ORA - A Day in the Life - Office of Regulatory Affairs: An Introduction
Module #1

Slide 1
Hello, my name is James Hildreth, and I am a First-Line Supervisor, or Supervisory Consumer Safety Officer, in the Office of Medical Device and Radiological Health Operations at the Food and Drug Administration, also known as the FDA. Today, I'll be giving a presentation titled "Office of Regulatory Affairs: An Introduction."

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I'm part of the section of FDA dedicated to field work, known as the Office of Regulatory Affairs, or ORA. This field work consists of things like conducting inspections at manufacturer facilities, following up on consumer complaints, tracking the effectiveness of product recalls, and considering legal action for non-compliance with the regulations. ORA employs about 1,600 consumer safety officers who collectively conduct an about 17,000 inspections worldwide each year. It's this section of the FDA that we will be learning about today.

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This presentation is the first of five modules in this series. This first module is an introduction to our organization and our roles within the FDA. Subsequent modules will cover the roles of Consumer Safety Officers, Supervisory Consumer Safety Officers, Compliance Officers, and Recall Coordinators.

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This is our overview for today's presentation. First, we will cover what ORA does. Second, we will outline the structure of ORA, also known as Program Alignment. Third, we will take a close look at the roles and structure of the Office of Medical Device and Radiological Health Operations. Finally, we'll discuss the staff roles that are most likely to have contact with industry representatives and the public. This introductory module lays the groundwork for this multi-module series.

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Let's get started with the operations of the Office of Regulatory Affairs.

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Known by its acronym, "ORA," this office is the lead for all FDA field work. ORA accomplishes many types of field work. Some examples include: conducting inspections of firms producing FDA-regulated products, investigating consumer complaints, enforcing industry compliance with regulations, collecting samples for lab analysis, and examining FDA-regulated products being imported into the country.

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This field work is done by approximately 4,500 employees, in 227 offices and 13 labs, throughout the country. Most people have heard of the FDA, but few people have heard of the Office of Regulatory Affairs, so let's see where ORA fits within FDA.

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Here is a high-level organizational chart of FDA. At the top, we have FDA, and within FDA are six primary centers. These centers are focused on the research, evaluation, and approval or non-approval of a specific type of FDA regulated product; there is a center for drugs, a center for medical devices, a center for tobacco, and so on.

In addition to the centers, there are eight offices and the Oncology Center of Excellence. For the purposes of simplifying the boxes in this slide, we combined these center and office components of FDA, rather than showing a separate box for each center and office. The current official organizational chart can be found on FDA.gov. This slide shows that ORA, which performs regulatory functions, is at the same level as FDA's six centers.

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ORA's divisions are each focused on specific product or industry types that FDA regulates, specializing in that type rather than addressing all regulated industries in a given geography. This organizational structure is known as Program Alignment.

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Basing its organization on specialization by product type put ORA at the center of a larger effort within the FDA to group employees by the type of product that they work on. There are seven key ORA programs that cover all FDA-regulated products. These seven programs are Biologics, Bioresearch monitoring, drugs, food, medical devices, imports, and tobacco products. ORA field staff are assigned to one of these seven programs. You may notice that the ORA laboratories are not listed as one of the seven program areas. ORA's 13 labs were also aligned into one of two areas: human food and animal feed labs, or medical product, tobacco, and specialty labs.

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The Program Alignment structure creates a specialized cohort of field staff that works together with the same product type. Because it groups the regulatory field staff together by assigned product type, these groups can now coordinate more efficiently with the FDA centers, whose staff are also assigned to those specific products.

For example, the FDA's Center for Devices and Radiological Health, or CDRH, with its pre-market focus on medical devices, aligns with the Office of Medical Device and Radiological Health Operations, which focuses on the regulation of medical devices in the field. These two groups work on the same product but at different points in the product's regulatory life cycle. This structure also affords staff the ability to more closely work with FDA experts for a specific product, regardless of their location within the FDA, and rely on their expertise when making decisions regarding the oversight of those products. This structure also functions to strengthen accountability among the various parts of the FDA responsible for a product type. It works to reduce duplication of efforts by the various offices, who, while focused on regulating the same products, may have different geographical oversight, resources, and tools to ensure that compliance.

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Program Alignment also aligns the workforce and management to the same cohort and the same product type, as opposed to the previous organizational structure in which the supervisor or manager may not have shared the same product assignment as the employee. This shared product assignment strengthens the entire workforce through specialization. Having staff concentrate on knowing a specific product type and its associated regulations also strengthens the relationship between FDA and regulated industries, as industry is also primarily organized by product type.

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Now, let's look at the ORA field staff group focused on medical devices and radiological health.

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The portion of the ORA field staff that performs regulatory monitoring of medical devices being manufactured, or are currently on the market, is the Office of Medical Device and Radiological Health Operations. This office is also called the Medical Device Program, or by its acronym, OMDRHO. This group comprises field staff who specialize in the regulatory compliance of medical devices, radiation-emitting products, and mammography.

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If we go back to the FDA organizational chart, you can see the Office of Medical Device and Radiological Health Operations is a sub-set of the Office of Regulatory Affairs. OMDRHO handles the medical devices and radiological health products for ORA. But how do they interact with CDRH?

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OMDRHO aligns with CDRH, where the center handles the pre-market side, and OMDRHO handles the post-market side of the medical device regulatory life cycle. Essentially, these offices are separate parts of the FDA that have a cooperative relationship based on the shared responsibility for the same product type.

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As part of this cooperation, the center employs scientific experts who work together with OMDRHO on policy and enforcement actions for all FDA-regulated medical devices and radiation-emitting products. OMDRHO and CDRH also partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations as part of FDA's implementation of the Medical Device User Fee and Modernization Act. This cooperative relationship also creates an opportunity to protect public health proactively. Together, CDRH and OMDRHO can follow a medical device through its total product life cycle. This total life cycle approach allows the FDA to focus on prevention of safety and efficacy issues before they occur. For this reason, the cooperative relationship between these two groups is very important, even though they are completely separate within the FDA organization.

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If we further break down the organization of OMDRHO, you can see the office is led by a program director. The next organizational layer is the division, of which there are three. Each division has a program division director as the lead manager. The divisions are spilt into two branches: a Compliance Branch and an Investigations Branch. The Compliance Branch is comprised of compliance officers, recall coordinators, and support staff. The Investigations Branch is comprised of the consumer safety officers, the supervisory consumer safety officers, and the support staff.

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The divisions are each assigned a geographic area of responsibility for medical device program operations, as outlined here. Each division covers multiple districts, identified by their three-letter abbreviation. These districts handle geographic-based operations not specific to a product type, as well as help support the programs, like ours, which operate in their geography. The districts and the divisions work together to accomplish the FDA mission.

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So who makes up OMDRHO? Well, we currently have approximately 230 staff in a range of positions, with the largest portion being consumer safety officers, also known as CSOs or Investigators.

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While all staff play important roles in accomplishing the mission of the FDA, four roles are more likely to interact with external customers: consumer safety officers, supervisory consumer safety officers, compliance officers, and recall coordinators.

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Core functions of OMDRHO include conducting inspections of regulated firms, and processing of regulatory actions, including recalls initiated by regulated industry. While we will go into further detail in future modules, the four roles in the previous slide are more likely to interact with external customers due to their responsibilities in accomplishing these functions.

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In general, the inspections of regulated firms are conducted by the consumer safety officers. These medical device inspections can be conducted for a variety of reasons, and their coverage can vary significantly with the purpose of the inspection. Most inspections are scheduled as routine, or surveillance, inspections.

While these routine inspections are identified using a risk-based approach, these inspections do not usually have a specified area of focus outlined in the assignment. “For Cause” inspections are conducted in response to specific information that raises questions or concerns associated with an FDA regulated firm or commodity. These assignments vary significantly based on the instructions in the assignment and the nature of the concern.

A Risk Based work plan assignment may be requested by CDRH based on data collected through the total product life cycle and may include in-depth coverage of specific areas of interest. CDRH may also request an inspection of a firm who has submitted a Premarket Approval application, or PMA, for a medical device.

These inspections may be conducted prior to the initial marketing approval of the device, called a Premarket Approval inspection, or shortly after approval for marketing of the device, called a Postmarket inspection. A premarket approval inspection is performed to assess the firm's ability to design and manufacture the device in accordance with the PMA and the Quality System Regulations.

A Postmarket inspection is typically conducted eight to twelve months after approval of the PMA, and is intended to assure the firm is making the device in accordance with the PMA and Quality System Regulations. Any of the above inspection types may be assigned at either domestic or foreign facilities, and OMDRHO CSOs are responsible for conducting these inspections wherever assigned.

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Although these inspections may have differences in coverage and focus, the process for each inspection type requires the gathering of information from a firm, and the evaluation of any inspectional findings. Where potential deficiencies are identified, those issues are documented, and recommendations made based on the nature of the findings. If the findings are significant, a recommendation may be made through the supervisory consumer safety officer for regulatory action to be considered. Those cases are referred to the compliance officers who process the regulatory action recommendation, such as issuing a warning letter, and communicating with the firm on compliance activities.

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Whether initiated because of inspection or not, a firm may address an issue with distributed devices by recalling that device. Depending on the actions needed to address the issue, the recall could include the correction of devices at a customer site, or the removal of the devices. These recalls are categorized by the FDA based on risk, with the lowest risk being a Class III, and the highest being a Class I. When the recall is reported to the FDA, the recall coordinator communicates with the firm about the recall. The recall may be terminated when a recalled issue is resolved, and all required actions are complete.

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Now that I've talked about some of the key functions of OMDRHO, let's take a look at some information about these work products for ORA and OMDRHO.

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Each year, ORA conducts thousands of domestic and foreign inspections of medical device manufacturers, with the majority being domestic inspections.

Tens of thousands of samples are collected and analyzed, and millions of lines of imported products reviewed. ORA issues thousands of warning letters citing noncompliance with law and regulation, and thousands more products are recalled.

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As shown in this table, OMDRHO's inspections, regulatory actions, and product recalls make up a significant portion of ORA's operations. You can find the data for these operations on the FDA.gov website.

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For current contacts related to one of the operations we discussed earlier, please reach out to one of the entities described on this slide to obtain the current contact information. The Immediate Office oversees foreign inspections, radiation-emitting products, including radiation emergency response, and mammography inspections. For any other programs, questions or issues, you may contact the appropriate division covering your facility.

Slide 30:
We've also provided links to some further information on the topics discussed today, including ORA and Program Alignment. If you're unsure which division covers your firm's geography, you can review the Division Boundary Maps on FDA.gov by following the last link.

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In this introductory module, we covered a lot of information, including organization and function of the Food and Drug Administration's Office of Regulatory Affairs, or ORA. We outlined the Program Alignment structure of ORA that organizes the Office by product type. We took a closer look at the roles and structure of the Office of Medical Device and Radiological Health Operations, also known as OMDRHO.

Finally, we discussed the staff roles that are most likely to have contact with external customers and provided some information on the operations conducted by these personnel to ensure that FDA regulated products are safe and effective.

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Let's conclude with your call to action. I encourage you to refer to our revised boundary map to identify which OMDRHO division covers your geographic area. And second, review the remaining four modules in this series to learn more about the roles in OMDRHO.

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The next modules will focus on the listed roles, one at a time. The modules will outline what an employee in each role does on a day-to-day basis. We hope viewing the varied responsibilities of these staff members will give you an idea of what a day in their life may look like.

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Thank you for joining us for this introductory module on the Day in the Life series. Have a great day.

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