U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

CDRH's Reorganization and the Benefits for IVDs

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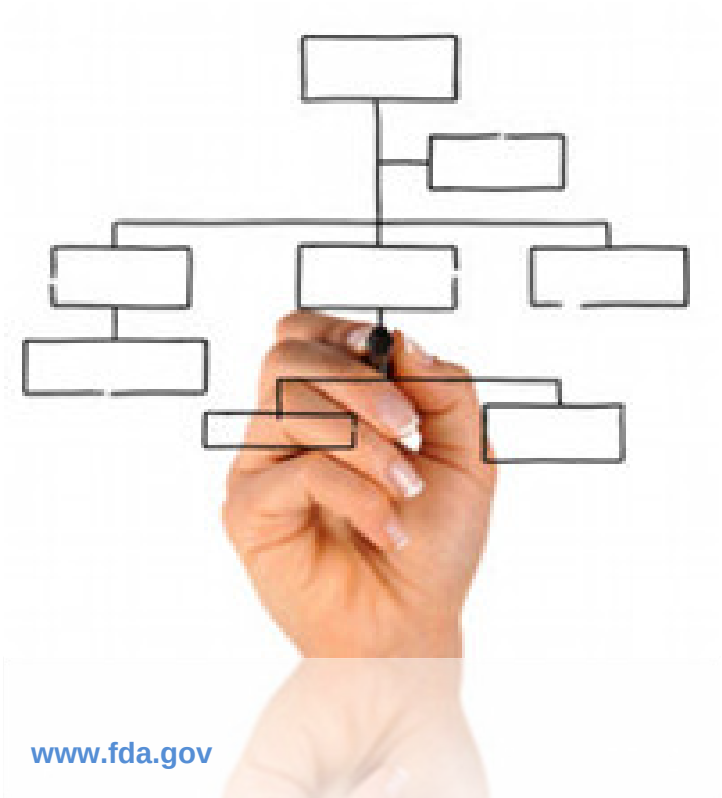
CDRH Reorganization



- CDRH completed its phased implementation of a Center reorganization in September 2019
- CDRH reorganization includes:
  - Adopting a TPLC model to streamline decision-making and improve efficiency
  - Supporting employees' professional growth

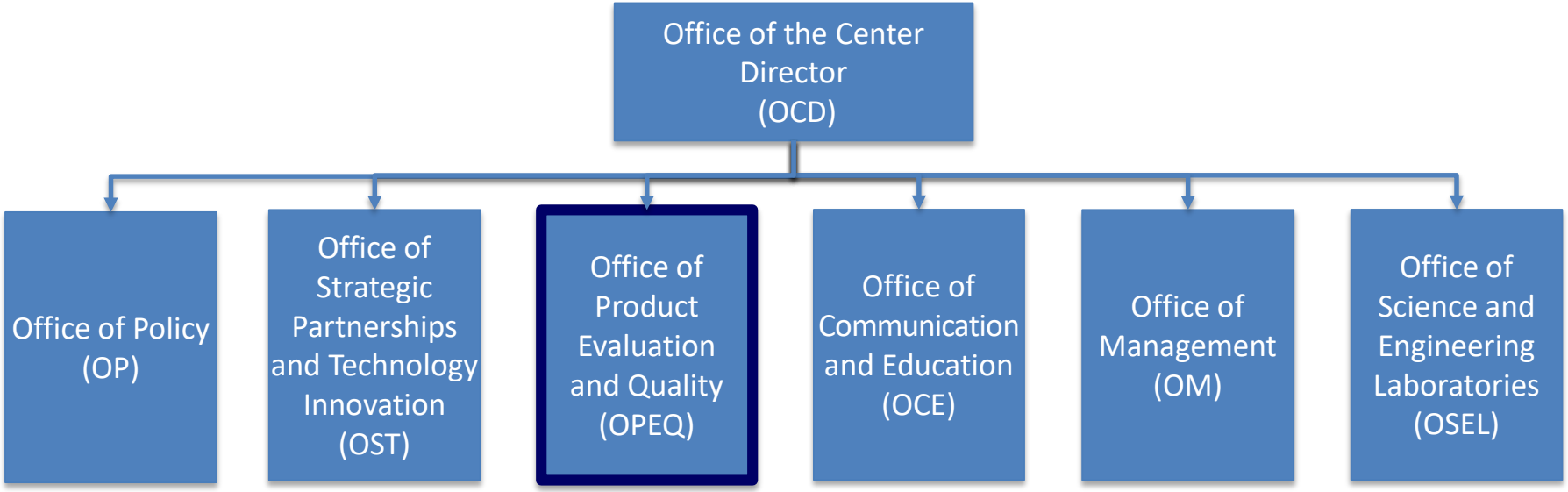
TPLC Reorganization Goals

- Create an **agile infrastructure** that can adapt to future organizational, regulatory, and scientific needs
- Reduce **supervisor to staff ratios** and establish **team lead** positions to manage work and improve consistency
- **Minimize organizational layers of review** and **implement** more efficient, **consistent work processes**
- Translate **increases in organizational efficiency** into reasonable **staff and manager workloads** and healthy work-life balances

TPLC Reorganization Goals

- **Enable information-sharing** to help us make better informed decisions
- Allow employees to **leverage their knowledge of pre- and post-market information** to optimize decision-making
- Facilitate employee professional development by increasing opportunities for **cross-skills development** and creating **multifunctional positions**

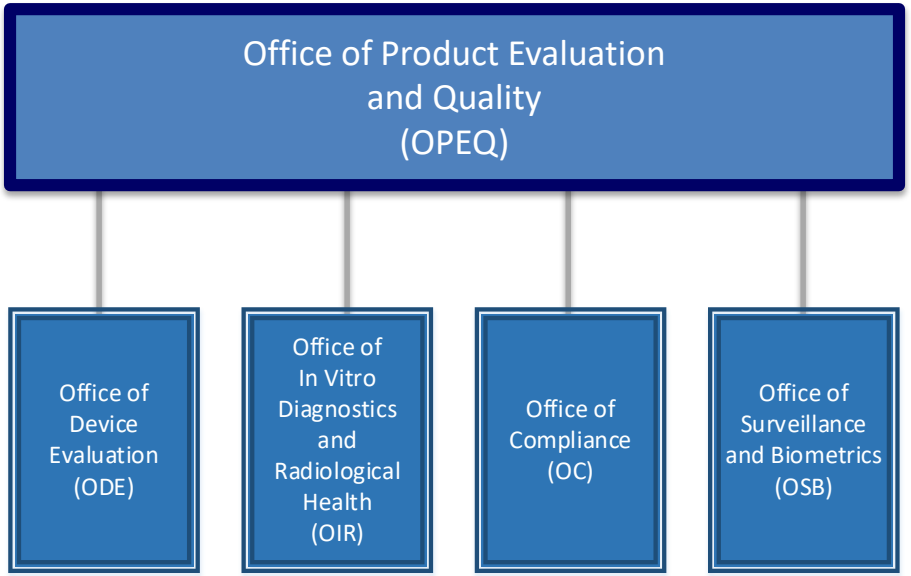
CDRH Reorganization



Super Office

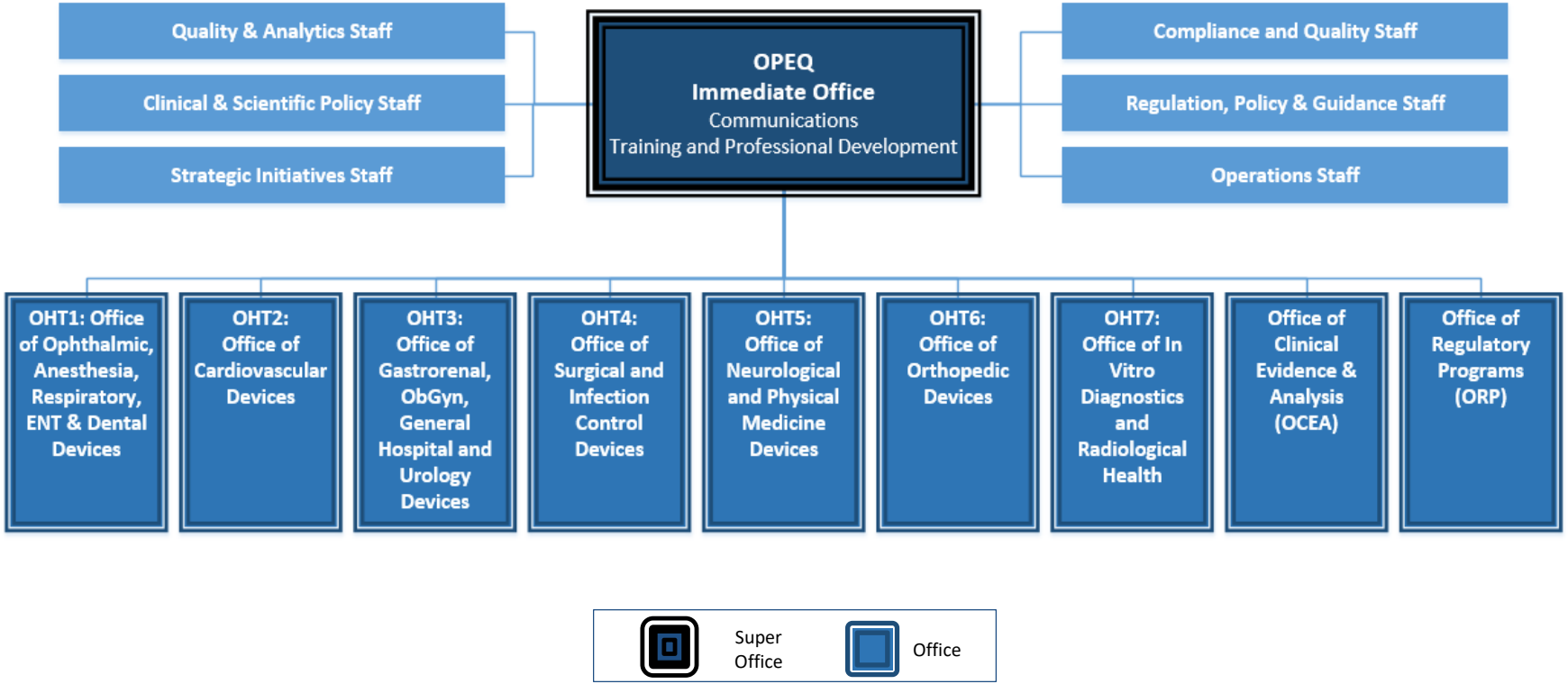
Office

Office of Product Evaluation and Quality (OPEQ)



- OPEQ is a Super Office
- ODE, OIR, OC and OSB reorganized into OPEQ

Office of Product Evaluation and Quality (OPEQ)



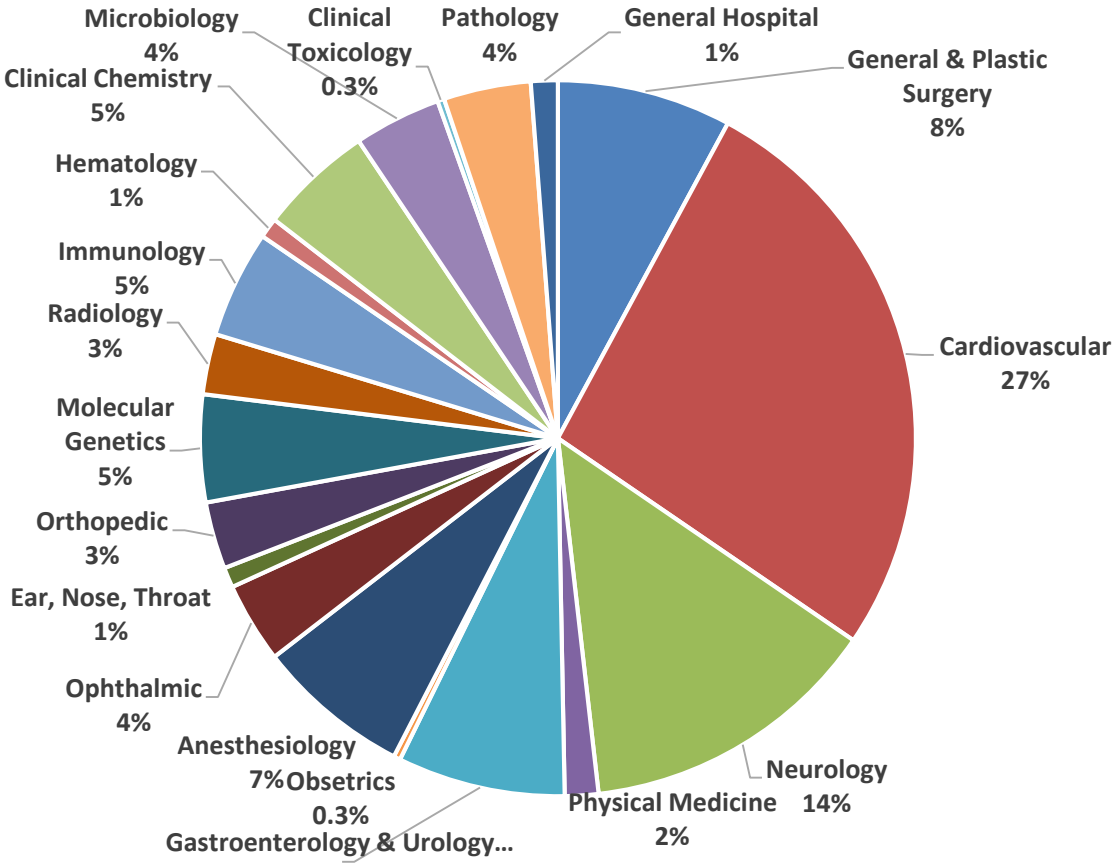
OPEQ Immediate Office

- **Provides consistent support and oversight for:**
  - Cross-cutting initiatives
  - Policy development and implementation
  - Compliance and Quality issues
  - Application of benefit-risk and least-burdensome principles
  - Operations and hiring
  - Internal quality management
  - Focal Point Program

Office of Clinical Evidence and Analysis (OCEA)

- Clinical trial policy
- Postmarket studies
- Biostatistical reviews
- Real-world evidence
- MedSun program
- Innovative programs
  - Early Feasibility Studies
  - Breakthrough devices
  - Safer Technologies Program (proposed in draft guidance)

Breakthrough Designations by Clinical Panel



As of July 31, 2020

Office of Regulatory Programs (ORP)

- Provides support and consistency with regard to:
  - Premarket submission policy
  - Imports, Exports, Registration and Listing
  - Inspections and Quality System
  - Medical Device Reports
  - Recalls
  - Market intelligence
  - Reviewer IT support and tools

CDRH Vision Statement

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