

Introduction to CDRH

May 2018



CDRH Mission...

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health.

We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.

We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.

We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.



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 U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.

Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.



Who We Are...

- CDRH is a team of over 1,700 dedicated, highly skilled, and internationally respected public health employees:
 - Physicians
 - Biologists
 - Chemists
 - Physicists
 - Engineers
 - Statisticians
 - Epidemiologists
 - Microbiologists
 - Nurses
 - Operations Research Specialist
 - Pharmacologists
 - Veterinarians
 - Toxicologists
 - Workforce Planning Specialists
 - Specialists in Public Health Education and Communication



What We Do...

- CDRH is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States.
- CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and enforces the Mammography Quality Standards Act (MQSA).

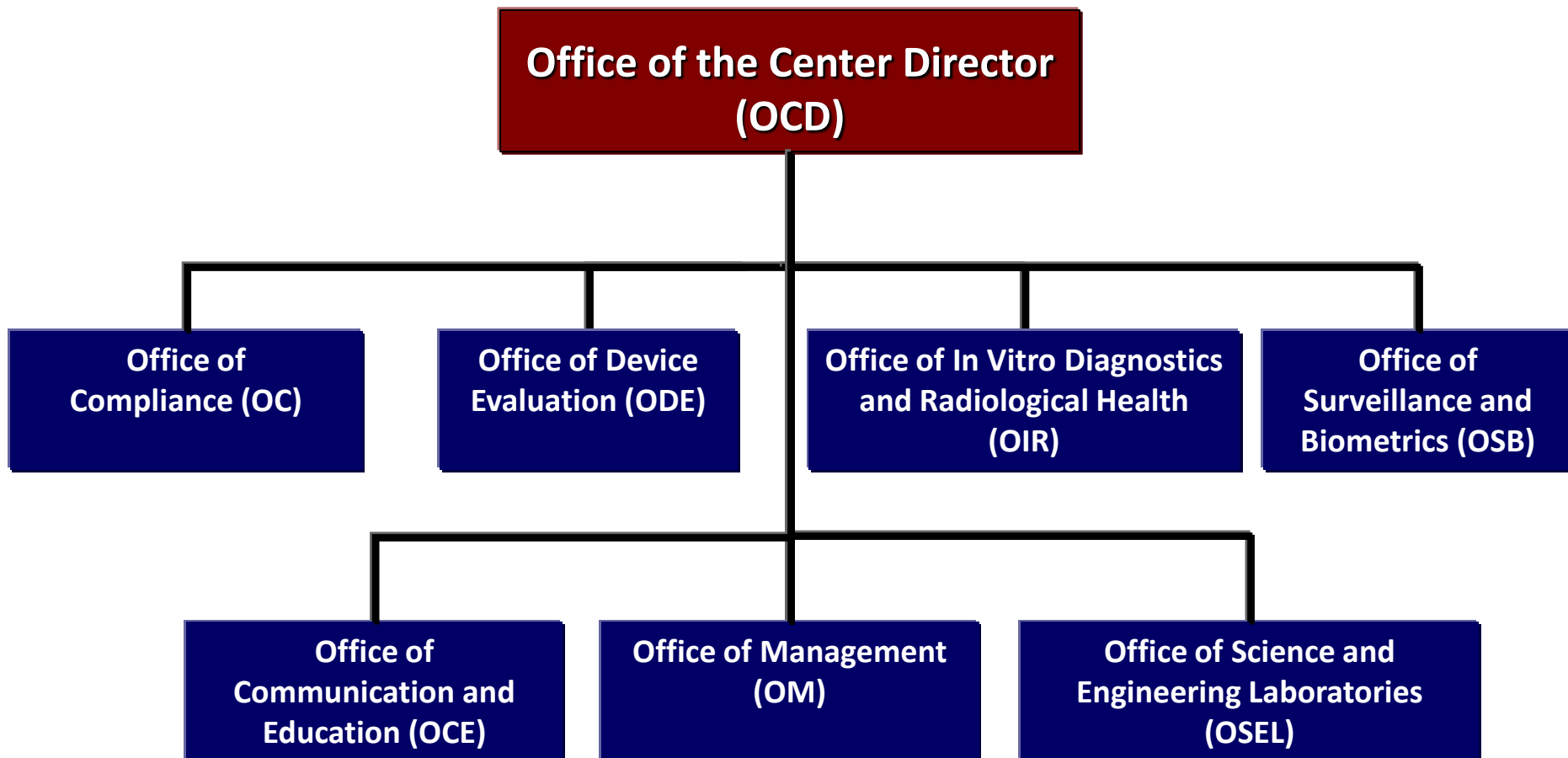


Regulatory Mandates

- 1938 Federal Food, Drug, and Cosmetic Act (FD&C)
- 1968 Radiation Control for Health & Safety Act (RCHSA)
- 1976 Medical Device Amendment of 1976
- 1988 Clinical Laboratory Improvement Amendments (CLIA)
- 1990 Safe Medical Devices Act (SMDA)
- 1992 Mammography Quality Standards Act (MQSA)
- 1992 Medical Device Amendments
- 1997 Food & Drug Administration Modernization Act (FDAMA)
- 2002 Medical Device User Fee and Modernization Act (MDUFMA)
- 2004 Project Bioshield Act
- 2005 Medical Device User Fee Stabilization Act (MDUFSA)
- 2007 Food and Drug Administration Amendments Act of 2007 (FDAAA)
- 2012 Food and Drug Administration Safety and Innovation Act (FDASIA)
 - Medical Device User Fee and Modernization Act (MDUFMA III)
- 2016 21st Century Cures Act
- 2017 Food and Drug Administration Reauthorization Act of 2017
 - Medical Device User Fee Amendments 2017 (MDUFA IV)



Center for Devices and Radiological Health (CDRH)





Office of the Center Director

- Provides scientific, policy, and managerial leadership and strategic direction to CDRH components and programs (strategic priorities, implementation of new legislation, user fee agreements, and TPLC)
- Advances the Centers position on medical device and radiological health issues to FDA and HHS officials, Congress, other government agencies and other stakeholders including the scientific, provider, patient and academic communities, the regulated industry, and international regulators
- Oversees Standards Management, Center Science Council, External Expertise and Partnerships, Digital Health, Innovation, Ombudsman, Information Technology, Data Standards/Management, Unique Device Identification, Knowledge Management, and Quality Management



Office of Compliance

- Leads Center's quality initiatives and priorities
- Manages regulatory compliance and enforcement programs
- Performs quality systems reviews, classifies recalls, evaluates allegations of regulatory misconduct and promotional claims
- Leads efforts on civil money penalties, injunctions and seizures
- Manages bioresearch monitoring program
- CDRH Liaison with ORA district offices, establishes workplan and assigns inspections among other field activities
- Administers the establishment registration and medical device listing program
- Collaborates with international partners in the Medical Device Single Audit Program
- Manages CDRH import and export programs



Office of Device Evaluation



- Manages program areas through which medical devices are evaluated or cleared for clinical trials and marketing
- Conducts reviews of the following medical device applications:
 - Premarket Notification [510(k)]
 - Premarket Approval Application (PMA)
 - Humanitarian Device Exemptions (HDEs)
 - Investigational Device Exemptions (IDEs)
 - De Novo Application



Office of In Vitro Diagnostics and Radiological Health

FDA

- Regulates all aspects of in vitro diagnostic tests (IVDs) and radiological devices
- Performs the functions of premarket, compliance, and postmarket surveillance within the office
- Manages the clinical laboratory improvement amendments (CLIA) categorization program
- Manages the CDRH Radiological Health Program, including the Mammography Quality Standards Act (MQSA)
- Regulates radiation emitting products



Office of Surveillance and Biometrics



- Provides statistical and epidemiological expertise and analysis of clinical data to assess device safety and effectiveness as part of premarket evaluation and postmarket surveillance
- Provides for the timely evaluation of medical device adverse event reports for signal identification and ongoing surveillance
- Oversees two nation-wide adverse event surveillance systems: Medical Device Reporting and Medical Product Safety Network
- Oversees two authorities for mandatory postmarket studies: Post-approval Studies and Section 522 Studies
- Oversees development and implementation of the Center's Signal Management Program



Office of Communication and Education



- Manages the development and clearance of external messages
- Oversees CDRH Internal Communication program
- Manages CDRH Executive Secretariat
- Manages CDRH internal and external websites
- Educates manufacturers of medical devices and radiation-emitting electronic products
- Manages the CDRH Small Business Determination Program
- Educates CDRH employees in support of CDRH's mission
- Manages CDRH Information Disclosure Program (Freedom of Information/Privacy)
- Coordinates all CDRH Public Meetings and Speaker Requests
- Manage CDRH Webcasts and Video Productions
- Manages all CDRH Conference Rooms (including AV support)



Office of Management

- Develops, implements, and manages a variety of Center-wide administrative management functions and services, including: Financial Management, Acquisitions and Procurement, Human Capital Management, and Facilities and Space Management
- Advises the Center Director on all administrative management matters to most effectively and efficiently utilize the Center's human and financial resources in support of CDRH's public health mission
- Works closely with other Center Offices to advise and assist in the development and implementation of administrative management policies and initiatives



Office of Science and Engineering Laboratories

FDA

- Support ODE and OIR by providing scientific and technical consultations for regulatory decisions
- Monitor emerging technologies to future proof FDA expertise
- Undertake scientific collaborations with industry through the MDIC, other government agencies (e.g. NIH) and academia
- Develop standardized test methods for CDRH and industry use
- Coordinates activities that support development of national and international standards
- House some Agency wide core facilities e.g. “Nano core” and HPC
- Performs product testing to confirm feasibility of premarket assessment methodologies and as “forensics” when problems emerge in post-market