



IMDRF

International Medical
Device Regulators Forum

U.S. FDA UPDATE

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BREAKTHROUGH DEVICES PROGRAM

Eligibility:

Devices subject to premarket approval applications (PMAs), premarket notification (510(k)) or requests for De Novo designation are eligible for breakthrough device designation if both of the following criteria are met:

Criteria	Description
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.
Second Criterion	The device also meets at least one of the following: a) Represents Breakthrough Technology b) No Approved or Cleared Alternatives Exist c) Offers Significant Advantages over Existing Approved or Cleared Alternatives d) Device Availability is in the Best Interest of Patients



BREAKTHROUGH DEVICES PROGRAM

- Replaces Expedited Access Pathway and Priority Review for medical devices.
- **Greater FDA interaction:** Opportunity to interact with the FDA's experts through several different program options to efficiently address topics during premarket review.
- **Prioritized Review:** Devices receive prioritized review including Q-Submissions, IDE applications, and marketing submissions.
- As of March 1, 2019:
 - 224 breakthrough device designation requests
 - 131 requests have been granted breakthrough designation
 - 10 devices have been approved through PMA process, granted De Novo classification, or cleared through 510(k) process.
- FDA final guidance issued December 2018, outlines program policies, features, and process for pursuing breakthrough designation.

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm>



LEAST BURDENSOME PROVISIONS: CONCEPT AND PRINCIPLES

- **Least burdensome:** gathering the minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time.
- **FDA final guidance** issued February 2019, helps implement FDA's total product lifecycle approach to least burdensome medical device regulation and allows FDA to focus resources on issues of highest public health concern.
- Aligns with **CDRH Strategic Priority for Simplicity** by simplifying policies and processes to focus on having the greatest public health impact.
- Least burdensome approach does not change applicable regulatory standards, content requirements, nor the requirement for valid scientific evidence.



SAFETY AND PERFORMANCE BASED PATHWAY

- FDA final guidance issued February 2019, modernizes and strengthens the 510(k) pathway and FDA's approach to device safety.
- Devices meet FDA-identified performance criteria to demonstrate it is as safe and effective as predicate device.
- FDA will issue future guidance to apply this pathway to certain types of devices with corresponding FDA-identified performance criteria.
- Benefits:
 - Promotes the use of modern predicate devices, and adoption of up-to-date benchmarks and standards for performance.
 - Promotes the use and development of international consensus standards rather than reliance on comparison to predicate devices.
 - Facilitates greater harmonization of pre-market requirements with other regulatory jurisdictions.

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm629679.htm>



NONBINDING FEEDBACK AFTER CERTAIN FDA INSPECTIONS

- Implements provisions enacted by Congress through the FDA Reauthorization Act (FDARA) of 2017 for FDA to provide nonbinding feedback after an inspection of a device establishment.
- FDA draft guidance issued February 2019 for public comment outlines recommendations for how manufacturers can request timely feedback on proposed corrective actions and describes how FDA evaluates and responds to such requests.
- Timely nonbinding feedback may support faster resolution of violative manufacturing conditions observed by FDA and ensure patients have continued access to safe and effective medical devices.
- FDA will implement uniform inspection processes and standards in future draft guidance as required by FDARA.





FDA'S SOFTWARE PRECERTIFICATION PILOT PROGRAM

- ✓ Launched pilot program in 2018.
- ✓ Latest releases: Working Model v1.0, regulatory framework, and 2019 test plan.
- ✓ Building a working model with continuous public input.
- ✓ Working with nine participating companies (large and small).
- ✓ Testing v1.0 throughout 2019 to ensure the same level of safety and effectiveness of products as compared to our traditional approach.





PRE-CERT UPDATE: WORKING MODEL v1.0

The Software Precertification Working Model v1.0 published on Jan 7, 2019 and included the following changes:

1. A description of the **Total Product Lifecycle approach**
2. Revisions to **Excellence Appraisal** (EA) descriptions for levels of Pre-Cert and FDA's intention to conduct appraisals in 2019;
3. Revisions to SaMD product-level elements for **review determination**;
4. A proposed list and descriptions of review elements for **streamlined review**, and an updated review process to apply to all submission types;
5. An updated description of the process for developing a **Real World Performance** analysis plan, examples of analytic types/sources, and how the types of RWP collected & the duration of collection may vary.





REGULATORY FRAMEWORK

FDA intends to implement Pre-Cert Pilot Program under the De Novo Pathway so that Excellence Appraised sponsors may:

1. **Submit a “Pre-Cert De Novo”** to receive device classifications through De Novo Pathway by submitting all applicable required information to FDA at different times (i.e., during the Excellence Appraisal, Review Determination, and Streamlined Review);
2. **Submit a Review Determination pre-sub** to confirm a SaMD sponsor is excellence appraised and is eligible for 510(k) under device classification created by Pre-Cert De Novo;
3. **Submit “Pre-Cert 510(k)”** under device classification created by Pre-Cert De Novo containing product-level information on modifications while leveraging EA data to satisfy some required elements of a 510(k) submission.





2019 TEST PLAN OVERVIEW

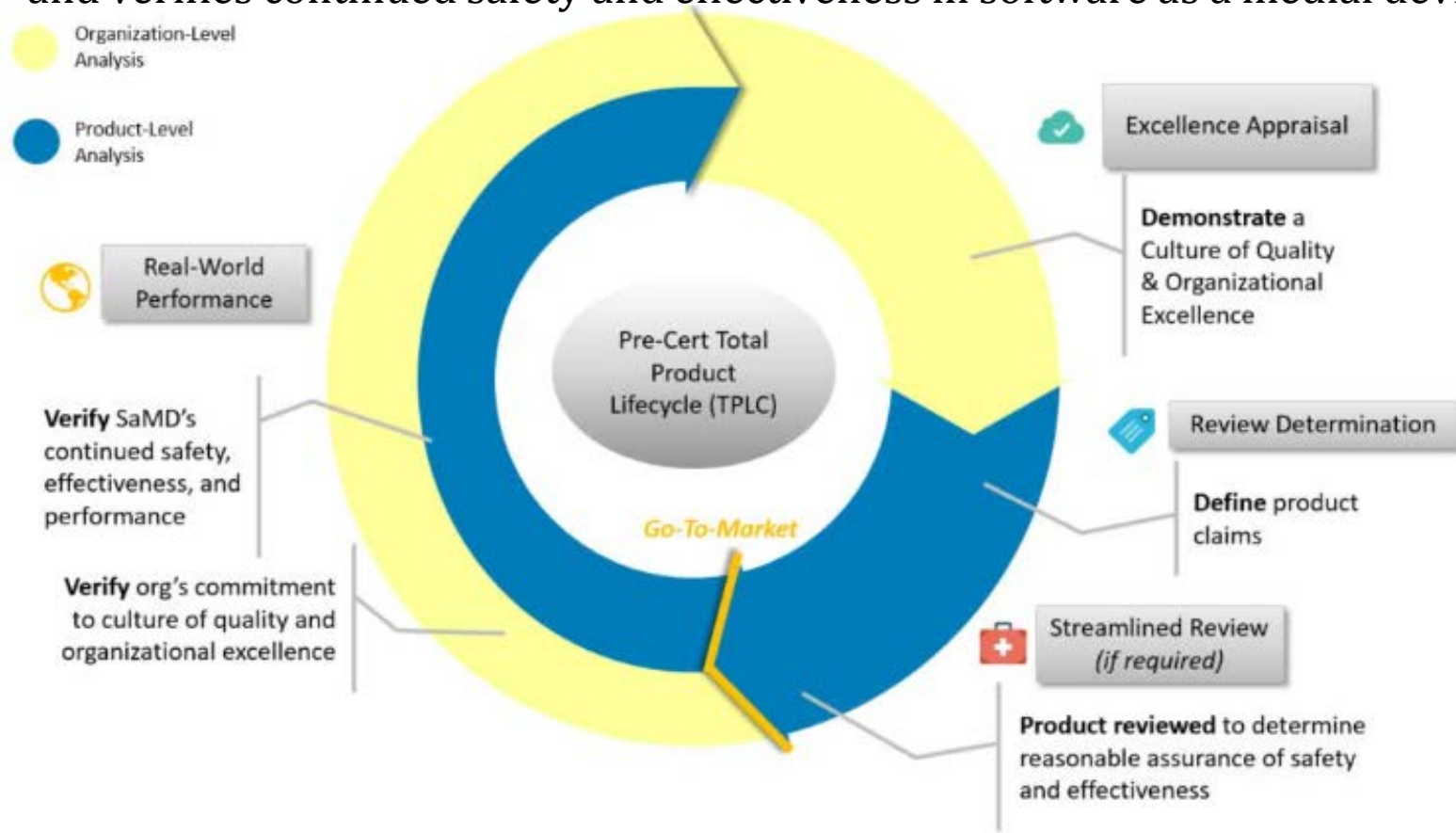
- **Objective:** Assess whether Excellence Appraisal (EA) + Streamlined Review (SR) together produce an equivalent basis for determining Reasonable Assurance of Safety and Effectiveness for a SaMD product prior to its introduction to the market, as compared to the traditional paradigm.
- **Structure:**
 - Sponsor submits full traditional submission
 - SR team conducts SR, then full review
 - Iterative refinement of EA and SR
 - Test plan to conclude when Pre-Cert framework remains stable over multiple submissions



DIGITAL HEALTH

TOTAL PRODUCT LIFECYCLE APPROACH

FDA proposes tailored, pragmatic, and least burdensome regulatory oversight that assesses organizations (large and small) to establish trust, leverages transparency, and verifies continued safety and effectiveness in software as a medical devices.





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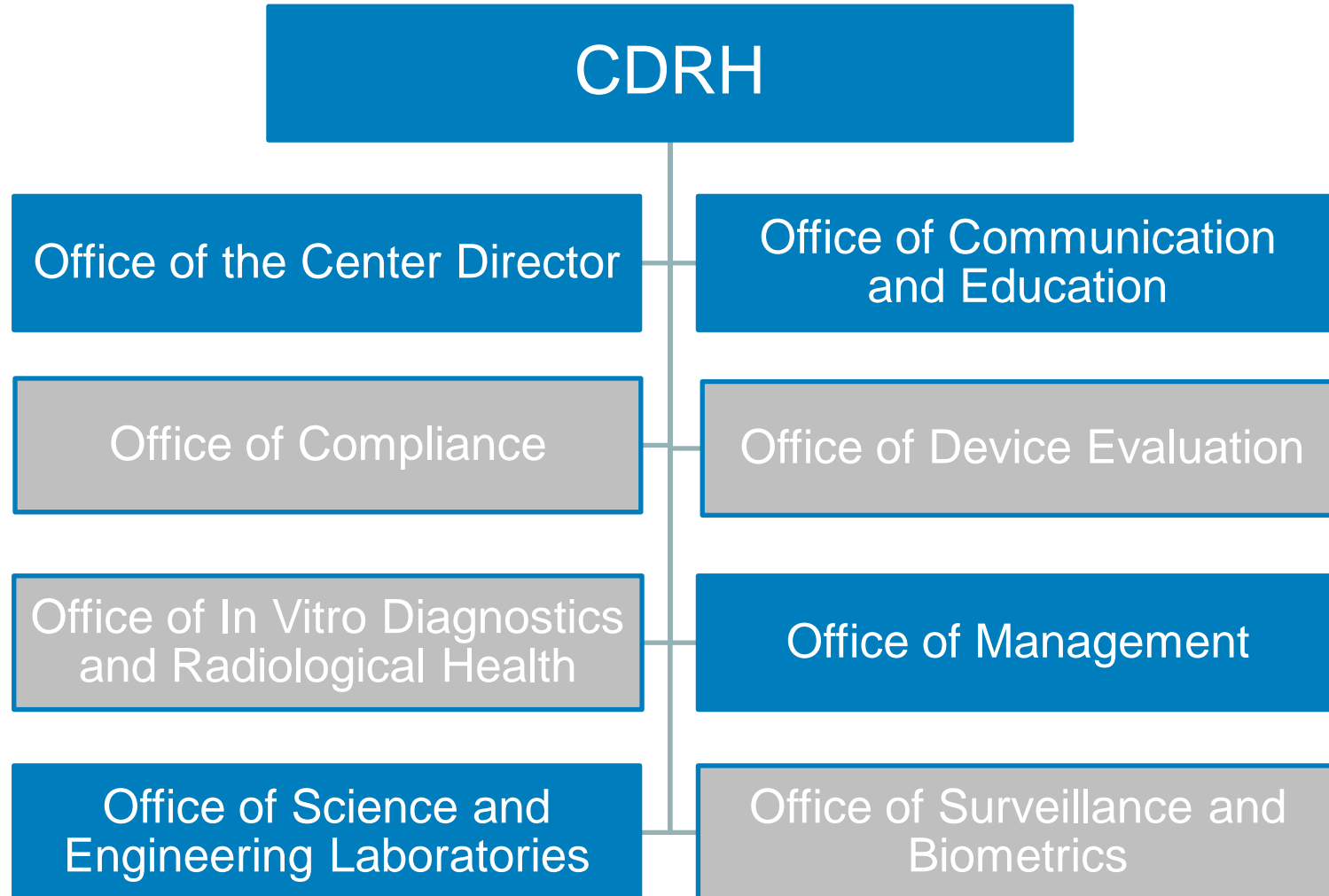
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INTEGRATING CDRH'S PREMARKET AND POSTMARKET OFFICES AND ACTIVITIES

- Historically, FDA's medical device center (CDRH) has been organized according to "Product Life Cycle"
- CDRH will move to a total product lifecycle (TPLC) design of one large office, comprised of seven smaller device-specific offices
- Device-specific offices would be responsible for premarket review, postmarket surveillance, manufacturing and device quality, and enforcement
- Benefits:
 - Facilitate information-sharing of pre- and post-market information to help make better informed decisions
 - Ensure process and policy consistency
 - Streamline the decision making process

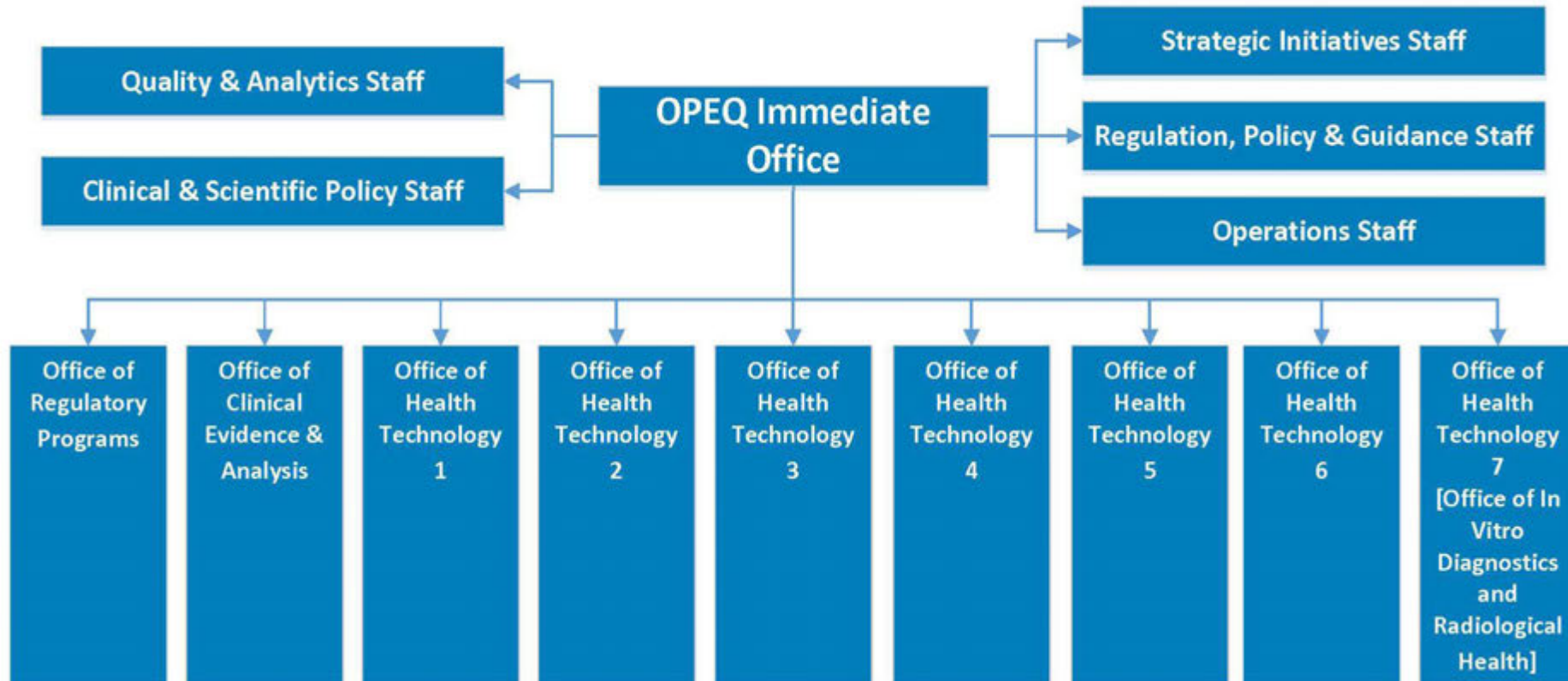


WHAT WILL CHANGE





OFFICE OF PRODUCT EVALUATION AND QUALITY (OPEQ)





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PRODUCT SPECIFIC OFFICES

OFFICE OF HEALTH TECHNOLOGY (OHT)

OHT	Scope of Products
OHT 1	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
OHT 2	Cardiovascular Devices
OHT 3	Reproductive, Gastro-Renal, Urological, General Hospital Device and Human Factors
OHT 4	Surgical and Infection Control Devices
OHT 5	Neurological and Physical Medicine Devices
OHT6	Orthopedic Devices
OHT 7 /OIR	In Vitro Diagnostics and Radiological Health



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THANK YOU