Office of Regulatory Affairs: An Introduction

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Did You Know?

- A specialized FDA section is dedicated to field work – Office of Regulatory Affairs (ORA)
- ORA completes over **17,000** inspections world-wide every year

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Presentation Series: Day In the Life

- 5 Modules
  1. **Introduction**
  2. Consumer Safety Officer
  3. Supervisory Consumer Safety Officer
  4. Compliance Officer
  5. Recall Coordinator

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Learning Objectives

1. Describe the basic function of FDA's Office of Regulatory Affairs
2. Discuss the characteristics and functions of Program Alignment
3. Describe the features of the Office of Medical Device and Radiological Health Operations
4. Identify the primary work products and staff titles in ORA

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Office of Regulatory Affairs: Background

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Who is ORA?

- FDA's Office of Regulatory Affairs
- Lead Office for all field work
- Inspects regulated products and manufacturers

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ORA Numbers

- Over 4500 Employees
- 227 Offices
- 13 Laboratories

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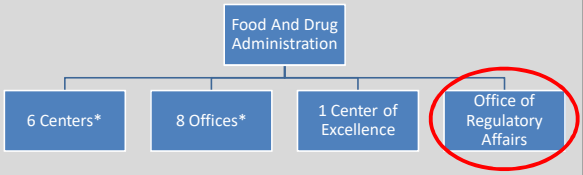
Where is ORA in FDA Structure?



* FDA Centers/Offices grouped together to simplify this chart; Official organization chart may be found at: www.fda.gov/media/121839/download

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Program Alignment

- Groups ORA employees together by product type
- Staff responsible for same products work together across the United States

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Program Alignment: Product Types

- Biologics
- Bioresearch Monitoring
- Drugs
- Food
- Medical Devices
- Imports
- Tobacco

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Program Alignment: Objectives

- Integrates FDA staff working with same products
- Optimizes coordination between ORA and FDA Centers
- Enables staff to work more closely with FDA experts
- Strengthens accountability and reduces duplication

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Program Alignment: Objectives

- Strengthens FDA workforce to improve public health response
- Aligns with regulated industry alignment by product type

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Office of Medical Device and Radiological Health Operations: Background

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Office of Medical Device and Radiological Health Operations

- Medical Device program within ORA
- Also known as "OMDRHO"
- Staff specialize in one of three areas:
  - Medical Devices
  - Radiological Health
  - Mammography

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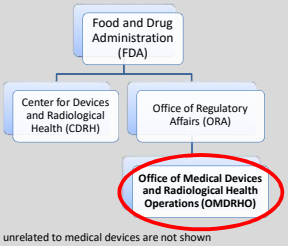
Location of OMDRHO in FDA Structure



Note: FDA Centers/Offices unrelated to medical devices are not shown

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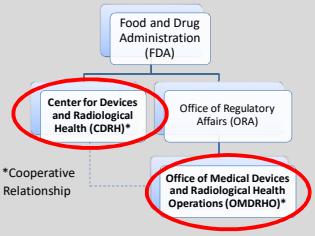
Cooperative Relationship with CDRH



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Cooperative Relationship with CDRH

- Expert resources provided
- Partnership on annual workplans and priorities
- Coverage of total product lifecycle

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OMDRHO Structure

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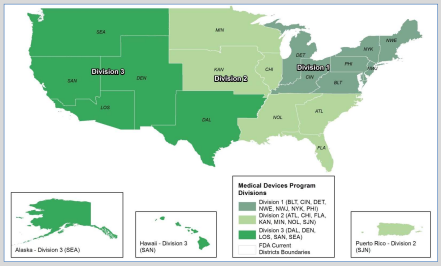
OMDRHO: Three Divisions



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OMDRHO Personnel Numbers

- **Over 230 Total Staff**
  - Directors/Managers: 12
  - Supervisory Consumer Safety Officers: 18
  - Consumer Safety Officers: over 140
  - Compliance Officers: 20
  - Recall Coordinators: 6
  - Support Staff: over 30

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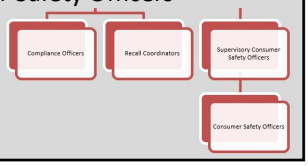
Most Common OMDRHO Staff Interactions with Industry

1. Consumer Safety Officers
2. Supervisory Consumer Safety Officers
3. Compliance Officers
4. Recall Coordinators



Core Functions

- **Inspections**
- **Regulatory Actions**
  - Includes Recalls

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Types of Inspections

- Routine or surveillance
- Directed or For-Cause
- Risk-based Workplan
- Premarket Approval Application (PMA)
- Postmarket Surveillance
- Domestic/Foreign

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Inspection Process

- Gather information from manufacturer
- Evaluate inspectional findings
- Document findings and make recommendations
- May lead to regulatory action, such as warning letter or recall

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Recall

- Originated when a manufacturer addresses product issue through a recall
- Categorized into Class based on risk
  - Class I: highest risk
- Terminated upon resolution of recall issue

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Work Products: Facts and Numbers

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ORA Numbers (FY2018)

- 16,336 Domestic Inspections
- 3,736 Foreign Inspections
- 43,099 Samples collected and analyzed
- 43.6 million lines of Imported Products reviewed
- 14,285 Warning Letters Issued
- 7,562 Recalled Products

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Comparison of OMDRHO and ORA (FY2018)

Function	OMDRHO	ORA
Domestic Inspections	1,690	16,336
Foreign Inspections	515	3,736
Warning Letters	31	14,285
Recalled Products	3,173	7,562
Injunctions	2	7

Data may be found at: https://www.fda.gov/about-fda/transparency/fda-data-dashboard

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For General Assistance

- **Contact OMDRHO Immediate Office:**
  - Foreign Inspections
  - Radiological Health Response
  - Mammography
- **Contact Divisions 1 – 3**
  - Other Programs, Questions or Issues

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References and Resources

- Office of Regulatory Affairs www.fda.gov/about-fda/office-global-regulatory-operations-and-policy/office-regulatory-affairs
- Program Alignment and ORA www.fda.gov/about-fda/office-regulatory-affairs/program-alignment-and-ora
- ORA Program Division Boundary Maps and Fact Sheets www.fda.gov/about-fda/office-regulatory-affairs/ora-program-division-boundary-maps-and-fact-sheets

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Summary

- FDA's Office of Regulatory Affairs (ORA) conducts the field work for FDA
- ORA's Program Alignment organizes this work by product type
- Office of Medical Device and Radiological Health Operations leads the medical device program for ORA
- The field work involves a large number of staff who conduct inspections and field work in order to ensure that products are safe and effective

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Your Call to Action

1. Refer to the OMDRHO boundary map to determine which division covers your geographic area.
2. View the remaining modules in this series to learn more about the individual OMDRHO staff roles.

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