How Is CDRH Structured?

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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

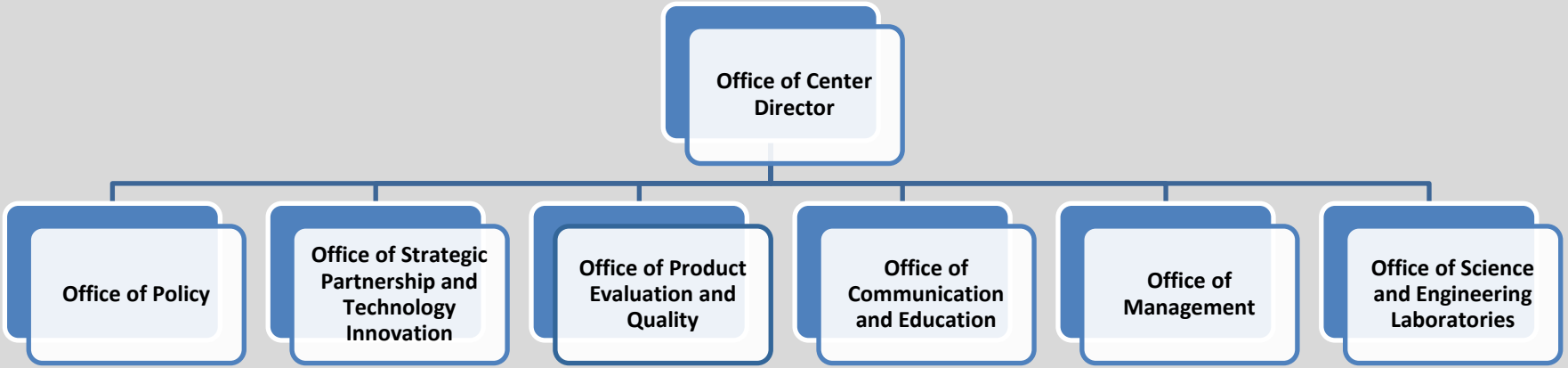
- Established in 1976 with passage of Medical Device Amendments
- Responsible for regulation of medical devices and radiological health products
  - Team-based approach to evaluating product safety and effectiveness

The People at CDRH

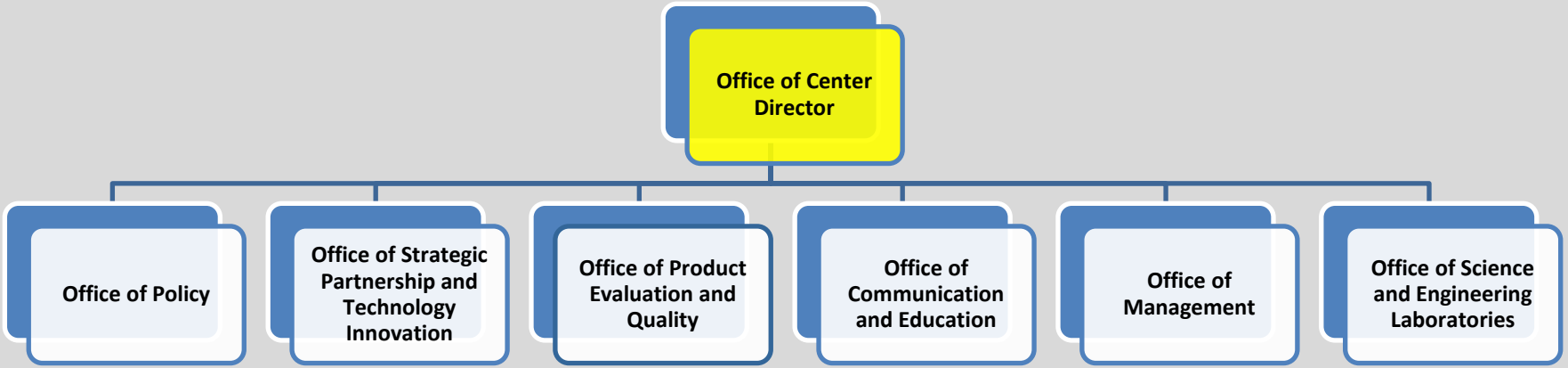
- Over 1700 professionals
- Disciplines:
  - Scientists: Biologists, Microbiologists, Chemists, Physicists, Toxicologists
  - Engineers
  - Clinicians (Physicians, Nurses)
  - Statisticians, Epidemiologists
  - Veterinarians
  - Lawyers and Policy Professionals
  - Communication, Education, Training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

CDRH Organization – At a Glance

CDRH Organization Chart



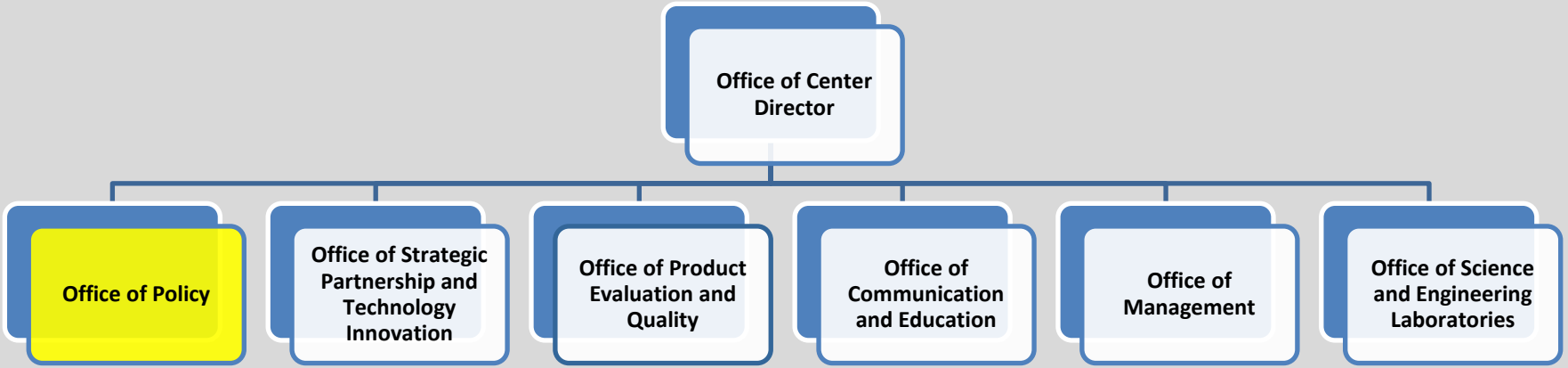
Office of Center Director (OCD)



Office of Center Director (OCD)

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

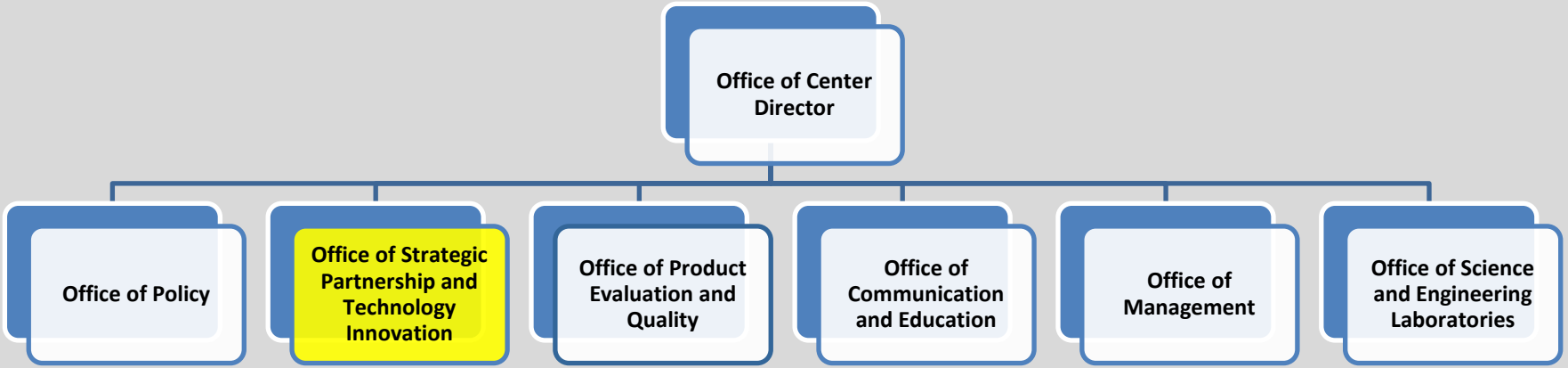
Office of Policy (OP)



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)



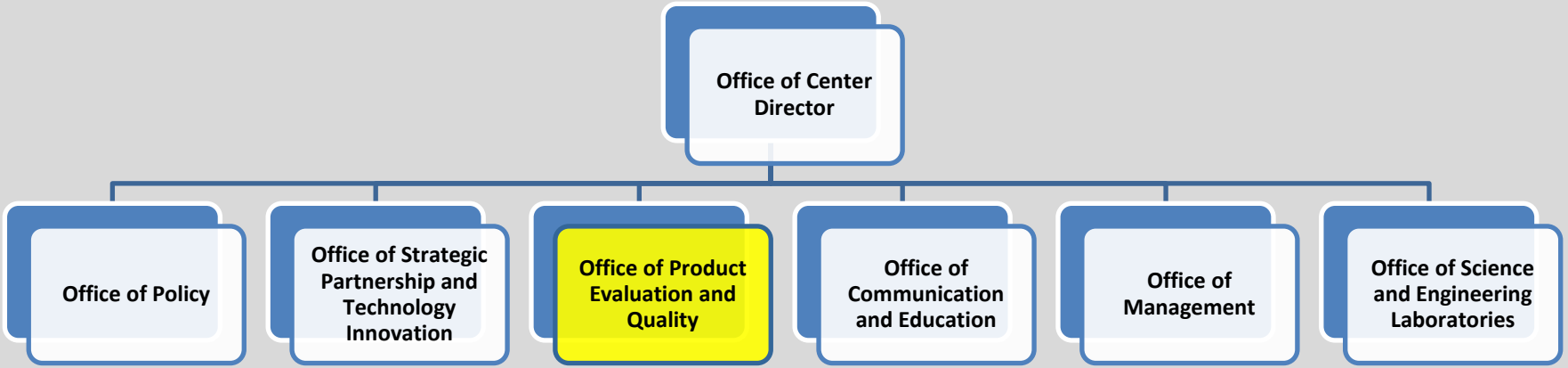
Office of Strategic Partnership and Technology Innovation (OST)

- 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

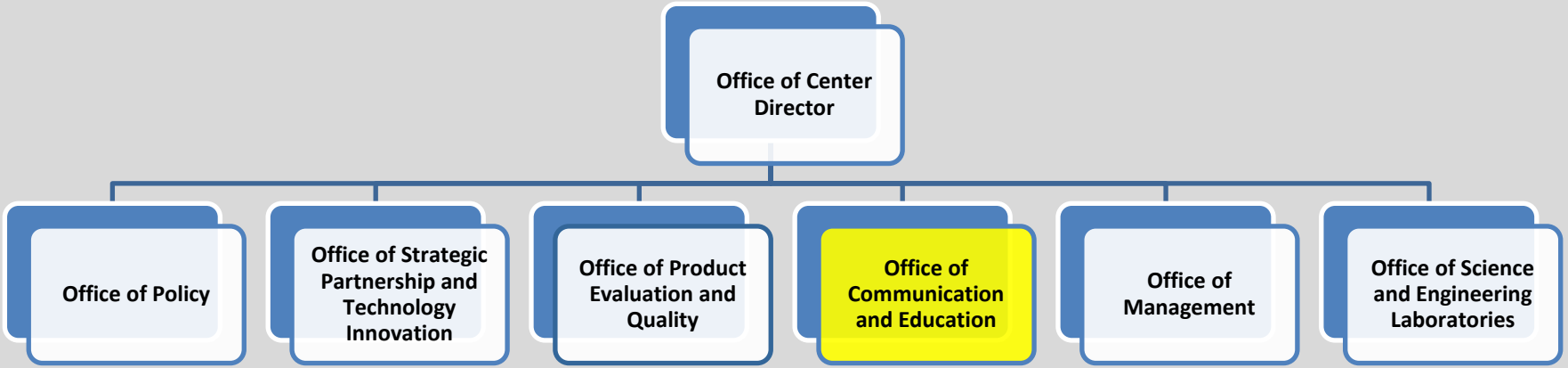
Office of Product Evaluation and Quality (OPEQ)



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)



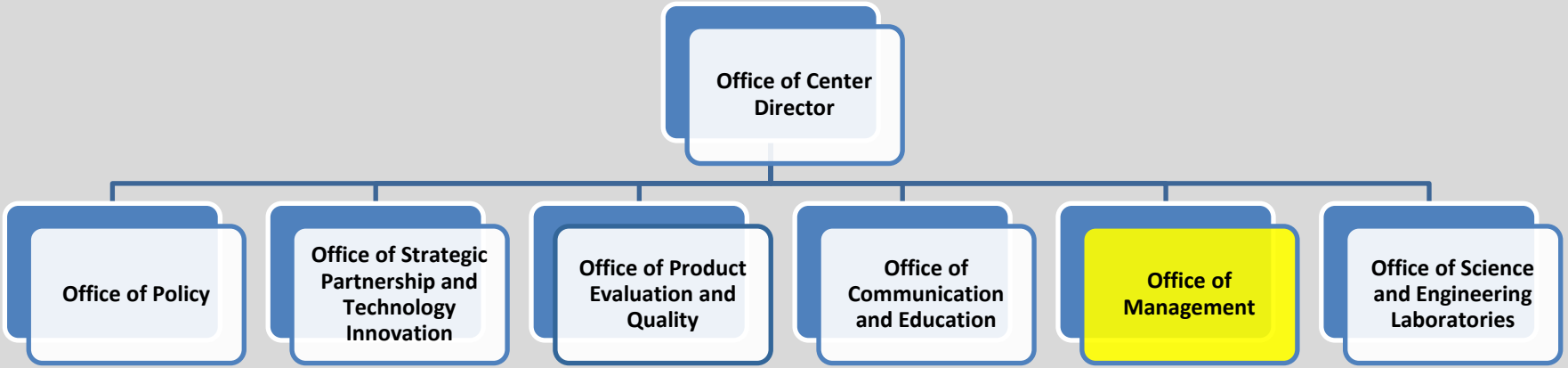
Office of Communication and Education (OCE)

- 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

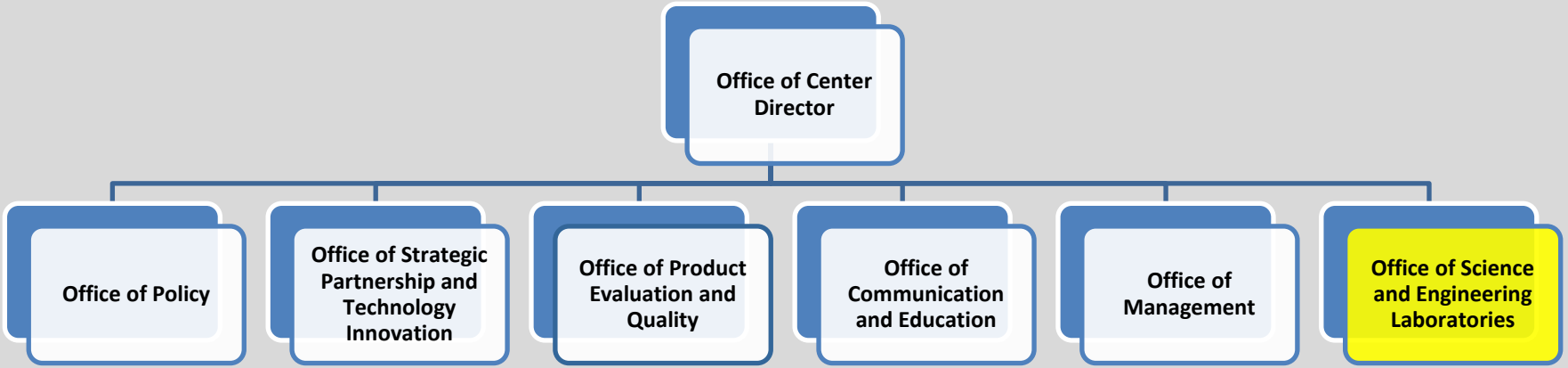
Office of Management (OM)



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)
- 8 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
OHT8	Radiological Health

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/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

- DICE will respond within 2 business days

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

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

Frequent Points of Contact

Topic	Group	Contact Info
Registration and Listing	OPEQ/ORP	reglist@cdrh.fda.gov
Exports	OPEQ/ORP	CDRHCECATS@fda.hhs.gov
Unique Device Identification	OST	www.fda.gov/medical-devices/unique-device-identification-system-udi-system/fda-udi-help-desk
Medical Device Reporting	OPEQ/ORP	MDRPolicy@fda.hhs.gov
Electronic Products – Accession Numbers	OHT8	RadHealthCustomerService@fda.hhs.gov
Ombudsman	OP	CDRHOmbudsman@fda.hhs.gov

References

- **Information about CDRH**

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

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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