How is CDRH Structured?

Slide 1
Hello! I'm Elias Mallis, Director of the Division of Industry and Consumer Education at the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. Welcome to CDRH Learn, FDA's preeminent catalog of multi-media educational modules about medical devices and radiological products! In this module, we'll going to answer the question "How is CDRH Structured?"

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When you think of an organization, you could describe it as a house. A house typically has a front door that lets you inside and windows that allow you to see. A house has different rooms that serve different functions, and sometimes those rooms are merged together to form a larger multi-purpose room. A house will hopefully have a roof that covers it and have utilities such as water and electricity for those inside the house. As we take our tour of the structure of the Center for Devices and Radiological Health, or CDRH, see if you can identify any parallels between the functions of the Center and parts of our house.

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This presentation is a companion to the CDRH Learn module on the Introduction of FDA's Regulation of Medical Devices, so I encourage you to watch that module to provide you with some context to this one. Let's review what we'll cover in this module. First, we'll describe the organizational structure of CDRH. We'll identify the Center's individual offices and their primary functions. We'll spend some time focusing on CDRH's "Super Office" and we'll conclude by identifying the most common points of contact you can use as a resource when interacting with CDRH.

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Before we begin the tour of our house, let's set the stage with some basics about CDRH.

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CDRH was established in 1976 with the passage of the key FDA legislation, the Medical Device Amendments. CDRH is responsible for the comprehensive regulation of medical devices and radiological health products. This is done by using a multi-disciplinary team-based approach where we evaluate both the safety and effectiveness of these products.

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So who are the people who make up CDRH? Well, we're more than 1700 professionals who come from a diverse range of backgrounds and professions. As a science-based regulatory organization, CDRH features a number of scientific disciplines, such as biologists and microbiologists, chemists, physicists and toxicologists. We have a number of specialized engineers and clinicians, including both physicians and nurses. Other disciplines include statisticians, epidemiologists, veterinarians, and lawyers, as well as specialists in communication, education, and training, and those who provide administrative support. All of these backgrounds come together to collectively do the work of the Center in promoting and protecting the public health.

Slide 7
Now let's take a stroll through our house by looking at the various aspects of the Center.

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This slide shows a high-level organizational chart for CDRH, current as of October 1, 2019. At the top of this structure, you'll find the Office of the Center Director. Six offices report to that Center Director. Let's review them all, one Office at a time.

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First, let's start at the rooftop of our house, with the Office of the Center Director.

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The Office of Center Director, or OCD, may be the smallest of the Center, but has the most over-arching strategic impact. OCD features the Center Director for CDRH and a small staff that provides the vision, leadership and strategic direction for the entire Center. OCD also leads the strategic international efforts with respect to the global regulation of medical products and also leads the Center's Quality Management Program.

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Let's go back to our org chart and move down a level to review the Offices that report to that Office of the Center Director. We'll move along our chart going from left to right, so we'll start with the Office of Policy, or OP.

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The Office of Policy provides leadership for CDRH policy-related activities. OP provides Center clearance for various policy issued by the Center, which includes guidance documents, regulations and orders. This Office interacts with the FDA Commissioner's Office and relevant Agency Offices on behalf of the Center.
And the CDRH Ombudsman is located in OP. The Ombudsman assists in resolving various disputes, grievances, and appeals for CDRH.

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Now let's take a closer look at the Office of Strategic Partnership and Technology Innovation, or OST.

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As the name suggests, the main themes of OST are external collaboration and technology. This Office probably has the most varied functions of any one Office. OST leads activities related to scientific collaboration and emerging technologies. OST leads partnerships that advance innovation and regulatory science.
These are largely done through collaborations with healthcare, industry, patient, and various scientific groups. OST helps to foster device innovation and leads the Center's efforts in dealing with public health emergencies.

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The Center's Standards and Conformity Assessment Program is managed in OST. The Office serves as a special projects incubator. And finally, on the technology side, OST strategically leads the Center's policy on cybersecurity, software, and digital health. It also oversees the Center's data technology, and information technology infrastructure.

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Let's now take a look at the Office of Product Evaluation and Quality, also known as OPEQ.

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OPEQ is the largest Office in CDRH. We refer to this as the Center's "Super Office," because OPEQ is responsible for most of the day-to-day regulatory activities for the Center, spanning the full spectrum of the total product life cycle. This is the multi-purpose room of the Center's home. I'm going to spend more time talking about OPEQ a little later in the presentation.

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Next, we'll take a look at the Office of Communication and Education, or OCE.

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OCE leads the external strategic regulatory and safety-related communications for the public. OCE also leads the communications that go internally to CDRH Staff. This Office is responsible for the portion of the FDA website that addresses medical devices and radiological health, and leads the Center's Freedom of Information Act, or FOIA, and Information Disclosure programs.

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OCE manages requests for CDRH staff who are invited to speak at public meetings, and also manages those meetings and workshops led by the Center. OCE heads the video, broadcasting, and webcasting services for the Center, just like the one that you're watching right now. OCE manages the wide-ranging education provided to CDRH Staff. And finally, my group in OCE leads the regulatory education that's provided to the public. This consists of developing regulatory videos like this, and other web content, as well as answering individual questions from the public by phone or email. With its role in interfacing both inside and outside of the Center, you could say that OCE is the front door, the windows, and the halls of our home.

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Moving to the right of our diagram, we have the Office of Management, or OM.

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OM is largely responsible for the two key resources of CDRH: people and money. OM is the utilities that allow our home to operate. OM develops and implements the Center's long-range, strategic and operational plans and budgets. OM leads the CDRH administrative functions. OM manages the Center's financial resources and is where the CDRH Small Business Program is operated. OM leads the human capital management and also administers the various CDRH advisory committee meetings.

Slide 23
Some homes have a dedicated place to do some hands-on work - whether it's a garage, a basement, or a workshop. Let's conclude our tour with that group in CDRH - the Office of Science and Engineering Laboratories, or OSEL.

Slide 24
OSEL leads the medical device and radiological health scientific research for CDRH. A main focus of this work is to develop methods, evaluation strategies, and testing standards that help the Center predictably and consistently evaluate the safety and effectiveness of products. OSEL supports the development of long-term regulatory processes and also provides expertise to advise the Center on specialized regulatory issues.

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Now that we've taken a tour of our home in CDRH, let's go back and spend some time in the Center's multi-purpose room - the Office of Product Evaluation and Quality.

Slide 26
OPEQ features an immediate office, 7 Offices of Health Technology, the Office of Regulatory Programs, and the Office of Clinical Evidence and Analysis. Over half of the Center's workforce is housed in OPEQ.

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OPEQ has a number of specific, detailed regulatory responsibilities. OPEQ implements the various premarket review programs. This includes the review of 510(k)s, IDEs, PMAs, HDEs, De Novos, and Q-submissions. For more information about these acronyms and programs, please check out the various educational resources at the FDA website. OPEQ is responsible for product compliance. This includes registration and listing, recalls, imports and exports, bioresearch monitoring, allegations, and product labeling. OPEQ evaluates devices in the postmarket setting, most notably through epidemiological evaluation and medical device reporting. OPEQ fosters the development of methodologies, analysis, and clinical trial infrastructure to evaluate device safety and effectiveness.

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OPEQ administers the Federal Law that supports the Clinical Laboratory Community, as guided by the Clinical Laboratory Improvement Amendments, or CLIA. OPEQ regulates radiation-emitting non-medical products.
OPEQ implements the mammography quality program, under the authority of the Mammography Quality Standards Act, or MQSA, of 1992. And finally, OPEQ sets strategy and oversees device-specific clinical evidence and analysis, and regulatory functions. As you can see, these cover many of the important regulatory responsibilities involved with the evaluation of the safety and effectiveness of medical devices and radiological products.

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Let's take a brief look at each of the offices within OPEQ, starting with the Immediate Office. This group leads the interpretation of regulatory policy and guidance for OPEQ. The Immediate Office provides support, strategy, and oversight to the other groups, and leads the clinical, scientific, quality, analytic, and strategic efforts.

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OPEQ features 7 Offices of Health Technology, or OHT. As you can see on the table in this slide, each OHT covers a specific product area. For example, OHT1 is responsible for products in the areas of ophthalmology, anesthesia, respiratory, ear, nose and throat, and dentistry, whereas OHT5 covers neurology and physical medicine. One good way to try to find out which OHT regulates your product is to go to the Product Classification Database. A link to this database is listed on this slide.

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Each OHT is responsible for the total product life cycle review, that is, premarket, compliance and quality, and surveillance, of its particular program area. For example, reviews of PMAs as well as administration of recalls for cardiovascular products are completed in OHT2. Each OHT is also responsible for leading the development of policy in its respective product area.

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The Office of Regulatory Programs, or ORP, manages OPEQ's regulatory programs, as the name suggests. ORP provides program support to the OHTs, leads the establishment support programs, such as registration and listing, and manages the Center's market intelligence programs, which involve the Center's programs on recalls, shortages, allegations, and MDRs.

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And finally, let's take a look at the Office of Clinical Evidence and Analysis, or OCEA. OCEA provides policy support for clinical evidence and human protection. OCEA provides regulatory oversight of device investigations, including both good laboratory and clinical practice, that is, GLP and GCP, respectively. Biostatistical and epidemiology analytics are managed from this office, and OCEA leads outreach and collaboration with hospitals and external stakeholders.

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We've covered a lot in the tour of the home of CDRH, and I've mentioned a lot of different groups and functions. You may be wondering - where do I go for help?

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A great place to start with any general questions is the Division of Industry and Consumer Education, or DICE. If you'd like to get immediate feedback, you may call us at the number listed on this slide for a live conversation. Or, if you prefer, you may email us for a written response. We'll usually get back to you within two business days. Please check out the DICE homepage listed on this slide, for more information and links to the educational resources to help you.

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Device Advice is one of the excellent resources designed for you. Device Advice is a comprehensive, regulatory educational resource about medical devices. Device Advice consists of hundreds of pages of web content spanning the total product life cycle about medical devices, on over 30 regulatory categories.

It includes detailed, written instructions, including various guides on how to complete various tasks. The website for Device Advice is simply: www.fda.gov/DeviceAdvice.

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Another great resource is CDRH Learn. CDRH Learn features multi-media, video training modules, such as presentations, computer-based training guides, and webinars. We have well over 100 CDRH Learn modules that you can access on many of the topics you're interested in. Most are less than 20 minutes long and the modules are mobile-friendly, so CDRH Learn can serve as an efficient resource wherever you are. The link to CDRH Learn is listed on this slide.

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Now this slide lists some of the most common topics where you may need to contact us directly. I've also listed the Office where the function is located in CDRH as well as the contact email or website. Feel free to use this as a resource in the future.

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On this slide, I've included a couple of references which you may find helpful. The first link provides more information about the organization of CDRH, and the 2nd link takes you to the Center's management directory.

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Let's recap what we covered in this module. The FDA's Center for Devices and Radiological Health is organized into 7 offices, led by the Office of the Center Director. The Office of Product Evaluation and Quality, or OPEQ, serves as the Center's "Super Office". And finally, OPEQ's Offices of Health Technology are organized into medical disciplines and are responsible for managing the core total product life cycle in that medical area.

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Let's conclude this module with your call to action. Become familiar with the structure of the Center for Devices and Radiological Health. Identify the Office or group with whom you interact for your regulatory needs. And finally, please use the available resources to help you comply with your regulatory responsibilities.

Thanks for joining me for this tour of CDRH. We'll see you next time!

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