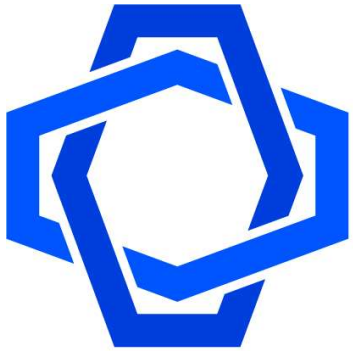

osma

Orthopaedic Surgical Manufacturers Association

Educational Program

Thursday, April 19th, 2018

Key Bridge Marriott

Arlington, Virginia

OSMA Continental Breakfast

7:30am – 8:00am

President

- Welcome
- Meeting Logistics
  - Sign-In Sheet
  - Name Tags
  - Group Dinner

6:00 pm Filomena
1063 Wisconsin Ave NW
Washington, DC 20007

- Introductions
- Reading of Meeting Guidelines

Reading of Meeting Guidelines

While attending OSMA meetings, the members are not to discuss or exchange information on markets, prices, commercialization methods, and/or costs of products or services. These same restrictions apply both to meeting topics and to any social activity connected to the OSMA meeting.

During any discussion of standards, guidelines or specifications for testing, no commercial aspects shall be discussed. The discussion must be confined to technical, engineering, safety and regulatory factors. No agreement for adherence to any standard, guidelines or testing parameters for specific products or services shall be made.

DOD Overview

Mark Melkerson
Director
Division of Orthopedic Devices
FDA

Mark Melkerson

Mark N. Melkerson is the Director for the Division of Orthopedic Devices (DOD). He received Bachelor of Science in mechanical engineering with a biomedical option and Master of Science degree in mechanical engineering from Michigan State University (MSU). He joined FDA in 1987 as a reviewer in the Orthopedic Devices Branch. Mr. Melkerson served as either the Acting Branch Chief or Acting Team Leader for the period of 1990 - 1996 and became the permanent Branch Chief of the Orthopedic Devices Branch in 1996. Mr. Melkerson served as Acting Deputy Director for the Division of Cardiovascular and Respiratory Devices before being selected as one of the Deputy Directors for DGRND in September of 2000. He acted as the Acting Associate Director for the Office of Device Evaluation (ODE) from March 2005 – July 2005. Mr. Melkerson acted as the Acting Director for DGRND from July 2005 – March 2006 before being named the permanent Director for DGRND. In a small two division reorganization in February 2009 Neurological Devices were transferred to another division leaving Mr. Melkerson as the Director of the Division of Surgical Orthopedic, and Restorative Devices. In an ODE wide reorganization in November 2012 the Division of Neurological and Physical Medicine Devices (DNPMD), Division of Surgical Devices (DSD), and Division of Orthopedic Devices (DOD) each became their own divisions. Mr. Melkerson was named as the Director of the Division of Orthopedic Devices but acted as Director of both DSD and DOD from November 2012 until November 2013.

Mr. Melkerson continues to participate as the one of the Center for Devices and Radiological Health (CDRH) representatives to the FDA's Tissue Policy Team. The Tissue Policy Team, led by CBER, has developed the HTCP (Human Cells, Tissues, and Cellular and Tissue-Based Products) Regulations as well as address comments received since issuing. He serves as the co-chair of the CBER/CDRH Tissue Engineering Steering Committee and has been doing so since March of 2005. Mr. Melkerson has also participated as the one of the Center for Devices and Radiological Health (CDRH) representatives to the FDA's Tissue Reference Group from September 2000 through March of 2005.

He was very active in the Global Harmonization Task Force efforts from 2005 through 2012 due to his national and international standards activity. He remains very active in standards serving as CDRH's primary liaison to International Standards Organization Technical Committee 150 and American Society for Testing and Materials (ASTM) International Committee F04, and ASTM F04.02 Division II - Orthopedic Devices.

Mr. Melkerson participates as a liaison to a Neurological Devices Forum, the American Academy of Orthopaedic Surgeons (AAOS) Biomedical Engineering Committee, the AAOS Biologic Implants Committee, the AAOS Committee on Exhibits, and the Orthopaedic Device Forum.

U.S. FOOD & DRUG ADMINISTRATION

Division of Orthopedic Devices Overview/Update

Orthopedic Surgical Manufacturers Association 2018 Spring Meeting

Mark N. Melkerson

Director

Division of Orthopedic Devices

Overview

1. DOD Organization and Activities
2. Guidance Updates
3. MDUFA IV
4. Compliance Activities
5. Experiential Learning Program (ELP)
6. 510(k) Review Trends
7. MR Testing Expectations

Division of Orthopedic Devices - Organization and Activities

Division of Orthopedic Devices (DOD)

Mark N. Melkerson, Director	
Deputy Director, Science and Policy ***Katherine Kavlock, Ph.D. (Acting)***	**Deputy Director, Clinical** ***Vincent Devlin, M.D.***
DOD Review Branches (Branch Chiefs)	
Joint and Fixation Devices Branch 1 ***Jesse Muir, Ph.D. (Acting Chief – New)***	**Joint and Fixation Devices Branch 2** ***Vesa Vuniqi, M.S. (Acting Chief – New)***
Anterior Spine Devices Branch ***Melissa Hall, M.S., Chief***	**Posterior Spine Devices Branch** ***Ronald Jean, Ph.D., Chief***
Restorative & Repair Devices Branch ***Larry Coyne, Ph.D., Chief***	

Division of Orthopedic Devices

Anterior Spine Devices Branch *Melissa Hall, M.S., Chief* *Brent Showalter, Ph.D. (Acting – New)*	Posterior Spine Devices Branch *Ronald Jean, Ph.D., Chief* *Colin O'Neill, M.S., SLR*
Anterolateral plates	Laminoplasty plates
Intervertebral body fusion devices	OCT Systems
Disc replacement prostheses	Pedicle screw systems
Nucleus replacement devices	Spinous process plates
Vertebral body replacement devices	Spinous process spacers
	Sacroiliac joint fixation devices

Division of Orthopedic Devices

Joint & Fixation Devices Branch 1 *Jesse Muir, Ph.D. (Acting Chief – New)* *Peter Allen, M.S., SLR*	Joint & Fixation Devices Branch 2 Vesa Vuniqi, M.S. (Acting Chief – New) Daniel Ramsey (Acting SLR – New)
Joint prostheses: • Knees • Shoulder • Elbow • Ankle • Toe	**Joint prostheses:** • Hips • Wrist • Finger
Fracture Fixation 1: • External fixators, etc. (Product codes: (JDW, HTY, KTT, HSB, NDK, JDR, JDQ, JDS, LXT)	**Fracture Fixation 2:** • Bone staples, plates, and screws (Product codes: JDR, HWC, HRS, OBT, etc.)
Orthopedic Stereotaxic, BGS	

Division of Orthopedic Devices

Restorative & Repair Devices Branch *Laurence Coyne, Ph.D., Chief* Sarah Brittain Nelson, Ph.D. (SLR – New)
Bone cements
BMPs
Bone void fillers
HA injectables
Ligaments and Tendons
Suture anchors (Product codes MAI and MBI)
Meniscal repair
Cartilage repair

Guidance Updates

Guidance Documents in Progress

- UHMWPE – The comment period closed in May 2016 and we are working on finalizing guidance.
- Technical Considerations for Additive Manufactured Devices – Final Document issues December 4, 2017
- Suture Anchors – The comment period closed in March 2017 and we are working on finalizing guidance.
- Patient Matched Guides – Feedback was received via questions issued in FR Notice. A draft guidance is working through review.

Not DOD specific:

- Deciding When to Submit at 510(k) for a Change to an Existing Device – October 17.

Use of Real World Evidence

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

Draft Guidance out for comment

Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial 2 Equivalence through Performance 3 Criteria -- Draft Guidance for Industry and Food and Drug Administration Staff

- This guidance provides FDA's current thinking on expanding the use of the Abbreviated 510(k) program for demonstrating substantial equivalence for premarket notification (510(k)) submissions. The intent of the guidance is to describe an optional pathway for certain, well understood device types, where a submitter would demonstrate that a new device meets FDA identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device.
- Comment period closes July 11, 2018

MDUFA IV

MDUFA IV

510(k) and PMA Program changes

- Categorization of deficiencies into Major, Minor, and Additional Consideration categories
- PMA and 510(k) performance goals now based on Total Time to Decision
- No other policy or process changes occurring for the 510(k) or PMA programs.
- Guidance Document (updated): "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions"

MDUFA IV

Pre-submission Program Changes

- At least 3 meeting dates proposed by the sponsor, we will select from the 3 dates or propose 2 new meeting dates by day 15
- Meeting date is expected to be finalized by day 30
- Written feedback is expected to be sent by day 70 or 5 calendar days prior to the meeting
- Guidance Document (updated): "Requests for Feedback on Medical Device Submissions; The Pre-Submission Program and Meetings with Food and Drug Administration Staff"

MDUFA IV

De Novo Program Changes

- User fee associated with de novo applications
- Performance goal of making a final decision within 150 FDA days.
- Guidance Document: "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals"

Compliance Activities

Case for Quality

Why

Risk to patients from quality issues and hampered innovation in manufacturing and product development practices

- High industry focus on meeting regulatory requirements over focusing on adopting best quality practices
- Low investment in automation and digital technologies to improve manufacturing and design
- No competitive market around medical device quality

What

Collaborative effort that focuses on organizational excellence and product quality

- New ways of assessing organizational performance and focusing on quality
- Adapting regulatory oversight to increase agility, responsiveness, and enable continuous improvement
- Increasing visibility into product quality to inform purchasing decisions and market choice

What does a focus on quality mean for the medical device ecosystem?

Increased manufacturing and product confidence

Faster time to markets, better information to drive regulatory decisions, improved resource allocation

Improved patient outcomes, reduced costs, and informed users

Voluntary Medical Device Manufacturing and Product Quality Pilot

Pilot Program

- **Third-party maturity appraisal that leverages the Capability Maturity Model Integration (CMMI) framework to assess a medical device organizations capability to produce high quality devices and increase patient safety**
- **Pilot was announced on December 28, 2017 and will run from January 2, 2018 and continue through December 28, 2018**

FDA Adjustments

- **Forgo surveillance, appropriate post-approval, and risk-based inspections**
- **Manufacturing change notice submissions**
  - Streamlined submission
  - Accelerated acceptance 48 hours vs 30 days
- **Manufacturing site changes**
  - Streamlined submission
  - Accelerated approval – 1 week Target
- **Original PMA Manufacturing Section**
  - Streamlined submission
  - Forgo pre-approval inspection

These changes reduce the burden and disruption of audits, accelerate the review and approval process for changes, and shift resources to innovation and improvement.

Value across stakeholders

Value analysis considered the submissions received at FDA in 2016 and the 30-dDy Changes submitted by one location of one manufacturer, the FTEs used during previous FDA audits, and estimated monthly revenue impact of approval delays for a recently released product.

FDA

- 30-Day Notices consumed 15-22 FTEs
- Site Changes consumed 5 FTEs

*Resource estimates are based on number of 30-Days received in 2016. For the 69 30 Days it is the equivalent of 1 FTE dedicated to that site for the year.

Manufacturers

- $30M/month top line.
- $1.2M/year savings 1 facility based on optimized processes and resource allocation (69 30-Day Notices)
- FDA audit cost (10 Days) - $140K
- Limited submissions and improvements due to regulatory resources
- European product lines optimized faster/better than US.

Patients/Providers

- 11 product quality improvements at one facility to patients 60-days sooner
- Increase product improvements
- Faster implementation of corrections to safety issues

- Voluntary PMA CtQ
  - focusing on activities critical to product and process quality starting September 29, 2017
  - Aim is to have the applicant discuss device design and manufacturing process quality information with FDA early on to assist FDA in its review of the PMA manufacturing section and post-approval inspections
  - Goal to streamline the premarket approval process while assuring that a firm's quality system includes rigorous controls for features and characteristics considered critical to the safety and effectiveness of the device

FR Notice: https://www.federalregister.gov/documents/2017/09/12/2017-19258/center-for-devices-and-radiological-health-premarket-approval-application-critical-to-quality-pilot?source=govdelivery&utm_medium=email&utm_source=govdelivery

- Participation PMA CtQ
  - Submit a request for a pre-PMA q-submission meeting and follow the outline of the guidance
  - List all PMA-related sites responsible for manufacture, processing, packaging or installation
  - List all critical characteristics of the device
  - Quality System deficiencies identified in FDA's review of the manufacturing section of the applicant's PMA
  - Had an FDA inspection of the PMA-related sites conducted within the last 5 years
    - Classification NAI/VAI (not OAI or been subject to a judicial action)

Experiential Learning Program

The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the pre-market review of the resulting medical devices.

- Stryker Instruments covering Design and Development, Manufacturing, and Servicing, November 2
- University of Nebraska Medical Center covering Wear Testing, December 5 -7
- DePuy Synthes covering Orthopedic Registries, April 11-12

Experiential Learning Program

- Multiple Biocompatibility ELP sessions
  - American Preclinical Services in Minneapolis, MN (OCTOBER 30, 2017)
  - NAMSA in Northwood, OH (NOVEMBER 14-15, 2017) and (JANUARY 24-25, 2018)
  - WuXi AppTec in Mendota Heights, MN (JANUARY 17-18, 2018)

510(k) Review: Tips and Requests

510(k) Review Tips/Requests

- The “long history of use” statement is no longer adequate by itself to address biocompatibility;
  - If the materials and manufacturing are identical to a predicate device (e.g., in-house or contract manufacturing), this should be explicitly stated;
  - If a justification is needed to address biocompatibility, please address all elements identified in the new guidance;
- For 3-D printed devices: in-house manufacturing versus contract manufacturing

510(k) Review Tips/Requests

- Please provide redlined labeling in a 510(k) submission, and ensure that the version supplied reflects all changes since the last clearance.
- Please provide an explicit listing (e.g., table) of all changes being effected/requested in the 510(k) submission, and provide this information in a single location (e.g., Device Description, Executive Summary).
- Please ensure that you do the full battery of testing on worst-case devices in accordance with relevant guidance documents.
- Please ensure that the identified points of contact in a 510(k) submission are prepared to address interactive requests/questions, and please consider identifying all possible points of contact
- 510(k) submissions that are well-organized and easy to follow generally require fewer requests for clarification.

MR Testing Expectations

MR Safety Labeling

- Not evaluated for MR safety
  - No electrical components
  - No highly ferromagnetic materials
- MR Safe
  - Non-metallic materials only
  - Requires rationale or engineering justification (e.g., resistivity testing)
- MR Conditional
  - Requires testing to establish the conditions under which a patient with the device may be safely scanned
  - Traditional submission, not special
  - Accept bundled submissions for identical device types

MR Conditional Labeling

- **For all tests**: use bath solutions as described in standards
- **Displacement Force – ASTM F2052**
- **Torque – ASTM F2213**
- **Image Artifact – ASTM F2119**
  - Report distance from artifact edge to device
    - Not artifact area or volume
  - Report image resolution
- **Radiofrequency induced heating – ASTM F2182**
  - Computational modeling to determine worst case construct
    - Report model validation & uncertainty analysis
  - Test devices in both 1.5 T and 3.0 T systems
  - Clearly describe both local and whole-body SAR measurements
  - For devices exhibiting high temperature rises, computational model of *in vivo* use (e.g., in Duke model) may be necessary

THANK YOU

QUESTIONS?


FDA
U.S. FOOD & DRUG
ADMINISTRATION

TPLC Future Direction & FDA Strategic Priorities

CAPT Raquel Peat, PhD, MPH
Director
Division of Premarket and Labeling Compliance
FDA

CAPT Raquel Peat, PhD, MPH

Captain (CAPT/O-6) Raquel Peat, PhD, MPH, MS is a microbiologist and an Officer in the United States Public Health Service. CAPT Peat has over 25 years of experience as a technical and regulatory expert, and as a manager and leader, in a variety of areas including drugs, medical devices and tobacco products. She is stationed at the Food and Drug Administration, as a Director for the Division of Premarket and Labeling Compliance in the Office of Compliance, Center for Devices and Radiological Health where she is in charge of enforcing premarket and postmarket requirements, as well as promotion, advertising and labeling requirements for medical devices. In the future Total Product Life Cycle reorganization, CAPT Peat will be the Director for the Office of Health Technology 6 in the Office of Product Evaluation and Quality and that office will be responsible for regulating orthopedic devices. She has received her degrees; Doctor of Philosophy and Bachelor of Science from University of Maryland, Master of Science from Johns Hopkins University and Master of Public Health from George Washington University.

FDA CDRH TPLC Future Direction & Strategic Priorities

CAPT Raquel Peat, PhD, MPH
Director
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and Radiological Health

CDRH Vision

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

What does it take?

- Focus on quality
  - Patient centric perspective
  - Value
  - Collaboratively seek solutions
  - Speed
- Accelerate Innovation
  - Enhanced data and capability
  - Proactive/Predictive
- Adaptive regulatory framework

It is all about the patients!

CDRH Total Product Life Cycle (TPLC) Transformation

Office of Product Evaluation and Quality


Change
Just Ahead

TPLC Reorganization Goals

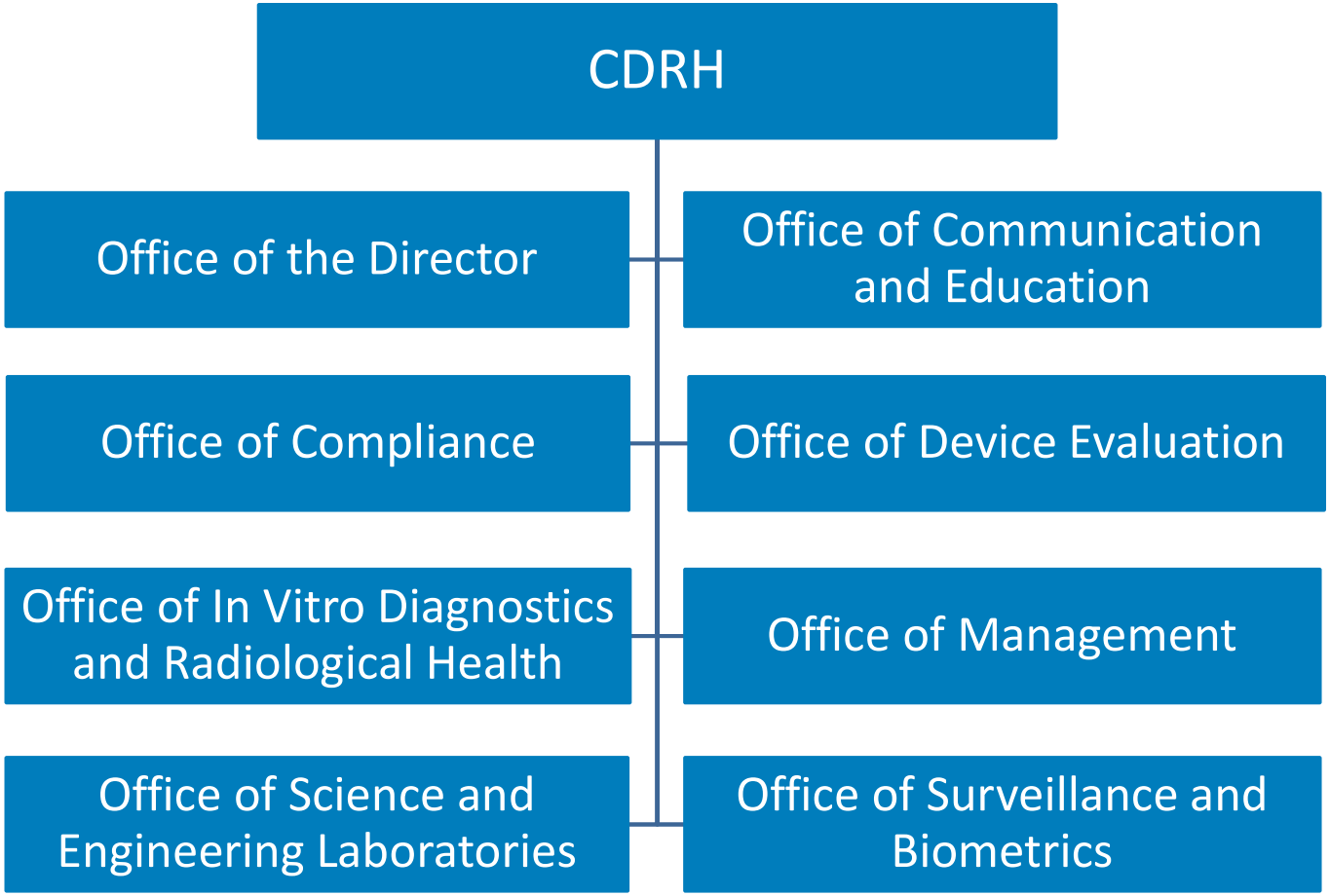
- Create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs.
- Facilitate information-sharing to help make better informed decisions.
- Facilitate professional development for all employees by increasing opportunities for cross-skills development and creating multifunctional positions.

TPLC Reorganization Goals

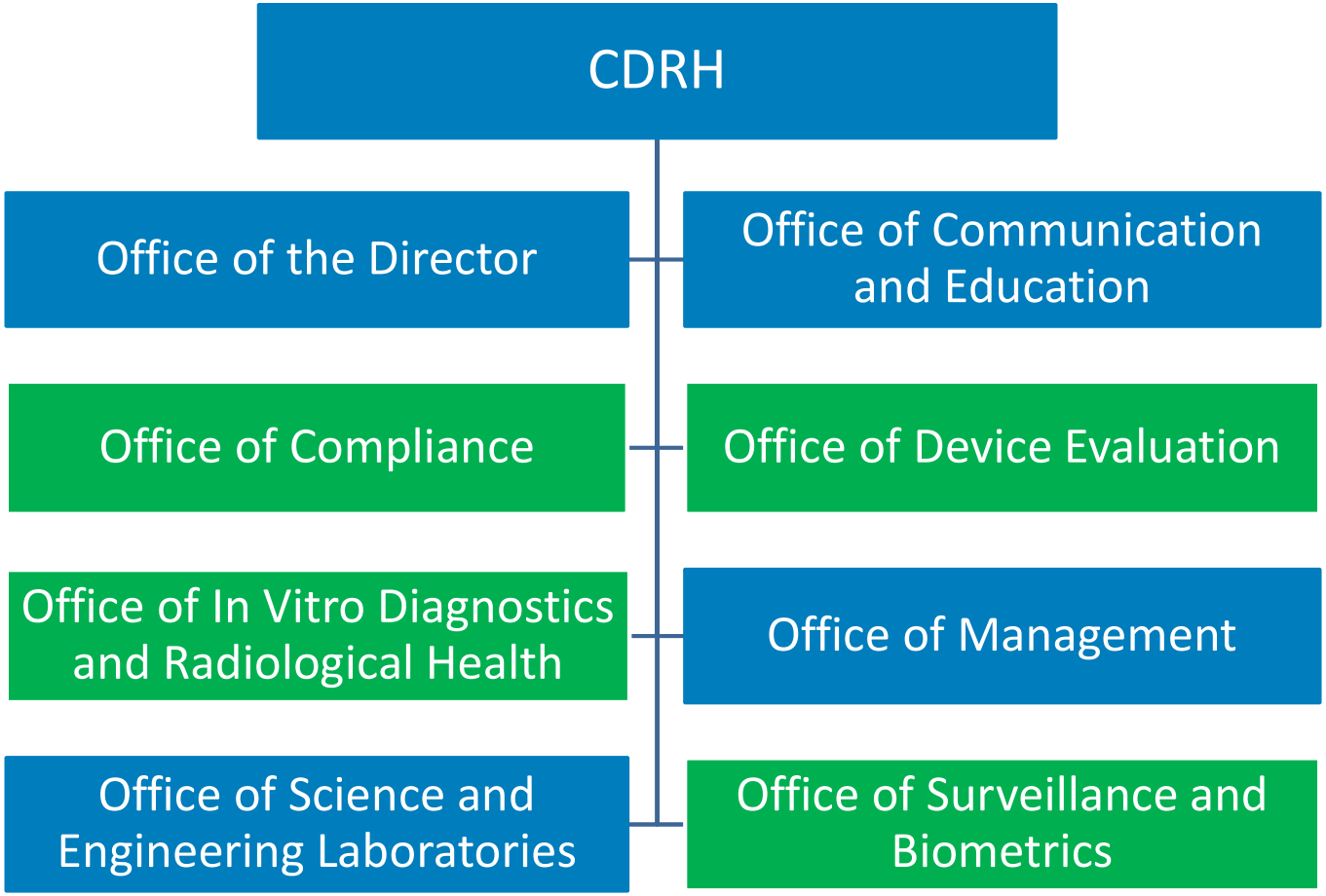
- Ensure process and policy consistency.
- Minimize organizational layers of review and facilitate employee professional development, to achieve more efficient work processes and allow employees to leverage their knowledge of pre- and post-market information to optimize decision-making.
- Allow for an increase in efficiency and organizational flexibility to translate into reasonable employee workloads, so that managers and staff can have healthy work-life balances.

HOW WE ARE CHANGING

Current Structure



What Will Change

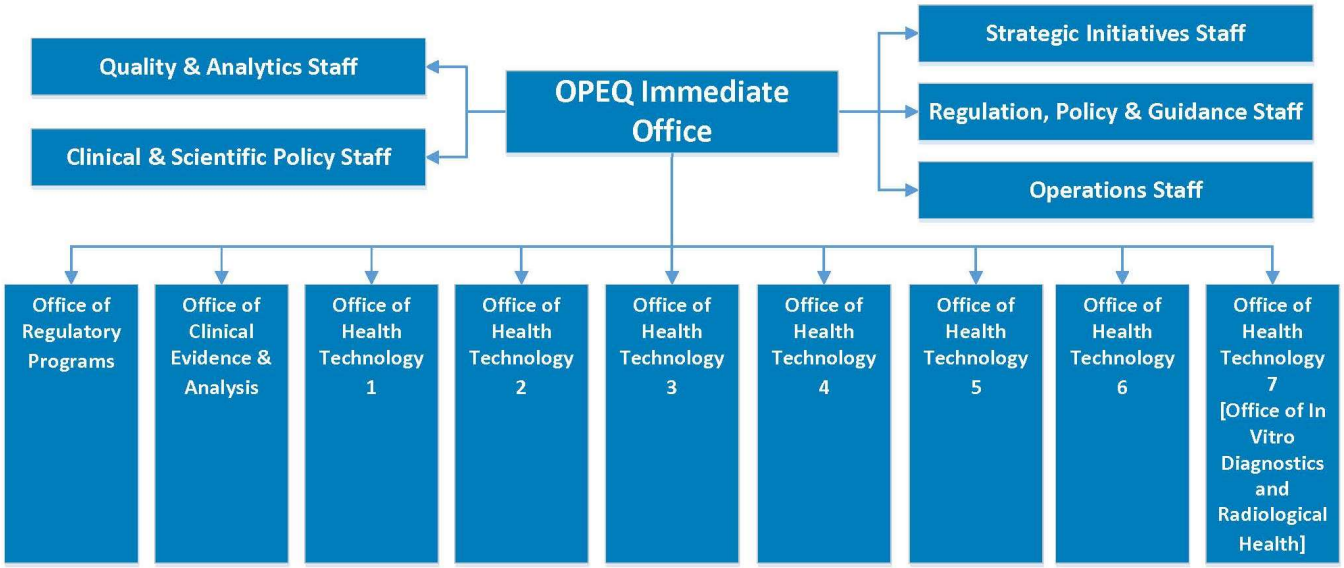


How Will These Offices Change

- Merging four CDRH offices into the Office of Product Evaluation and Quality (OPEQ):
  - Office of Compliance
  - Office of Device Evaluation
  - Office of Surveillance and Biometrics
  - Office of In Vitro Diagnostics and Radiological Health

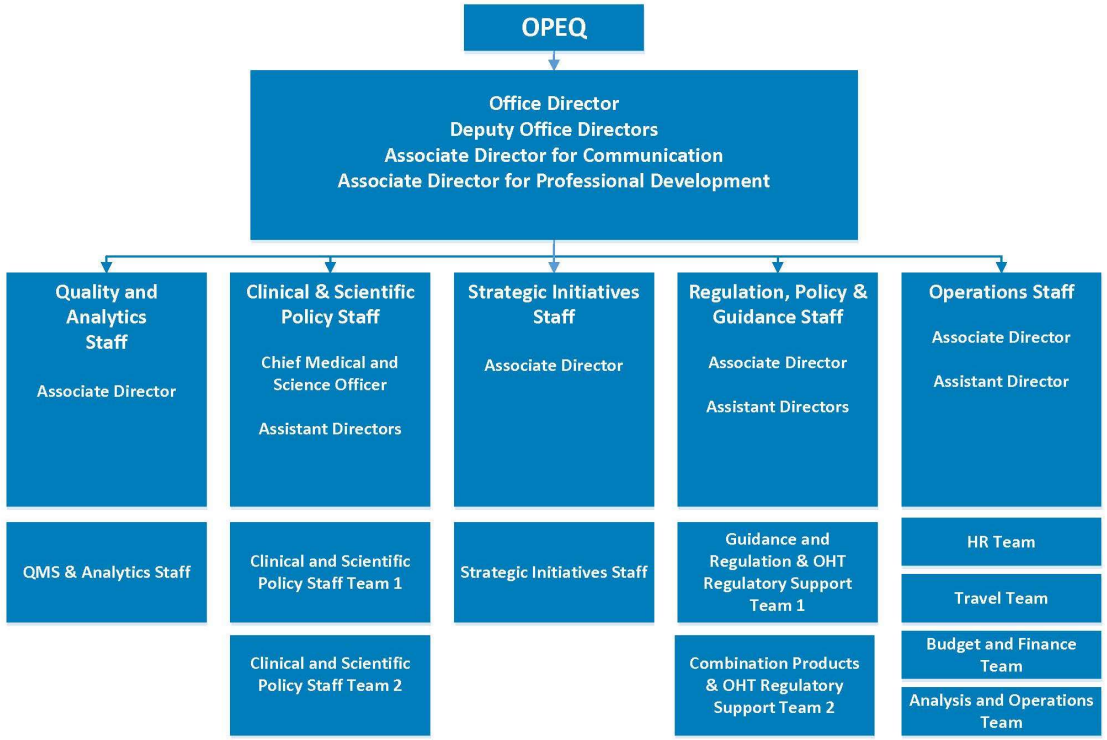
Future Design

Office of Product Evaluation and Quality (OPEQ)



Future Design

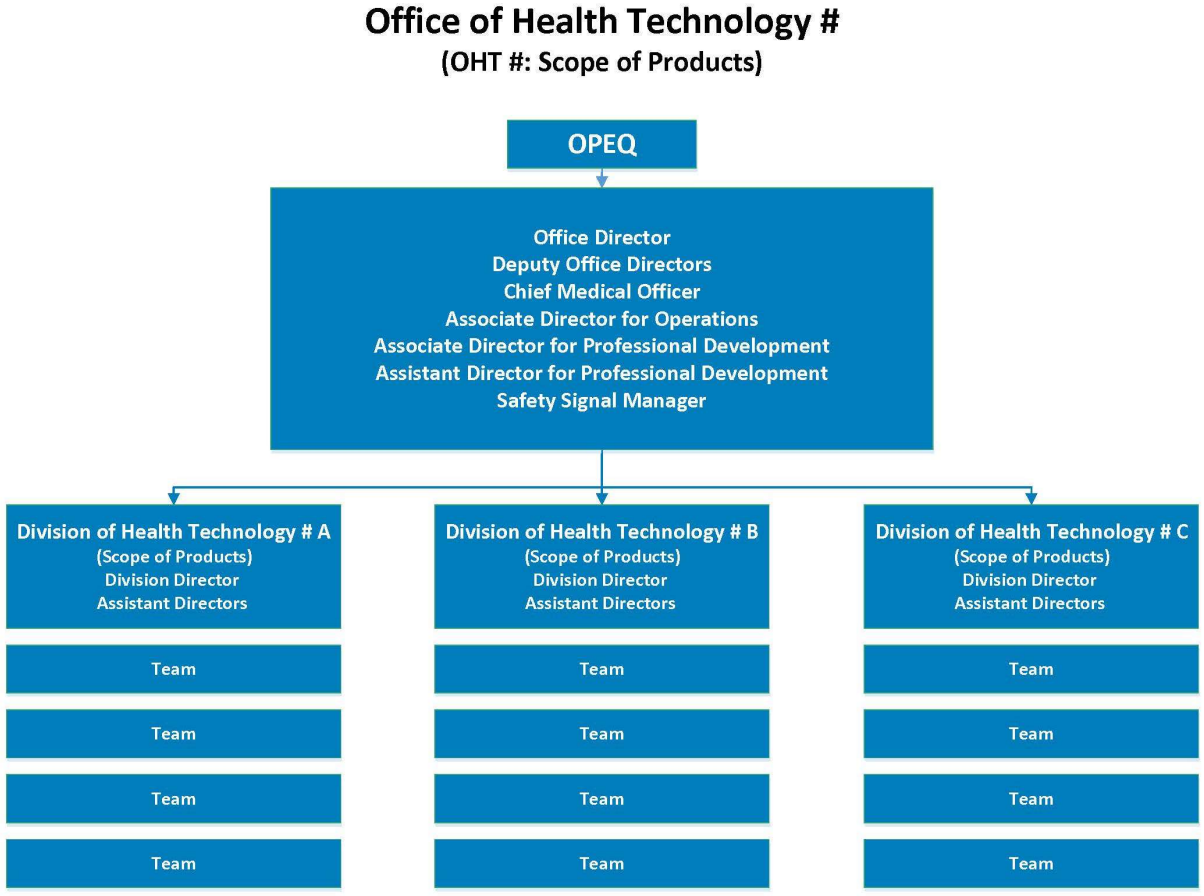
Office of Product Evaluation and Quality (OPEQ) Immediate Office



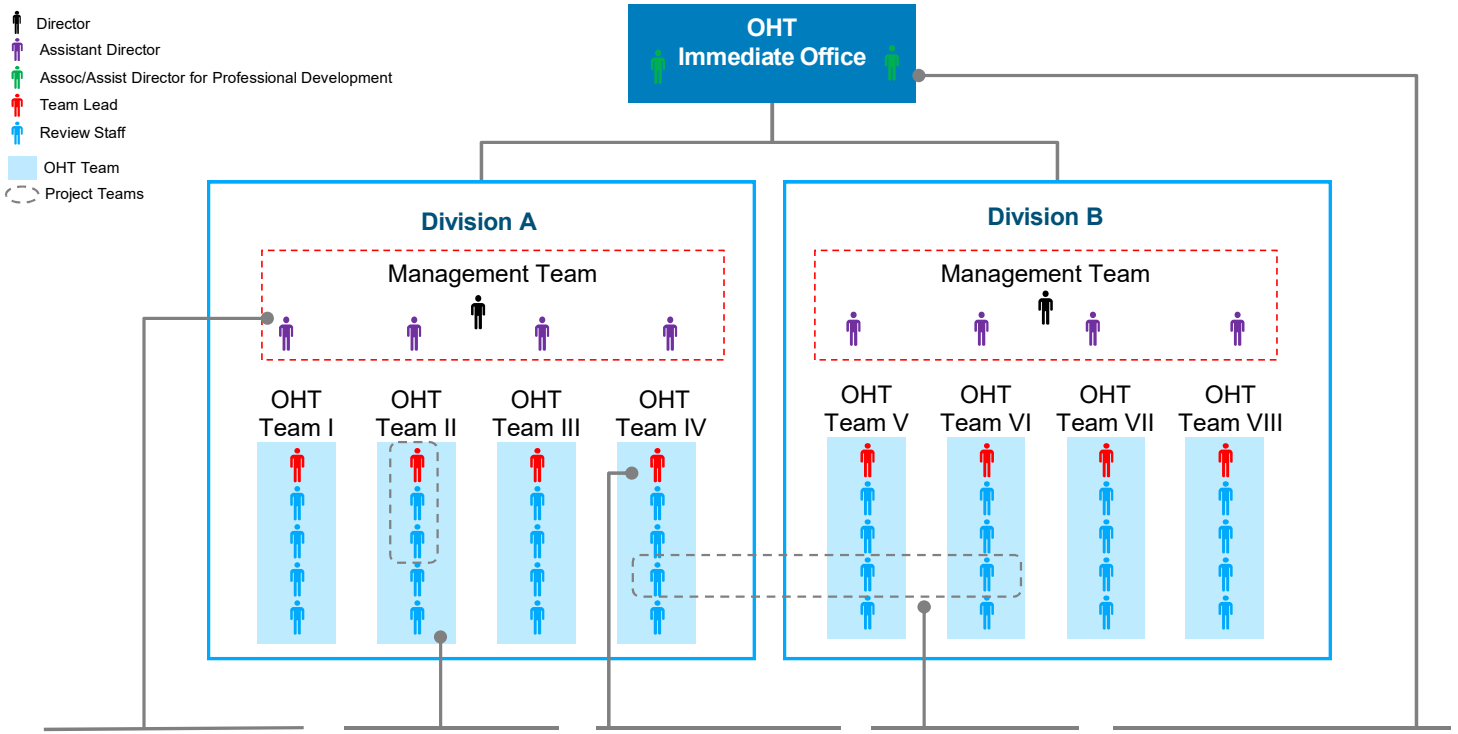
OPEQ Design Features

- Working in teams
  - Team management approach
  - Teams within and across divisions
- Common management chain for compliance, premarket and surveillance programs
- Division is the lowest organizational structure
- Empowering staff by driving decision-making to lowest appropriate level
- Emphasis on professional development & work-life balance

Future Design



Future Team Design: OHTs



Assistant Directors work as a team to lead Division; each supervises staff within a specific team and shares responsibility for Division performance

Teams are ~8-12 individuals focused on common nexus of device technology and therapeutic area; can be stood up/down quickly

Team Lead provides technical oversight of work, helps set priorities, and ensures standards of expertise are maintained

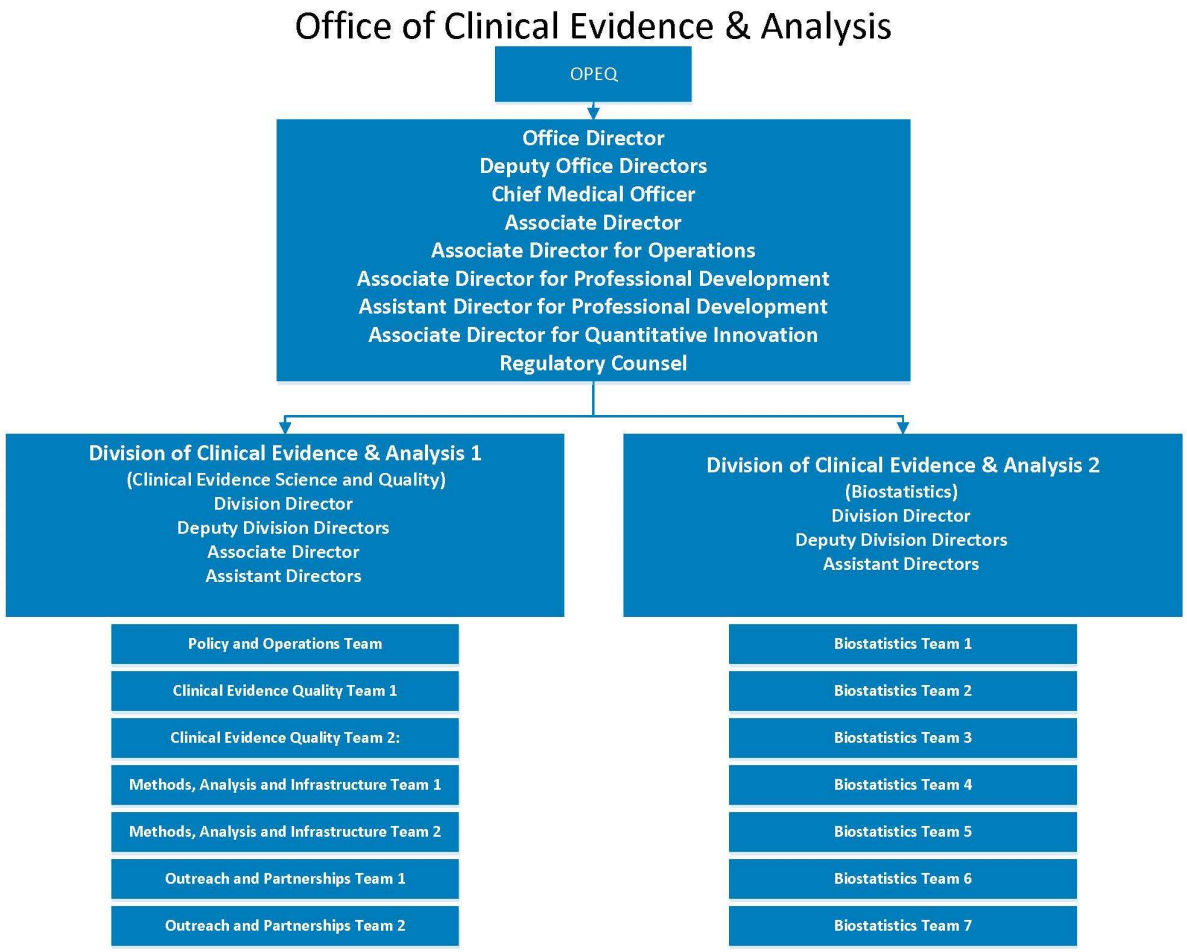
Cross-cutting teams address strategic priorities and special projects

Assistant Director for Professional Development facilitates staffing, monitors and helps balance workload, identifies and addresses professional development needs, and coordinates training

Future Product Specific Offices

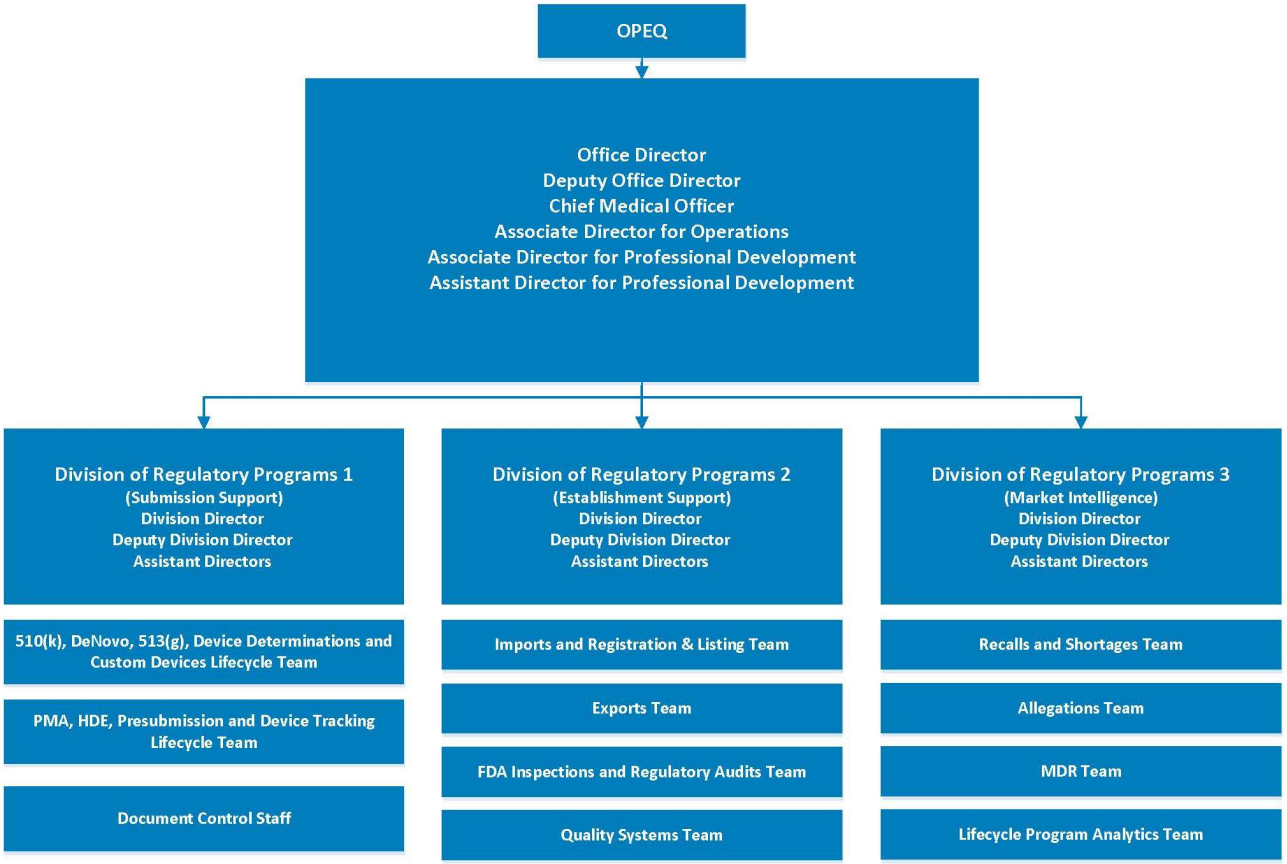
OHT	Scope of Products within OHT	Office Director
OHT 1	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices	Malvina Eydelman, M.D.
OHT 2	Cardiovascular Devices	Bram Zuckerman, M.D.
OHT 3	Reproductive, Gastro-Renal, Urological, General Hospital Device and Human Factors	Ben Fisher, Ph.D.
OHT 4	Surgical and Infection Control Devices	Binita Ashar, M.D.
OHT 5	Neurological and Physical Medicine Devices	Carlos Pena, Ph.D.
OHT6	Orthopedic Devices	Raquel Peat, Ph.D., MPH
OHT 7 /OIR	In Vitro Diagnostics and Radiological Health	Donald St. Pierre (Acting)

Future Design

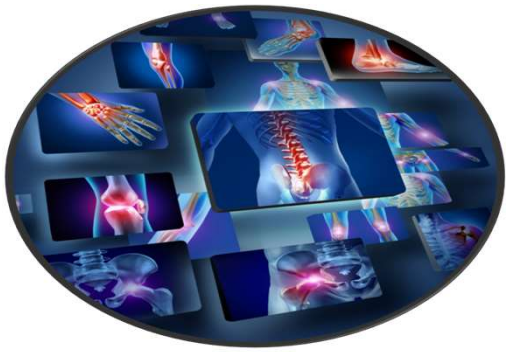


Future Design

Office of Regulatory Programs



OFFICE OF HEALTH TECHNOLOGY 6



Future Design

Office of Health Technology 6

(OHT 6: Orthopedic Devices)

OPEQ

Office Director
Deputy Office Directors
Chief Medical Officer
Associate Director for Operations
Associate Director for Professional Development
Assistant Director for Professional Development
Safety Signal Manager

Division of Health Technology 6 A (Joint Arthroplasty Devices) Division Director Assistant Directors	Division of Health Technology 6 B (Spinal Devices) Division Director Assistant Directors	Division of Health Technology 6 C (Restorative, Repair and Trauma Devices) Division Director Assistant Directors
Knee Arthroplasty Devices	Intracolumnar Spinal Devices	Restorative, Repair, Trauma and Fracture Fixation Devices
Hip Arthroplasty Devices	Extracolumnar Spinal Devices	Stereotaxic, Bone Growth Simulators and Fracture Fixation Devices
Shoulder Arthoplasty Devices		

OHT 6 A focuses on Joint Arthroplasty Devices
Some examples of our products are shown below:

Knee Arthroplasty Devices

Partial Knee Arthroplasty

Total Knee Arthroplasty

Shoulder Arthroplasty Devices

Total Shoulder Arthroplasty

Reverse Total Shoulder Arthroplasty→

Hip Arthroplasty Devices

Total Hip Arthroplasty

Acetabular Shell Systems→

OHT 6 B focuses on Spinal Devices

Some examples of our products are shown below:

Intracolumnar Spinal Devices

←Intervertebral Body Fusion Cages

Vertebral Body→ Replacements

←Total Disc Replacements

Extracolumnar Spinal Devices

←Pedicle Screw Instrumentation

Anterior/Lateral → Plates

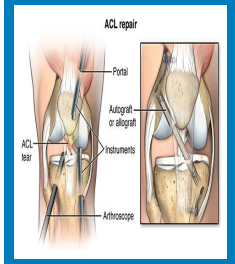
←Spinous Process Plates

OHT 6 C focuses on Restorative, Repair and Trauma Devices
Some examples of our products are shown below:

Restorative, Repair, Trauma and Fracture Fixation Devices

←Bone Void Filler

Bone Cement→



Tendon and ←Ligament Repair/Replacements

Fracture Fixation Devices→

Stereotaxic, Bone Growth Stimulators and Fracture Fixation Devices

←Stereotaxic (Mako robot)

Bone Growth → Stimulator

←Intramedullary rod, also known as an intramedullary nail (IM nail) or inter-locking nail or Küntscher nail (without proximal or distal fixation)

Value Added for You

- Improving our internal processes, coordination and communication → more straightforward & streamlined interactions with CDRH
- Consolidating our structure → provides you with "one stop shopping" in many cases
- Creating a more agile organization → better response to changing regulatory needs and new technologies

Value Added for You

- Ensuring more consistent policy application across OPEQ → easier for you to know what to expect
- Streamlining decision making → more informed interactions with CDRH staff
- Focus on professional growth and creating a better work-life balance for our employees → increased longevity of your points of contact within the organization due to reduced staff turn-over

NEXT STEPS

Next Steps

- Reorganization package
  - Under review; seeking approval in 2018
- People
  - Planning & conducting critical training
  - Hiring with the future in mind
- Processes
  - Develop core processes and procedures for OPEQ
  - Simplicity is our strategic priority

Next Steps

- Structure
  - IT changes to support reorganization
  - Piloting OPEQ structure as appropriate
- Will communicate with our customers to facilitate interactions with the redesigned CDRH

Please tell us what information is important for you to know during this transition.

FDA U.S. FOOD & DRUG ADMINISTRATION

CDRH Strategic Priorities

CDRH Strategic Priorities 2018-2020

Making Our Vision A Reality

The Strategic Priorities will focus on the enhancement and widespread application of three approaches we've already started.

Employee Engagement, Opportunity, and Success

Simplicity

Collaborative Communities

Our Measure of Success

By December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets.

2018-2020 Strategic Priorities

Employee Engagement, Opportunity, and Success

- Reduce unnecessary burdens
- Foster creativity and teamwork
- Facilitate open dialogue
- Promote an environment of trust and mutual respect
- Create opportunities for professional growth and personal development
- Provide a reasonable work life balance

2018-2020 Strategic Priorities

Simplicity

- Continuous process improvement
- Streamline our policies, processes, programs, and approaches, as appropriate
- Stop doing or streamline what we determine is not sufficiently “value added”
- Remove unnecessary burdens (both on our stakeholders and ourselves)
- Spend more time on what matters most

2018-2020 Strategic Priorities

Collaborative Communities

- Forum where public and private sector members work together to solve both shared problems and problems unique to other members.
- An environment of trust and openness, where participants feel safe and respected to communicate their concerns.
- Members share a *collective responsibility* to help each other obtain what they need to be successful.

THANK YOU!


FDA
U.S. FOOD & DRUG
ADMINISTRATION

ODE Update/FDARA

Constance Soves, Ph.D.
Acting Regulatory Advisor
ODE
FDA

Constance Soves, Ph.D.

Constance Soves has been with the Office of Device Evaluation (ODE) at the FDA since 2011. She began as a scientific reviewer for the Anterior Spine Devices Branch (ASDB) in the Division of Orthopedic Devices and is currently serving as a Regulatory Advisor for ODE. She holds a Ph.D. in Biomedical Engineering from the University of Michigan.

ODE Updates

OSMA Fall Meeting

April 19, 2018

Constance P. Soves
Regulatory Advisor

Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Outline

- Current ODE Structure
- Guidance Updates
- FDA Reauthorization Act of 2017 (FDARA)

CURRENT ODE STRUCTURE

Current ODE Structure

Name	ODE Role
William Maisel, MD, MPH	Director
Angela Krueger *(acting)*	Deputy Director, Engineering & Science Review
Barbara Zimmerman	Deputy Director, Premarket Program Management
Randall Brockman, MD	Deputy Director, Clinical
Aron Yustein *(acting)*	Chief Medical Officer
Rebecca Nipper *(acting)*	Associate Director, Guidance & Regulation
Owen Faris, PhD	Clinical Trials Director

Other Groups in ODE

Name	ODE Role
Sharyn (Lesa) Dowtin	Director, Program Management Office
Joshua Nipper	Chief, Premarket Approval (PMA) Staff
Soma Kalb	Chief, Investigational Device Exemption (IDE) Staff
Marjorie Shulman	Chief, Premarket Notification (510(k)) Staff
Sergio de del Castillo *(acting)*	De Novo Program Lead
James Swink	Advisory Panel Coordinator

GUIDANCE UPDATES

Guidance Updates

- Overview of Significant Guidances
  - 510(k) Modifications Guidances (General & Software)
  - Least Burdensome Guidance
  - Accessories Guidance
- FY18 Guidance Priorities

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510(k) Modifications Guidances: General & Software

Published on October 25, 2017

FDA Guidance Goals

- FDA made targeted changes to original *Deciding When to Submit* guidance from 1997:
  - Clarity, including interpretation of key regulation terms such as “could significantly affect”
  - Flowcharts – matched with text
  - Key principles
  - Materials changes
  - Examples to illustrate use of guidances
  - Documentation recommendations and examples
- Separate software guidance based on same key principles
- Addition of risk assessment paradigm

Guidance Scope

- Both guidances apply to legally marketed devices subject to 510(k) requirements
  - Excludes PMA devices and 510(k)-exempt devices
- General Guidance and Software:
  - General guidance **does not** apply to software-specific changes.
  - General guidance **does** apply to non-software changes to software devices or devices containing software (e.g., labeling).
  - When multiple changes affect labeling/hardware in addition to software, assess the changes using both guidances.
  - If use of either guidance leads to a "New 510(k)" conclusion, submission of a new 510(k) is likely required.
  - Guiding Principles are aligned between the guidances.

Guidance Structure

- Guiding Principles
- Logic scheme
  - Labeling changes (Section A)
  - Technology, engineering, and performance changes (Section B)
  - Materials changes (Section C)
  - IVDs (Section D)
  - Considerations for risk-based assessments of modified devices (Section E)
- Examples

How to Use The Guidances

- Guidances describes a logic scheme for determining when a 510(k) is required
- Include flowcharts for ease of use, but flowcharts are not intended to be used stand-alone
- In cases with multiple changes, manufacturers should use all applicable flowcharts and companion text
- Changes not addressed in Sections A through D should be evaluated with a risk-based assessment using the recommendations provided in Section E.

Reminder: Flowcharts are provided as a visual aid, but do not capture all necessary considerations. Refer to accompanying text when using flowcharts.

Software Modifications

- Same General Principles as with the General Guidance
- Software-specific policy
  - 4 Questions
    - Strengthen cybersecurity?
    - Return the system into specification of most recently cleared device?
    - Impacts of changes to risks/risk controls?
    - Significantly affect clinical functionality/performance specs?
  - Additional considerations
- Software-specific examples in Appendix of Software Modifications Guidance only

Additional Info

- General Modifications Guidance:

  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf

- Software Modifications Guidance:

  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.pdf

- Webinar held November 16, 2017

  https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm581811.htm

Least Burdensome Guidance

- The Least Burdensome Provisions: Concept and Principles (Draft)
  - ➢Published December 15, 2017
  - ➢Comment period closed March 15, 2018

LB Principles

- LB principles should be interpreted broadly and applied across the total product lifecycle.
- CDRH has applied the LB approach and its goals in policies and programs, including:
  - Benefit-Risk Framework
  - Expedited Access Program (now Breakthrough Devices)
  - Utilization of RWE
  - Enforcement discretion policies (MMA, MDDS, General Wellness)
  - PMA retrospective review for reclassification, reduced premarket data collection, or pre/postmarket shift
  - Cures Act Class I and Class II exemptions

Least Burdensome Definition

The minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time.

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Guiding principles

- FDA intends to request the minimum information necessary to adequately address the regulatory question or issue at hand.
- Industry should submit material, including premarket submissions, to FDA that are least burdensome for FDA to review within applicable regulatory requirements.
  - Industry should submit well-organized, clear, and concise information.

Guiding principles

- FDA intends to use the most efficient means to resolve regulatory questions and issues.
- The right information should be provided at the right time (e.g., just-in-time data collection) to address the right questions.
- Regulatory approaches should be designed to fit the technology, taking into account its unique innovation cycles, evidence generation needs, and timely patient access.
- FDA intends to leverage data from other countries and decisions by or on behalf of other national medical device regulatory authorities to the extent appropriate and feasible.
- FDA intends to apply least burdensome principles in international medical device convergence and harmonization efforts.

Additional Info

- Least Burdensome Concepts and Principles (Draft):
  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf
  (Comment period closed March 15, 2018)

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Accessories Guidance

Published on December 20, 2017

Key Take-Aways

- FDA is taking a risk-based approach to classifying accessories when used as intended with a parent device
  - New types of accessories can be a lower classification than the parent device
- Provides clarification on the definition of a medical device accessory
- Outlines pathways for classification of accessories (Section 513(f)(6) of the FD&C Act)

Historical Classification of Accessories

- Inclusion in the same classification as the parent device
  - Through 510(k) Premarket Notification clearance
  - Premarket Application (PMA) approval
  - Explicit inclusion in classification regulation or reclassification order for the parent device
- Issuance of a unique, separate classification regulation for the accessory

What's New

- 21st Century Cures and FDARA amended the FD&C Act to change the authority and methods by which CDRH classifies medical device accessories:

  "…classify an accessory… based on the risks of the accessory when used as intended and level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used."

Accessory Classification Processes

- New Accessories:
  - Request for classification of an accessory type that has not been previously classified under the FD&C Act, cleared under a 510(k), or approved in a PMA
  - Bundled with PMA or 510(k)
  - Timeline for decision (grant or deny) aligns with PMA or 510(k) decision timeline

Accessory Classification Processes

- Existing Accessories:
  - Request for classification of an accessory type that has been previously classified under the FD&C Act, cleared under a 510(k), or approved in a PMA
  - Standalone request made by a manufacturer or importer who has been granted marketing authorization for that accessory
  - Manufacturer may request a meeting prior to submitting request utilizing pre-sub process
  - Decision (grant or deny) issued within 85 days

Accessory Decisions

- If granted, written order classifies accessory into class I or class II (special controls)
  - Federal Register Notice published announcing classification
- If denied, letter sent to manufacturer including a detailed description and justification for accessory classification determination.

Other Classification Options

- De Novo Request – for new accessories
- Reclassification under sections 513(e) and 513(f)(3) of the FD&C Act – for existing accessories

Additional Info

- Accessories Guidance:

  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf

- Webinar *(does not discuss new FDARA provisions)*

  https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm534952.htm

FY18 Guidance Development

- **Final Guidance Topics (A-List)**
- Medical Device Accessories: Describing Accessories and Classification Pathway for New Accessory Types (revision) ✓
- Unique Device Identification: Policy Regarding Compliance Dates of Class I and Unclassified Devices ✓
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
- Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases ✓
- Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics ✓

FY18 Guidance Development

- **Draft Guidance Topics (A-List)**
- Export Certificates
- Multifunctional Device Products: Policy and Considerations
- The Least Burdensome Provisions: Concept and Principles ✓
- Humanitarian Devices Exemption (HDE) Program
- 510(k) Third Party Review Program
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program
- Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria ✓
- The Application of Acceptable Unce… to Support Marketing Authorization Decisions for Medica…
- Principles and Procedures for the R… Voluntary Consensus Standards
- Validation of Automated Process Equipment Software

Published 4/12/18
Comment period open through 7/11/18

FY18 Guidance Development

- **Final Guidance Topics (B-List)**
- Human Factors List of High Priority Devices
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics
- Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product
- **Draft Guidance Topics (B-List)**
- Premarket Submissions for Patient Matched Guides to Orthopedic Implants
- Replacement Reagents Policy for Technologically Similar Instruments for In Vitro Diagnostic Devices

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FDA REAUTHORIZATION ACT OF 2017 (FDARA)

Overview of FDARA

- Reauthorizes user fee collections for
  - Medical Devices (MDUFA)
  - Prescription Drugs (PDUFA)
  - Generic Drugs (GDUFA)
  - Biosimilars (BsUFA)
- Includes additional medical devices provisions related to
  - pediatric devices
  - inspections processes
  - the export certificate process
  - the regulation of contrast imaging agents
  - classification of accessories
  - evaluating the use of real world evidence in the postmarket context
  - over the counter hearing aids
  - third party servicing of medical devices

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Pediatric Devices

- FDARA sec. 502
- Requires additional information in CDRH's annual pediatric report to Congress, including:
  - An assessment of pediatric device labeling needs based on a review of real world evidence on the off-label use of medical devices in children; and
  - The number of devices for which extrapolation was used to support approval of pediatric labeling
- Allows emergency use of an HDE device if permitted by either an institutional review board or an "appropriate local committee"
- Allows pediatric device consortia (PDC) grant money to be spent on regulatory consultation activities
- Requires a public meeting about the development, approval/clearance, and labeling of pediatric medical devices to be held within 1 year of enactment (by 8/18/18)

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Pediatric Medical Device Development Public Meeting

August 13-14, 2018

FDA Main Campus

Silver Spring, MD

For information and registration:
https://go.usa.gov/xQbbM

Accessories

- FDARA sec. 707
- Decouples accessory classification from classification of the parent device
- Requires FDA to respond to accessory classification requests within 85 days for accessories previously classified
- Allows FDA to mass classify accessories that can be classified into Class I (similar to process used for Cures exemptions)
- Became effective 60 days after enactment (10/17/17)
- Issued guidance: Medical Device Accessories - Describing Accessories and Classification Pathways (12/20/17)

Questions from OSMA

"For the OSMA spring meeting as part of instrument classification, we would appreciate some clarity on the following topics:

- FDA's submission expectations for reclassification of orthopedic instruments from Class I to Class II based on their guidance Medical Device Accessories – Describing Accessories and Classification Pathways.

- What product codes FDA does expect industry to use for an implant-specific accessory. Will there be new pro codes planned for introduction in 2018/2019 covering class II product codes for non-implant accessories/instruments?"

Questions from OSMA

“Can FDA provide us with a status update on the medical device accessory pathway?”

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Thank you!

Email: constance.soves@fda.hhs.gov
Phone: (301) 796-6951

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