# Training-on-the-Job (“Job Shadowing”) CDRH perspective

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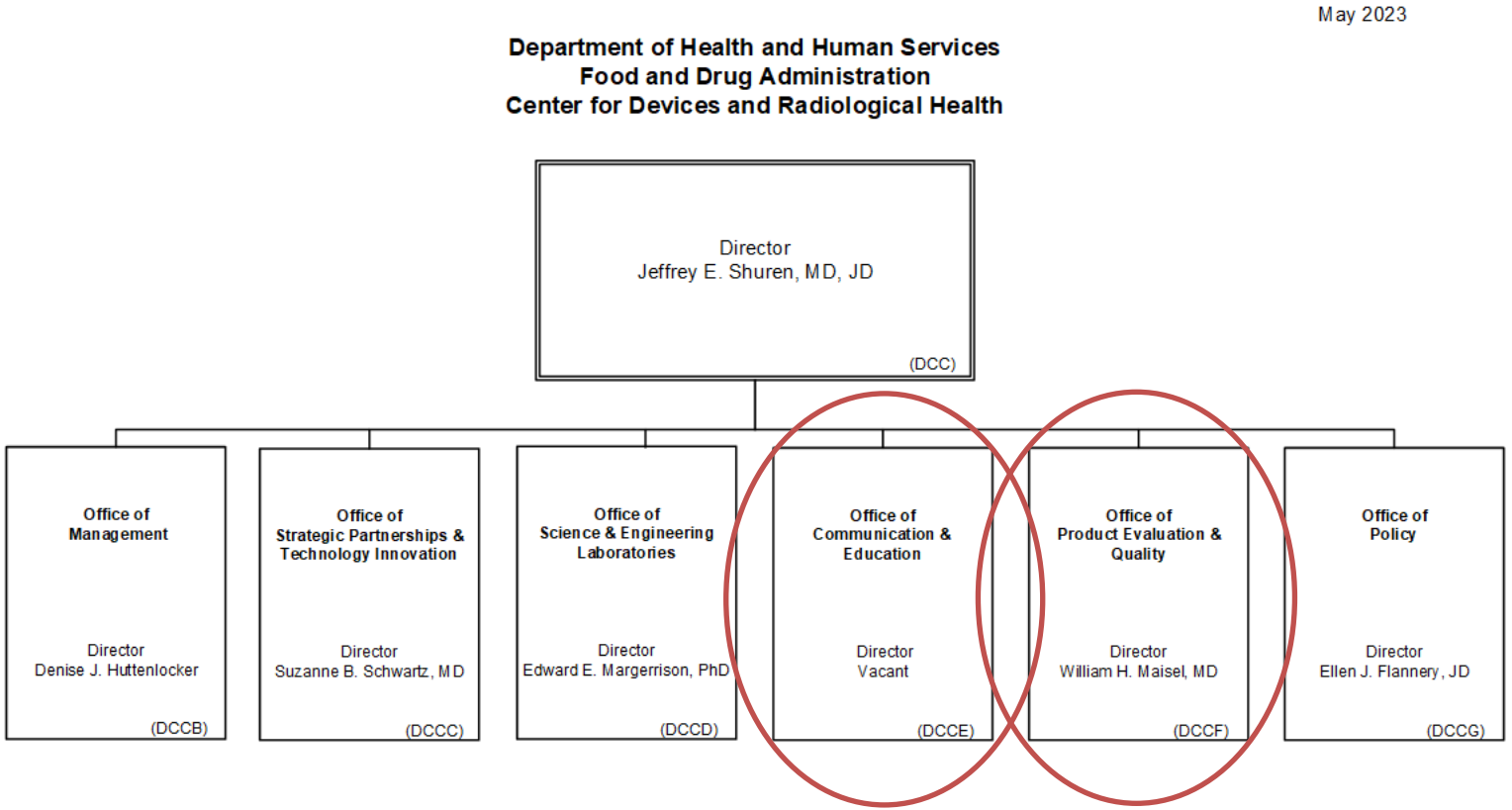
# CDRH Organizational Structure



# CDRH Office Structure

- Review offices are responsible for evaluation of medical devices and IVDs across the total product life cycle
  - Pre-market
  - Post-market
  - Compliance/Enforcement
    - Medical Officers may be asked to participate in any of these
- Offices are organized into teams of reviewers based mainly on device type
  - Lead reviewers
  - Medical officers
  - Other technical experts

# CDRH Reviewer Training

- Needs to cover many topics and include general and device-specific content
- Resources providing training include:
  - CDRH Division of Employee Training and Development
  - OPEQ-level Professional Development Staff
  - Office-level Assistant Director for Professional Development
  - Supervisors and peers

*number of people trained

# CDRH Reviewer Certification Program

- Core curriculum for all reviewers, including medical officers
  - Basics of medical device regulations and laws
  - Medical device regulatory pathways and review processes
  - “Soft skills” and administrative requirements
- Also includes mock 510(k) review and group project
- Iterative changes to program over the years

# Why we need on the job training

- Varied backgrounds and experiences pre-FDA; one curriculum may not address all employees needs
- Different device areas require differences in typical technical expertise needs
- Different device areas differ in the proportions of regulatory submission types
- 2013 independent assessment: “premarket reviewer training is limited”
  - After formal training: Only 57% of premarket staff confident with their understanding of contemporary review processes
  - After OTJ training: 92% of premarket staff confident with their understanding of contemporary review processes

**OTJ training intended to support new reviewer during the first 12 months and beyond, in addition to complementing formal onboarding**

# OTJ training goals and responsibilities

- Team effort to ensure that new reviewers have resources to guide on-the-job training and address continued training needs
  - Peer preceptor (“Shadowing”)
  - Supervisor
  - Assistant Director for Professional Development
  - Other programs (some curriculum-based)

# Shadowing

- New reviewers assigned a preceptor
  - An experienced reviewer selected by the supervisor who trains, shares their wisdom and past experiences to help others enhance their technical knowledge and skills.
  - Oversight and signatory of review memos
  - Device-specific institutional knowledge
  - Directs new reviewer to SMEs, resources as necessary
  - Less frequent need for support after 6 – 12 months

# Management Support

- Supervisor
  - Provides agreement on Individual Development Plan
  - Holds routine 1:1s to discuss files and challenges
  - Directs to professional development resources
- Assistant Director for Professional Development
  - Supports overall professional development goals

# Key Skills to Learn OTJ

- Introduction to team, contact information, regular meetings
- Internal and external sources for scientific/clinical topics
- Critical systems: databases and HR
- Time management and prioritization
- Briefing, facilitation skills
- Work/life balance check

# Trainings, Tools, and Resources

- Regular rounds on scientific/regulatory/administrative topics
- Focal Point Program: ensure review consistency across key technical areas
- Communities of Practice: share information and best practices
- Ad-hoc training on CDRH strategic priorities and statutory requirements
- Employee Assistance Program: support for work- and non-work-related difficulties

# Other training opportunities

- Formal Mentor program
  - Outside supervisory chain
  - Matched based on similar backgrounds and career goals
- CDRH Leadership Readiness Program
  - Curriculum-based
  - Includes mentorship, leadership shadowing/interviews, and group project components
- CDRH Experiential Learning Program
  - Call for external stakeholders to offer training or on-site visits to FDA
- Additional coursework offered across CDRH
- Attendance at professional meetings/conferences

# Summary

- OTJ training complements CDRH didactic training and includes CDRH-wide vs individualized components
- Requires additional training resources and time, but serves as an effective complement
- Intended to prepare reviewers not only for file reviews but also to develop their overall careers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# Reviewer Training Tracks

- Premarket
  - Preparing SE, approval packages, complex reviews
  - Request or complete consulting reviews
  - Participate in working groups
- Postmarket
  - Adverse event reports, databases
  - Conduct trend analyses for internal and external customers
- Quality and Compliance
  - Inspectional History, review of inspectional reports
  - Recalls
  - Allegations
- *Medical Officers will likely participate in all types of reviews*

# Harmonization Efforts

- Reviewer competencies recognized by IMDRF
  - Competence, Training, and Conduct Requirements for Regulatory Reviewers | International Medical Device Regulators Forum (imdrf.org)
  - Foundational, Functional, Technical competencies
- Discussing ‘Regulatory Core Curriculum’ needs with various stakeholders