

# How Is CDRH Structured?

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U.S. Food and Drug Administration



# Learning Objectives

- Describe the organizational structure of FDA's Center for Devices and Radiological Health
- Identify the individual Offices in CDRH
- Describe the core functions of CDRH's "Super Office"
- Identify the most common points of contact for the Center

# CDRH Basics

# CDRH Background

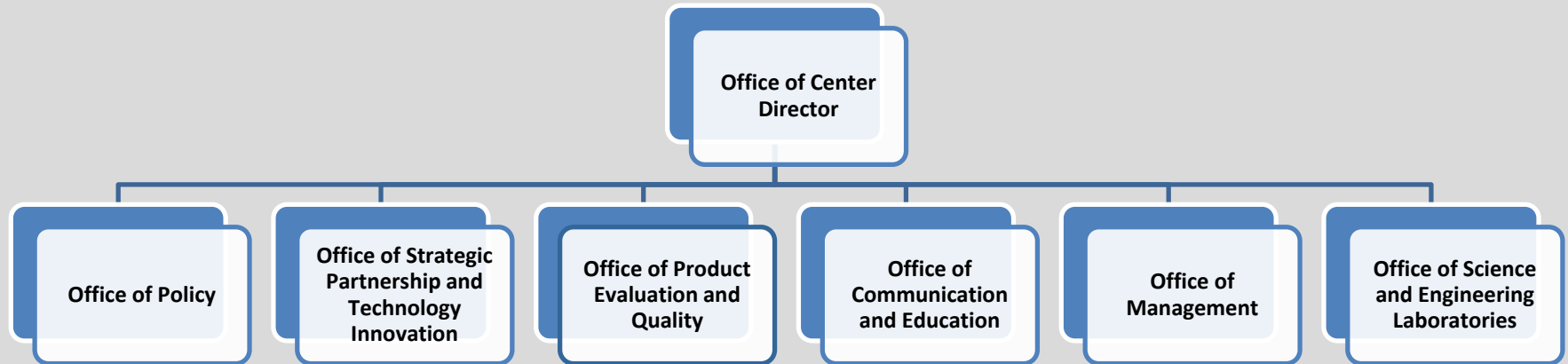
- Established in 1976 with passage of Medical Device Amendments
- Responsible for regulation of medical devices and radiological health products
  - Team-based approach to evaluating product safety and effectiveness

# The People at CDRH

- Over 1700 professionals
- Disciplines:
  - Scientists: Biologists, Microbiologists, Chemists, Physicists, Toxicologists
  - Engineers
  - Clinicians (Physicians, Nurses)
  - Statisticians, Epidemiologists
  - Veterinarians
  - Lawyers and Policy Professionals
  - Communication, Education, Training Specialists
  - Administrative Staff

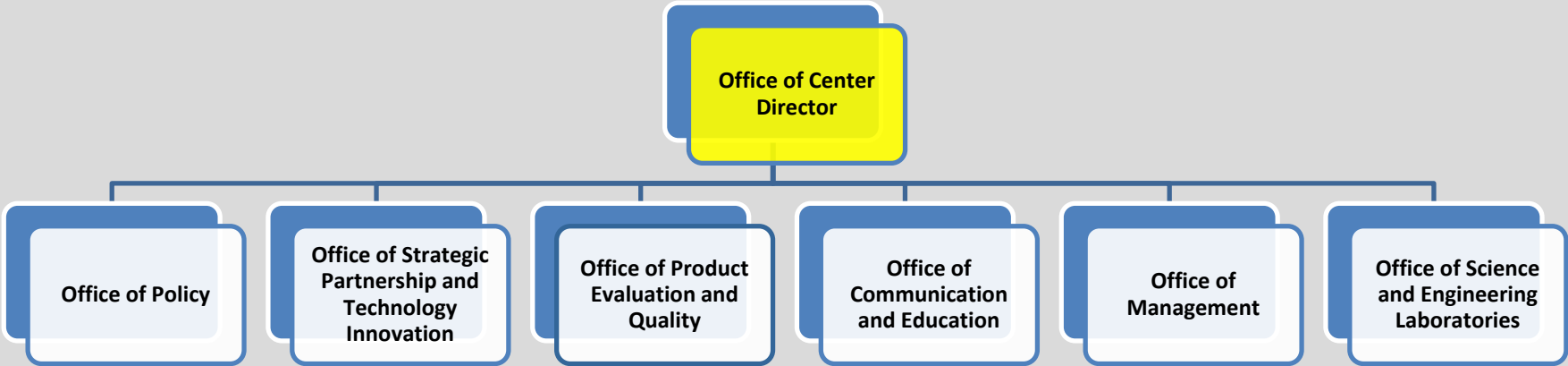
# CDRH Organization – At a Glance

# CDRH Organization Chart





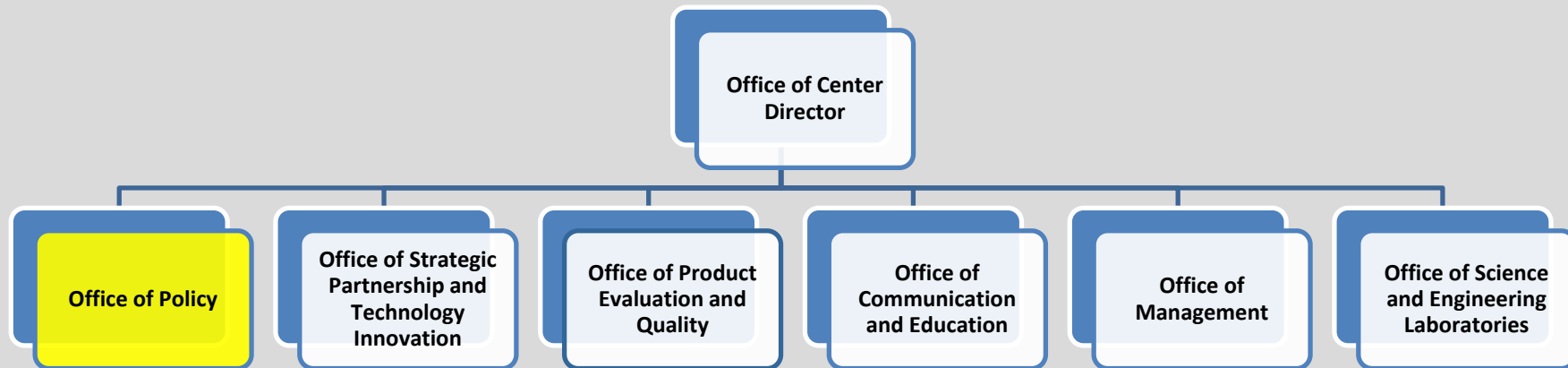
# Office of Center Director (OCD)



# Office of Center Director (OCD)

- Provides Center-wide vision, leadership, and strategic direction
- Leads strategic international efforts
- Leads Center's Quality Management program

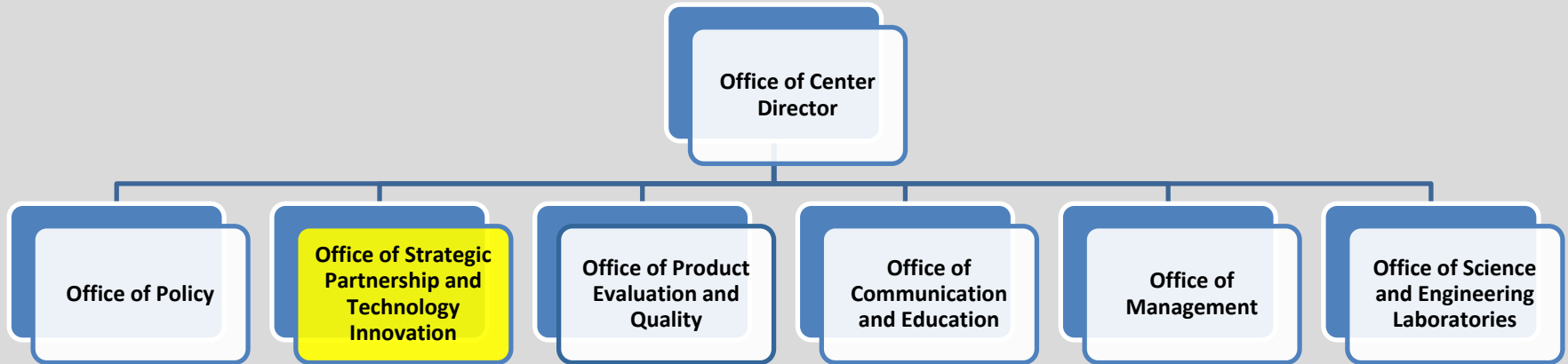
# Office of Policy (OP)



# Office of Policy (OP)

- Provides leadership for CDRH policy-related activities
- Provides Center-clearance for policy including guidance documents, regulations, orders
- Interfaces with FDA Commissioner's Office and relevant Agency Offices
- Assists in resolution of disputes, grievances and appeals (Ombudsman)

# Office of Strategic Partnership and Technology Innovation (OST)



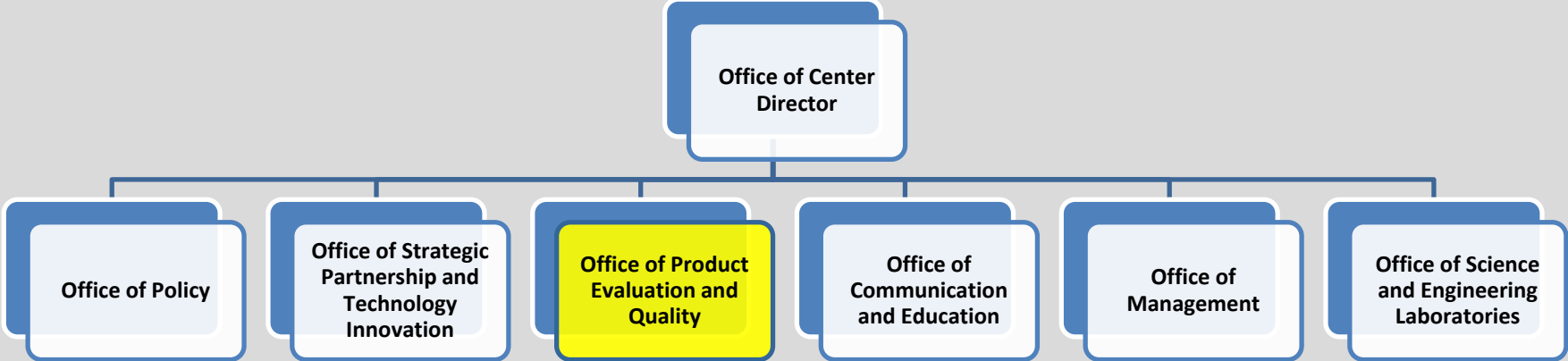
# Office of Strategic Partnership and Technology Innovation (OST)

- Leads scientific collaborative and emerging technology-related activities
- Leads partnerships to advance innovation and regulatory science
  - Notably with healthcare, industry, patient, scientific groups
- Fosters device innovation
- Leads CDRH effort for public health emergency preparedness and response

# Office of Strategic Partnership and Technology Innovation (OST)

- Leads Center's standards and conformity assessment program
- Serves as special projects incubator
- Strategically leads policy on cybersecurity, software, digital health
- Oversees Center's data, technology and information technology infrastructure

# Office of Product Evaluation and Quality (OPEQ)



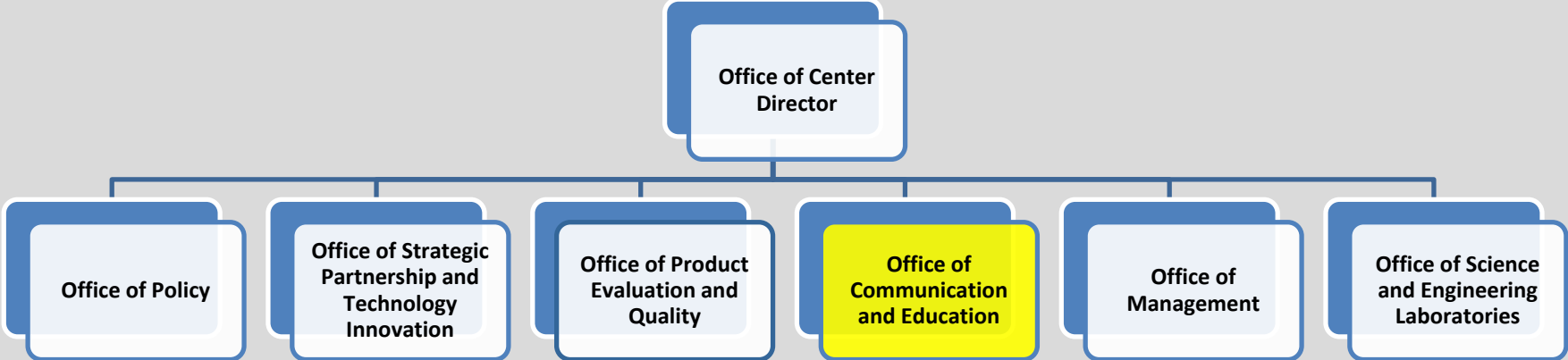


# Office of Product Evaluation and Quality (OPEQ)



- Largest Office in CDRH (“Super Office”)
- Responsible for most day-to-day regulatory transactional activities for Center, spanning total product life cycle

# Office of Communication and Education (OCE)



# Office of Communication and Education (OCE)



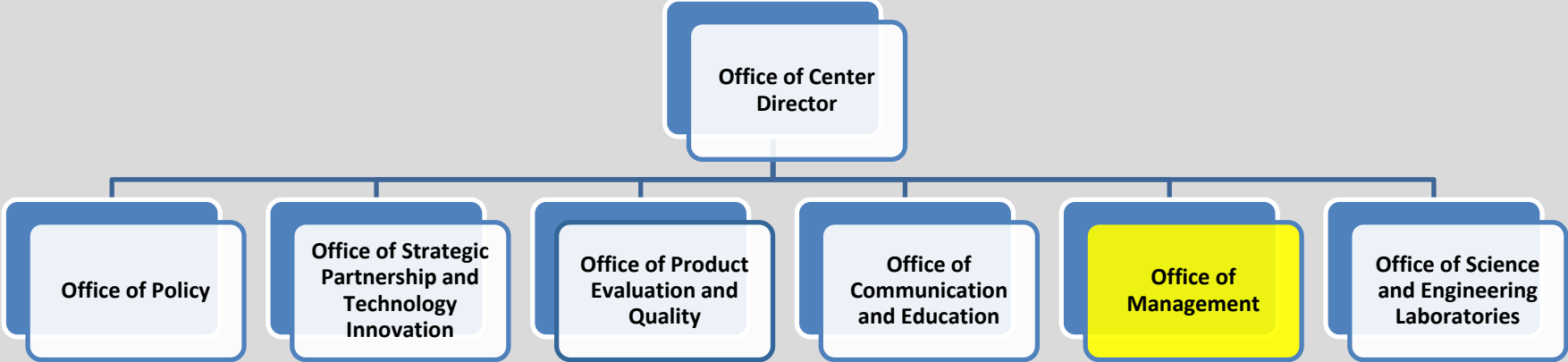
- Leads strategic regulatory and safety related communications to public
- Leads communications to CDRH Staff
- Manages FDA portion of website for medical devices and radiological health
- Leads Center Freedom of Information Act and Information Disclosure programs

# Office of Communication and Education (OCE)



- Manages speaker requests, public meetings and workshops
- Heads video, broadcasting, and webcasting services
- Manages wide-ranging education to CDRH Staff
- Leads regulatory education for public:
  - Develops regulatory videos and web content
  - Answer individual questions by phone and email

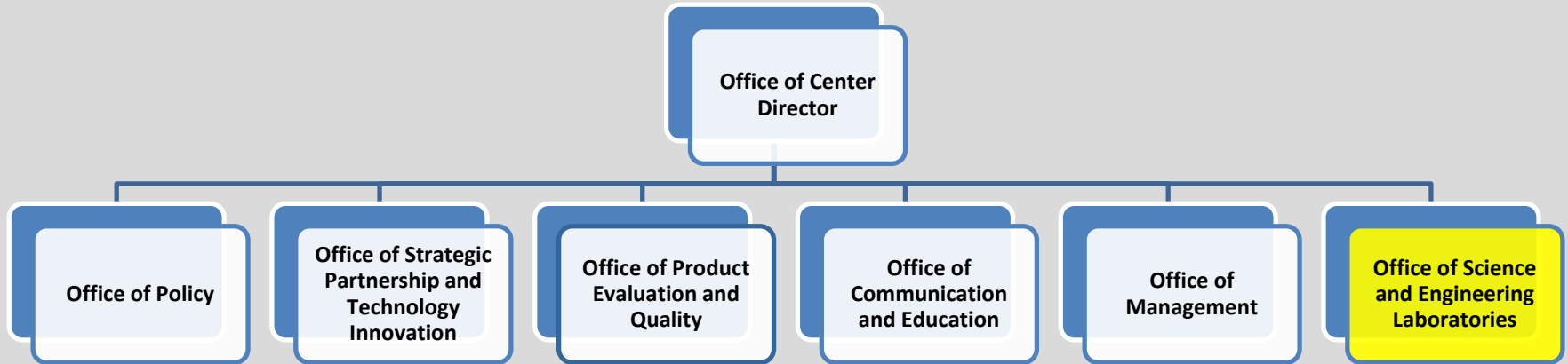
# Office of Management (OM)



# Office of Management (OM)

- Develops and implements Center long-range, strategic, and operational plans and budgets
- Leads Center administrative functions
- Manages Center financial resources, including contracts
  - Leads CDRH Small Business Program
- Leads human capital management
- Administers CDRH Advisory Committee Meetings

# Office of Science and Engineering Laboratories (OSEL)



# Office of Science and Engineering Laboratories (OSEL)

- Leads medical device and radiological health scientific research
  - Includes development of methods, evaluation strategies, and testing standards
- Supports development of long-term regulatory processes
- Consults on specialized regulatory issues



# Office of Product Evaluation and Quality

# OPEQ – The Center’s “Super Office”

- Immediate Office (OPEQ-IO)
- 7 Offices of Health Technology (OHT)
- Office of Regulatory Programs (ORP)
- Office of Clinical Evidence and Analysis (OCEA)

# OPEQ Core Functions

- Implements premarket review programs:
  - notably 510(k), IDE, PMA, HDE, De Novo, Q-submissions
- Ensures product compliance:
  - registration and listing, recalls, imports and exports, bioresearch monitoring, allegations, labeling
- Evaluates devices in postmarket setting:
  - epidemiology and medical device reporting
- Fosters development of methodology, analysis, and clinical trial infrastructure for evaluation of device safety and effectiveness

# OPEQ Core Functions

- Administers Federal Law that supports Clinical Laboratory Community
  - Clinical Laboratory Improvement Amendments (CLIA)
- Regulates radiation-emitting non-medical products
- Implements Mammography Quality Program
  - Mammography Quality Standards Act (MQSA) of 1992
- Sets strategy and oversees device-specific clinical evidence and analysis and regulatory functions
  - for comprehensive, total product life cycle evaluation

# OPEQ Immediate Office (IO)

- Leads interpretation of regulatory policy and guidance
- Provides support, strategy and oversight to OPEQ Offices (OHTs, ORP, OCEA)
- Lead clinical, scientific, quality, analytic, and strategic efforts

# Office of Health Technology (OHT)

Office Title	Product Area
OHT1	Ophthalmic, Anesthesia, Respiratory, Ear, Nose and Throat (ENT), Dental
OHT2	Cardiovascular
OHT3	Gastro-renal, Obstetrics and Gynecology, General Hospital, Urology
OHT4	Surgical, Infection Control
OHT5	Neurological, Physical Medicine
OHT6	Orthopedic
OHT7	In Vitro Diagnostics, Radiological Health

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm)

# OHT Responsibilities

- Total product life cycle review of product area
  - premarket
  - compliance and quality
  - surveillance
- Development of policy in product area

# Office of Regulatory Programs (ORP)

- Manages regulatory programs
  - Provide program support to OHTs
- Leads establishment support programs
- Manages market intelligence programs:
  - involving recalls, shortages, allegations, MDR





# Office of Clinical Evidence and Analysis (OCEA)

- Provides policy support for clinical evidence and human protection
- Provides regulatory oversight of device clinical investigations
  - Including good laboratory/clinical practice (GLP and GCP)
- Provides biostatistical and epidemiology analyses
- Outreaches and collaborates with hospitals and external stakeholders

# Where Do I Go?

# For General Questions

## Division of Industry and Consumer Education (DICE)

**Phone: (800) 638-2041**

- Hours of operation: 9 am-12:30 pm; 1-4:30 pm

**Email: [dice@fda.hhs.gov](mailto:dice@fda.hhs.gov)**

- DICE will respond within 2 business days

**[www.fda.gov/DICE](http://www.fda.gov/DICE)**

# Device Advice

- Written content
- Hundreds of pages of total product life cycle regulatory information
- Over 30 regulatory categories
- “How to” guides

[www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

# CDRH Learn

- Multi-media video training modules
- Presentations, computer-based training, webinars
- Over 100 modules
- Most are less than 20 minutes
- Mobile-friendly

[www.fda.gov/Training/CDRHLearn](http://www.fda.gov/Training/CDRHLearn)

# Frequent Points of Contact

Topic	Group	Contact Info
Registration and Listing	OPEQ/ORP	<a href="mailto:reglist@cdrh.fda.gov">reglist@cdrh.fda.gov</a>
Exports	OPEQ/ORP	<a href="mailto:CDRHCECATS@fda.hhs.gov">CDRHCECATS@fda.hhs.gov</a>
Unique Device Identification	OST	<a href="http://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/fda-udi-help-desk">www.fda.gov/medical-devices/unique-device-identification-system-udi-system/fda-udi-help-desk</a>
Medical Device Reporting	OPEQ/ORP	<a href="mailto:MDRPolicy@fda.hhs.gov">MDRPolicy@fda.hhs.gov</a>
Electronic Products – Accession Numbers	OHT7	<a href="mailto:RadHealthCustomerService@fda.hhs.gov">RadHealthCustomerService@fda.hhs.gov</a>
Ombudsman	OP	<a href="mailto:CDRHombudsman@fda.hhs.gov">CDRHombudsman@fda.hhs.gov</a>

# References

- **Information about CDRH**

[www.fda.gov/about-fda/office-medical-products-and-tobacco/center-devices-and-radiological-health](http://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-devices-and-radiological-health)

- **CDRH Management Directory**

[www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization](http://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization)

# Summary

- FDA's Center for Devices and Radiological Health is organized into 7 offices
- The Office of Product Evaluation and Quality serves as the Center's "Super Office"
- OPEQ's Offices of Health Technology are organized into medical disciplines and manages core total product life cycle responsibilities



# Your Call to Action

1. Become familiar with the structure of the Center for Devices and Radiological Health
2. Identify the Office or group with whom you interact for your regulatory needs
3. Use the resources to help you comply with your regulatory responsibilities

