Collaborative Communities
3. Medical Device Safety Action Plan
4. Benefit-Risk throughout the Product Life Cycle



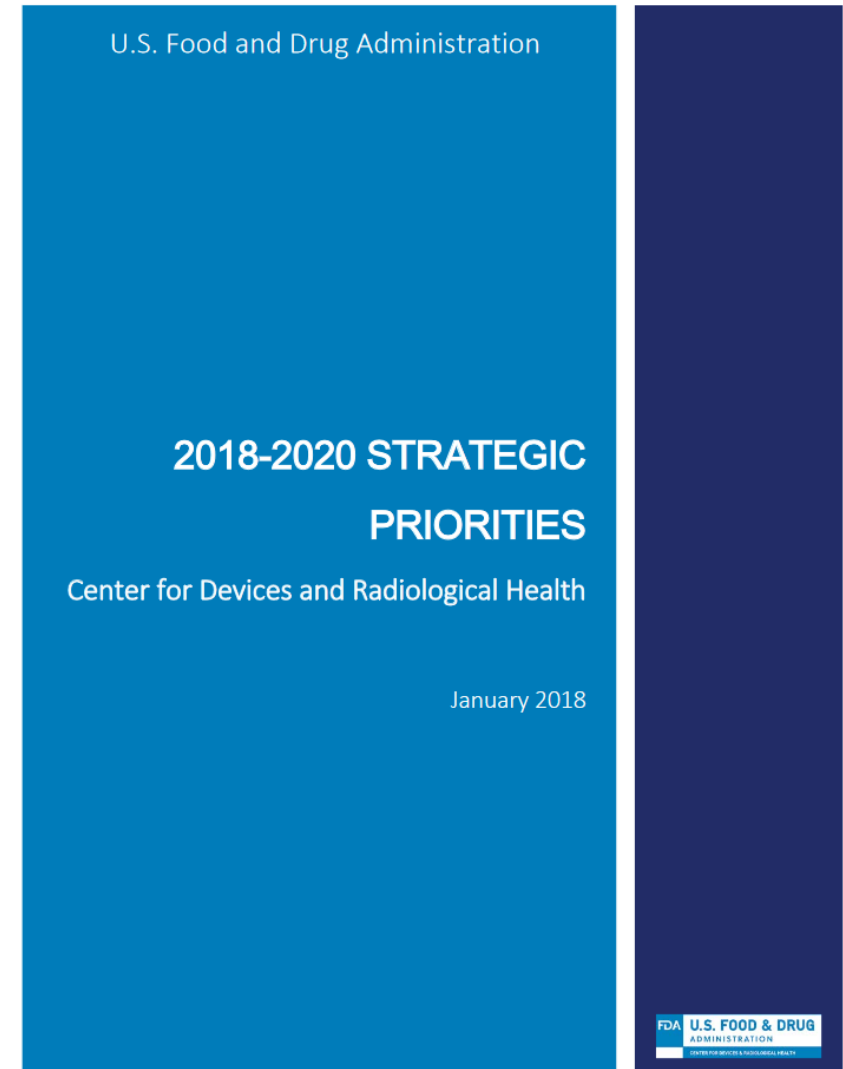
Wherever possible, topics will follow TPLC!

Concept→Prototype→Preclinical→Clinical→Manufacturing→Marketing→Commercial Use→Obsolescence

# CDRH 2018-2020 Strategic Priorities



- Employee engagement
- ✓ Simplicity
- ✓ Collaborative communities





# STREAMLINING AND SIMPLIFYING

# Streamlining & Simplifying Mission



- “Simplicity means that in everything we do, we continually streamline our policies, processes, programs, and approaches, as appropriate, to more effectively, efficiently, and quickly achieve our mission and vision.”
  - Remove “not value added”
  - Develop decision aids
  - Remove unnecessary burdens we impose on ourselves
  - Be pragmatic, balance risk/benefit/uncertainty in decision making
  - *While not changing the regulatory standard of reasonable assurance of safety and effectiveness, or the reliance on valid, scientific evidence*

# Streamlining & Simplifying Specific Projects - I



## Issued New Least Burdensome guidance

- “The minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time”
- The minimum information
  - Less burdensome sources of clinical data
  - Use of nonclinical data
  - Acceptance of alternative approaches
- By the most efficient means
  - Reducing the burden of traditional clinical studies
  - Using benefit-risk assessments
  - Streamlining processes
  - Smart regulation
  - Global harmonization
- At the right time
  - Balancing premarket and postmarket information needs
  - Just-in-time testing

### **The Least Burdensome Provisions: Concept and Principles**

### **Guidance for Industry and Food and Drug Administration Staff**

Document issued on February 5, 2019.

The draft of this document was issued on December 15, 2017.

This document supersedes “The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles,” issued on October 4, 2002.

<https://www.fda.gov/media/73188/download>

# Streamlining & Simplifying Specific Projects - II



- Reevaluated every PMA device type
  - For which can annual reporting be stopped?
  - For which can some data collection shift from premarket to postmarket?
  - For which can down-classification occur?
  - 30% of device evaluated were changed according to 1 or more criteria
- Exempted more devices from premarket notification\*
  - More than 1000 class II, medium-risk devices given exemption  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>

\*Not from other general controls, quality assurance programs, suitability for intended use, adequate packaging and labeling, and establishment registration and device listing

# Streamlining & Simplifying Specific Projects - III



- Improving business processes
  - Evaluating all core processes
  - Streamlining, combining, cutting waste, conserving resources
  - By December 31, 2020, CDRH will *lean* at least 80% of its core processes





# COLLABORATIVE COMMUNITIES

# Collaborative Communities

## Definition



- “A Collaborative Community is a continuing forum where public and private sector members proactively work together to 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”



# Collaborative Communities Definition



- Collaborative Communities ARE
  - Collective responsibility to help each other
  - FDA participates, does not drive or direct or mandate
- Collaborative Communities ARE NOT
  - Advisory committees, task forces, or working groups
  - FDA initiated, FDA prescribed, FDA designed

# Collaborative Communities Progress



- Developing tools for CDRH and the public  
Toolkit for developing a Collaborative Community  
(<https://www.fda.gov/media/116467/download>)
  - A collection of materials designed to help a community become established, to encourage effective collaboration, and to foster rich communities that are adequately prepared to take on healthcare challenges
  - Each component is intended to help existing as well as burgeoning communities work with one another



# Collaborative Communities

## Progress



- Examples of what could become Collaborative Communities
  - NEST (**N**ational **E**valuation **S**ystem for health **T**echnology)
  - Case for Quality
  - UDI (Unique Device Identifier System)

**Medical Device Safety Action Plan:**  
Protecting Patients,  
Promoting Public Health



# MEDICAL DEVICE SAFETY ACTION PLAN



# Medical Device Safety Action Plan

## “Protecting Patients, Promoting Public Health”

- Integrate CDRH's premarket and postmarket offices and activities to advance the use of a TPLC approach to device safety
- Spur innovation towards safer medical devices
- Advance medical device cybersecurity
- Establish a robust US medical device patient safety net
- Streamline and modernize timely implementation of postmarket mitigations

# Medical Device Safety Action Plan

## Total Product Life Cycle Reorganization

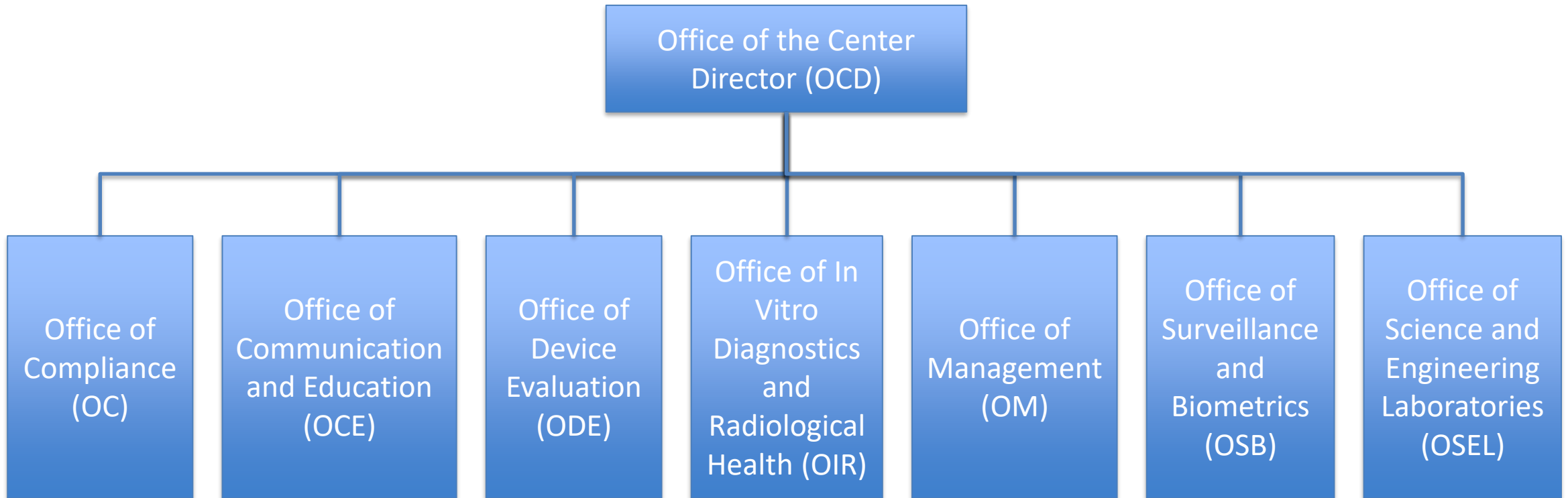


- Goals
  - Generate efficiencies to better realize CDRH's mission and vision
  - Integrate premarket and postmarket along product lines
  - Consolidate and integrate review, quality, surveillance, and enforcement into a team-based approach
- Timeline
  - Started March 18, 2019
  - OPEQ reorganization completed May 1, 2019
  - Full implementation by September 30, 2019



# Medical Device Safety Action Plan

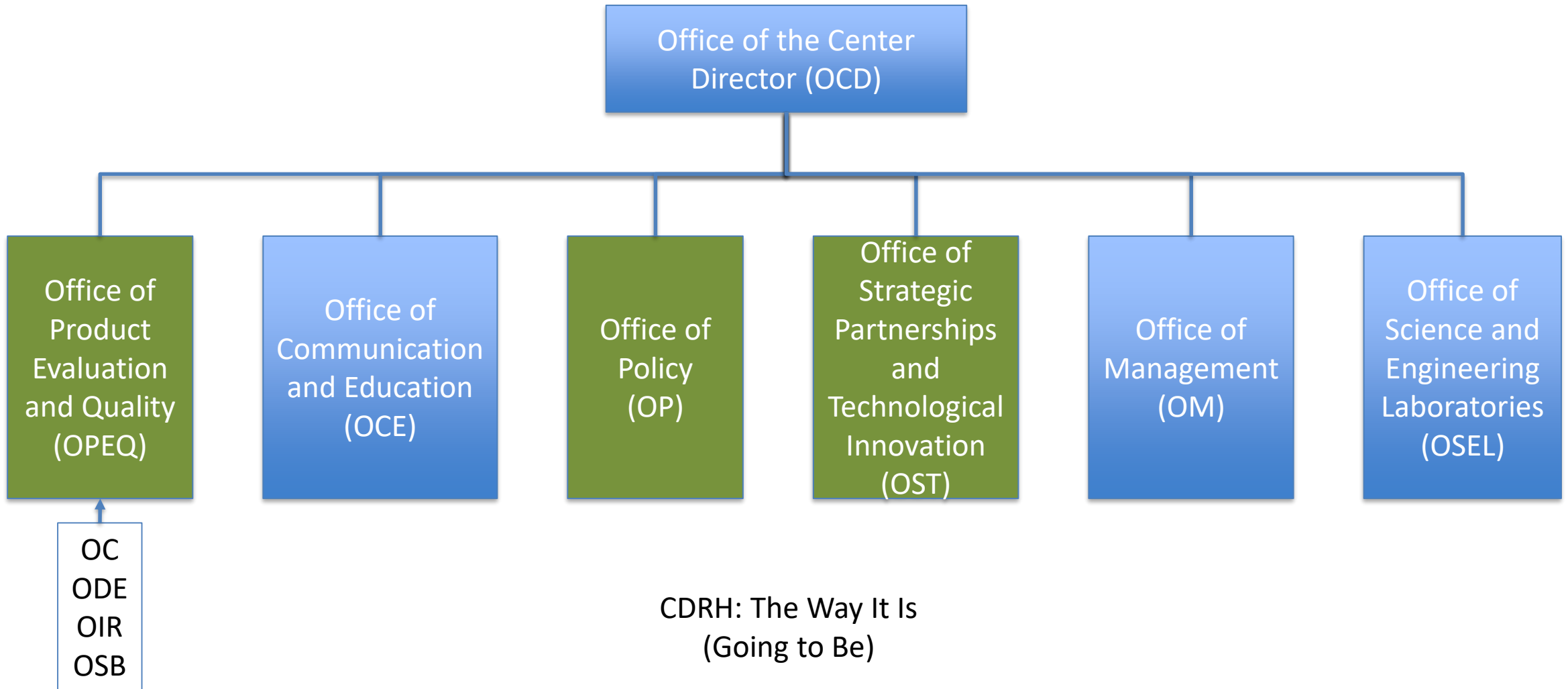
## Total Product Life Cycle Reorganization



CDRH: The Way It Was

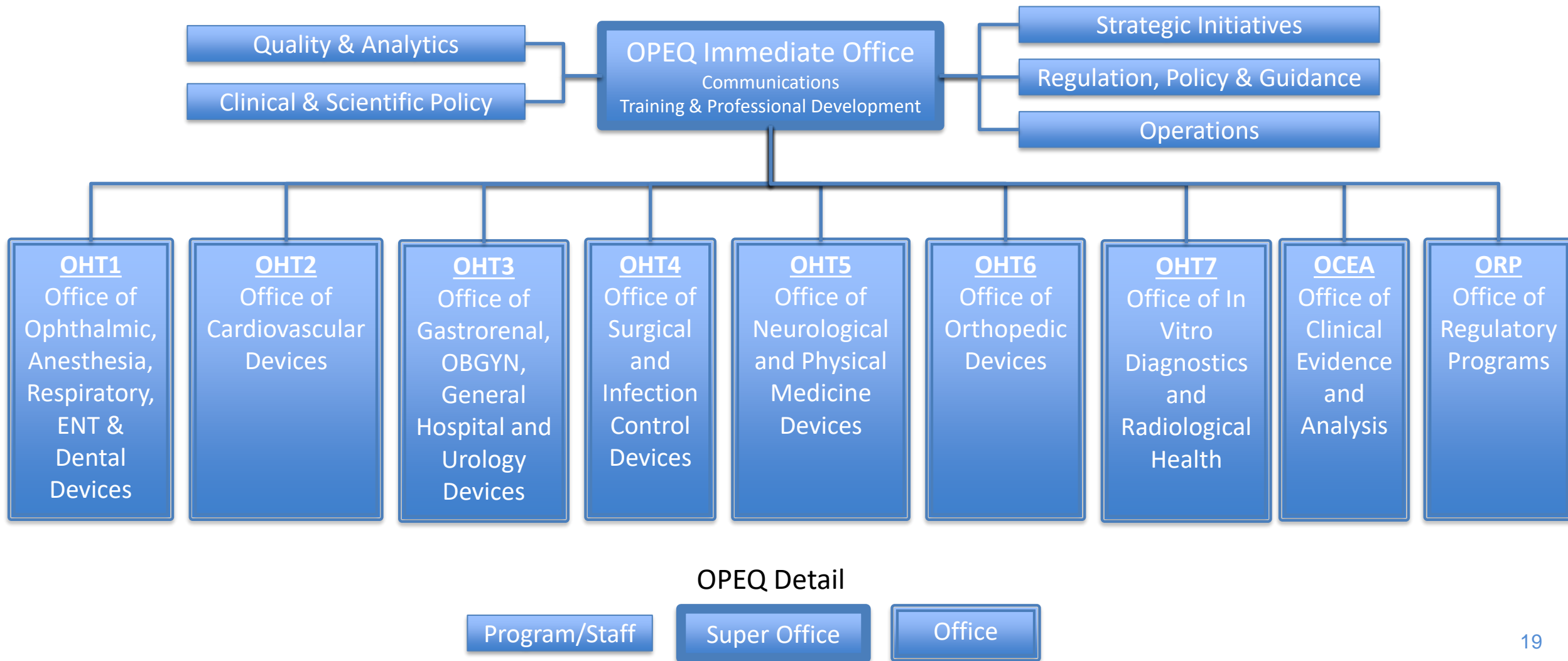
# Medical Device Safety Action Plan

## Total Product Life Cycle Reorganization



# Medical Device Safety Action Plan

## Total Product Life Cycle Reorganization



# Medical Device Safety Action Plan Innovation



- Problem
  - The marketplace often does not provide strong incentives to enhance device safety in the absence of a demonstrated safety concern
- Solution
  - Provide regulatory incentives and scientific expertise to help drive the marketplace to develop safer technologies

# Medical Device Safety Action Plan Innovation



- How?
  - Increase interaction during product development (quasi-Breakthrough Program)
  - Focus more regulatory science research activities on safety innovation
  - Develop toolkits for developers to better assure their devices are safe
  - Provide more streamlined pathways for comparative safety claims
  - Working with technology incubators who seek to advance safety innovation

# Medical Device Safety Action Plan Innovation



- How?
  - Build on the Case for Quality Initiative
    - Create a competitive marketplace for device quality
    - Pilot the use of a progressive maturity model appraisal approach
    - Establish organizational performance metrics and device quality metrics
    - Integrate maturity model evaluations into regulatory decision making

# Medical Device Safety Action Plan

## Cybersecurity



- Problem
  - External threats to device software are becoming more frequent and sophisticated
- Solution
  - Consider potential new premarket authorities to require manufacturers to
    - Build capability to update and patch device security into a product's design
    - Provide appropriate data regarding this capability as part of the device's premarket submission
    - Develop a "Software Bill of Materials" that must be provided to FDA as part of a premarket submission, and made available to medical device customers and users
    - Adopt policies and procedures for coordinated disclosure of vulnerabilities as they are identified

# Medical Device Safety Action Plan

## Cybersecurity



- Solution
  - Update the medical device cybersecurity guidance to better protect against moderate risks (e.g., ransomware) and major risks (e.g., remote, multi-patient, catastrophic attack)
  - Explore the development of a CyberMed Safety Analysis Board
    - A public-private partnership, resource for device makers and FDA
    - Complement existing device vulnerability coordination and response mechanisms
    - Broad range of expertise - hardware, software, networking, biomedical engineering, clinical
    - Assess vulnerabilities, evaluate patient safety risks, adjudicate disputes, assess proposed mitigations, consult to organizations
    - A “go-team” that could be deployed in the field to investigate a suspected or confirmed device compromise



# Medical Device Safety Action Plan

## Patient Safety Net



- NEST – National Evaluation System for health Technology
  - Purpose
    - Combine active surveillance and evaluation with passive surveillance
    - Standardize data capture, quality, and completeness
    - Link and aggregate large data sets for advanced analytics
    - Detect potential safety risks quickly, facilitate more timely assessment across diverse populations and across the range of clinical settings
  - Structure
    - Public-private partnership
    - Managed by Medical Device Innovation Consortium – the NESTcc (<https://nestcc.org/>)

# Medical Device Safety Action Plan

## Patient Safety Net



- Additional activities
  - Promote implementation of Unique Device Identifiers
  - Issued guidance on using Real World Evidence to support regulatory decisions

# Medical Device Safety Action Plan

## Postmarket Mitigations



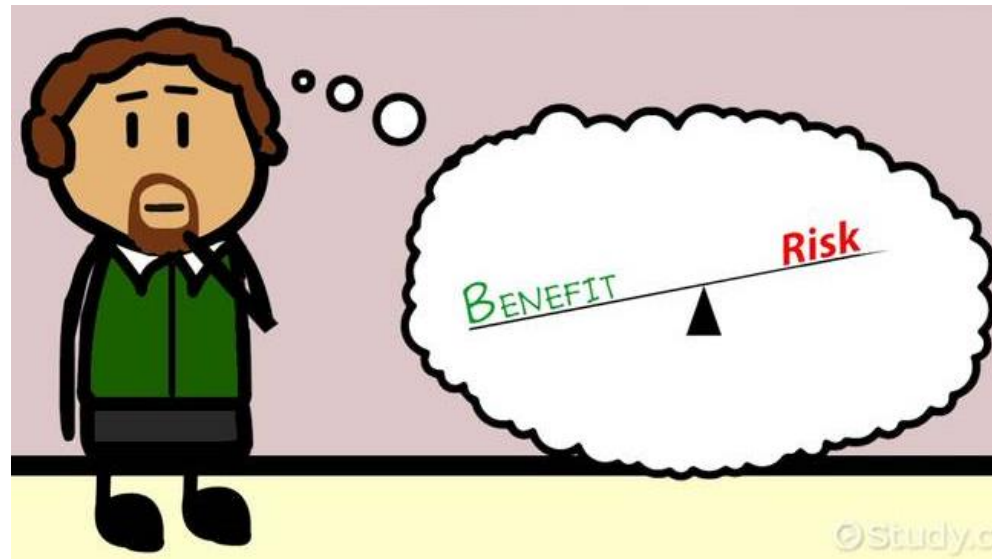
- Current state
  - If FDA identifies new information that impacts the benefit-risk profile of a type of device, FDA can require companies to implement mitigations (e.g., labeling, user training, device features) through the imposition of additional special controls
- Establishing special controls *requires rulemaking*
  - Extensive use of resources and time

# Medical Device Safety Action Plan

## Postmarket Mitigations



- Solutions
  - ✓ Work with individual manufacturers to voluntarily implement mitigations
  - Explore whether, under current statutory authorities, FDA can impose special controls more quickly through the issuance of an umbrella regulation
  - Explore potential new authorities



# BENEFIT-RISK THROUGHOUT THE PRODUCT LIFECYCLE

# Benefit-Risk Throughout The Product Lifecycle



- Multiple guidance documents available
- Premarket
  - Benefit-risk factors to consider when determining substantial equivalence in premarket notifications (510(k)) with different technological characteristics
  - Factors to consider when making benefit-risk determinations for medical device investigational device exemptions
  - Factors to consider when making benefit-risk determinations in medical device premarket approval and de novo classifications
  - Consideration of uncertainty in making benefit-risk determinations in medical device premarket approvals, de novo classifications, and humanitarian device exemptions (draft)
- Postmarket and Compliance
  - Factors to consider regarding benefit-risk in medical device product availability, compliance, and enforcement decisions

# A Common, Factor-Oriented Approach



- Benefit factors
  - Type
  - Likelihood
  - Duration
  - Patient subpopulations

# A Common, Factor-Oriented Approach



- Risk factors
  - Type
  - Likelihood
  - Severity
  - Mitigations
  - Patient subpopulations



# A Common, Factor-Oriented Approach



- Other factors
  - Firm history (post-market)
  - Patient preferences

# Benefit-Risk Decision Tools

- Increase consistency, transparency, and harmonization
- Conserve resources
- Under development and testing

# Q&A

# Guidance Document Links

- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics  
<https://www.fda.gov/media/89019/download>
- Factors to Consider When Making Benefit-risk Determinations for Medical Device Investigational Device Exemptions  
<https://www.fda.gov/media/92427/download>
- Factors to Consider When Making Benefit-risk Determinations in Medical Device Premarket Approval and De Novo Classifications  
<https://www.fda.gov/media/99769/download>
- Consideration of Uncertainty in Making Benefit-risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions (draft)  
<https://www.fda.gov/media/115672/download>
- Factors to Consider Regarding Benefit-risk in Medical Device Product Availability, Compliance, and Enforcement Decisions  
<https://www.fda.gov/media/98657/download>



# Thank You!

Adam E. Saltman, M.D., Ph.D.

Medical Officer, FDA CDRH OPEQ IO CSP

(Office of Product Evaluation and Quality, Immediate Office, Clinical & Scientific Policy)

[Adam.Saltman@fda.hhs.gov](mailto:Adam.Saltman@fda.hhs.gov)

301-796-2909