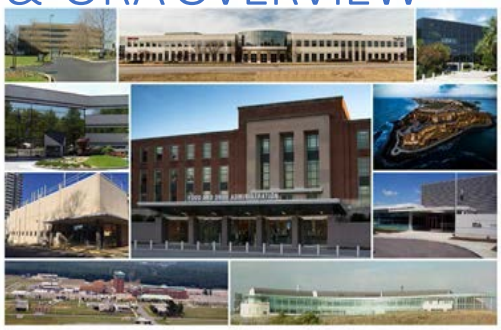
RECRUITMENT TOOLKIT
FREQUENTLY ASKED QUESTIONS AT OUTREACH EVENTS & ORA OVERVIEW



Frequently Asked Questions

1. **What open positions do you currently have?**
   Answer: You can locate the current openings in FDA ORA at www.fda.gov/orajobs. The USAJobs Pathways website is: https://www.usajobs.gov/Help/working-in-government/unique-hiring-paths/students/

2. **What opportunities do you have for current students?**

   Provide the Pathways One Pager which explains the program.

   Answer: *The Pathways Program offers federal internship and employment opportunities for current students, recent graduates and those with an advanced degree. The Pathways Program offers three different paths.*

   Internship Program: The Internship Program is for current students. If you're a current student in high school, college, trade school or other qualifying educational institution, you may be eligible. This program offers paid opportunities to work in federal agencies and explore federal careers while completing your education.

   Recent Graduate Program: The recent graduate program is for those who have graduated, within the past two years, from a qualifying educational institution or certificate program. The recent graduate program offers career development with training and mentorship.
   You must apply within two years of getting your degree or certificate (veterans have up to six years to apply due to their military service obligation).

   Presidential Management Fellowship (PMF) Program: This program is for recent graduates with an advanced degree—either a professional or graduate degree such as a master's, Ph.D. or J.D. You may be eligible if you:

   - Have completed an advanced degree from a qualifying educational institution or program within the past two years.
   - Are a current graduate student and will complete all of your degree requirements (including dissertations) by the PMF application deadline.

3. **What opportunities do you have for recent graduates?**
   Answer: *Two programs for recent graduates are the Recent Graduate Program and the Presidential Management Fellowship Program:*

   - **Recent Graduate Program**: The recent graduate program is for those who have graduated, within the past two years, from a qualifying educational institution or certificate program. The recent graduate program offers career development with training and mentorship.
     You must apply within two years of getting your degree or certificate (veterans have up to six years to apply due to their military service obligation).

- **Presidential Management Fellowship (PMF) Program:** This program is for recent graduates with an advanced degree—either a professional or graduate degree such as a master's, Ph.D. or J.D. You may be eligible if you:
    a) Have completed an advanced degree from a qualifying educational institution or program within the past two years.
    b) Are a current graduate student and will complete all of your degree requirements (including dissertations) by the PMF application deadline.

4. **What hiring opportunities exist for seasoned professionals?**
Answer: *FDA ORA has career opportunities as CSO's, Chemists and Biologists available for seasoned professionals. Look for the job announcements that are "Open to the Public" or "direct hire." When ORA has an opening, we post the positions on USAJobs and they can be found using our ORA weblink: www.fda.gov/orajobs*

5. **How do I apply for a job with FDA/ORA?**
Answer: *USAJobs is the best FREE resource to learn how to apply for government jobs. To locate jobs within ORA, go* to www.fda.gov/orajobs. *There are numerous ways to apply for a job with FDA ORA.*

    - One of the best sources to learn the correct way to apply for a job with the government are to view videos on USA Jobs and videos on You Tube: https://www.youtube.com/watch?v=Gih8-cwTCQU&feature=emb_logo
    - Go to USAJobs.gov and type in FAQs which provides links to various questions and answers about USA Jobs and the application process: https://www.usajobs.gov/Help/faq/

6. **I've applied for positions before and was not selected. How can I get help with my resume?**
Answer:
USA Jobs has a Help Center that has links and videos for help with building a resume and uploading a resume to your USAJobs profile.

https://www.usajobs.gov/Help/how-to/account/documents/resume/

The hiring agency determines whether or not a job seeker meets the minimum qualifications for a job. USAJOBS displays the information and application status they receive from the hiring agency. USA Jobs is the best resource to answer all your questions. There is a lot of help available on the website USAJobs.gov: https://www.usajobs.gov/Help/faq/

7. **I'm on a student visa and I'm looking for an employer to sponsor my work visa or green card. Do you sponsor work visas or green cards?**
Answer: *FDA ORA is a regulatory center and is not able to sponsor work visas or green cards. Other FDA centers offer this opportunity so please refer to USA Jobs and search for positions at FDA.*

8. **What does a Consumer Safety Officer do in ORA?**
Answer: *Please provide the CSO Outreach 1 pager or the CSO backgrounder. You can also say:*

- *As a Consumer Safety Officer (CSO), you will be responsible for conducting inspections and investigations in an industry regulated by the Food and Drug Administration and submitting written computer-generated reports accompanied by supporting evidence documenting violations of the laws that we enforce.*
- *CSOs routinely examine products covering six primary areas: pharmaceuticals, medical devices, human and animal foods, biologics, bioresearch monitoring, and imports to ensure compliance with U.S. law. This includes imported products at ports of entry around the country.*
- *FDA works closely with our U.S. Customs and Border Protection counterparts to cover ports of entry along with nine International Mail Facilities (IMF). In some districts, a CSO assigned to import operations may be trained/assigned to one of the United States border locations or IMF.*

9. **What major is required for the CSO position. Do you think I would qualify for a CSO position?**
Answer: *Please hand out the CSO Outreach 1 pager and point to the qualifications section: Qualifications for a CSO are:*

- *A bachelor's or graduate/higher level degree in quality assurance or a related degree that includes at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.*

- *The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.*

10. **I've heard that FDA has direct hire. What does that mean?**
Answer: *A Direct-Hire Authority (DHA) is an appointing (hiring) authority that the Office of Personnel Management (OPM) can give to Federal agencies for filling vacancies when a critical hiring need or severe shortage of candidates exists. FDA ORA can post the job announcements and hire qualified candidates quicker under this authority. Currently FDA ORA has a Direct Hire Authority to hire CSOs, Nurse, Pharmacists, Math Statisticians, Chemists, Biologists and Microbiologists. ORA is engaging in a major hiring effort over the course of the next few months and will post additional job announcements for 100+ CSO vacancies nationwide. You can find the announcements on USAJobs and, www.fda.gov/orajobs.*

11. **Do you hire administrative support from outside of the government?**
Answer: *On occasion ORA hires staff external to the government for administrative positions, but the majority are recruited from current federal employees. The best place to search for current openings is www.fda.gov/orajobs.*

12. *How can Veterans apply for positions at FDA ORA?*

Answer: **Special Hiring Authorities for Veterans** are just that…designed for veterans. Knowing about these authorities and identifying your eligibility can enhance your job search. These special authorities represent a few of many appointing authorities that agencies may use as authorized. Veterans are not *entitled* to appointment under any of these authorities, but knowledge that an agency intends to consider candidates pursuant to such an authority may enhance a veteran's chances to be considered. Check the vacancy announcements, which should clearly state Who May Apply. There are several Special Hiring Authorities for Veterans

- **Veterans Recruitment Appointment (VRA**) is an excepted authority that allows an agency to non-competitively appoint an eligible veteran.

- **The 30% or More Disabled Veteran** authority allows an agency to non-competitively appoint any veteran with a 30% or more service-connected disability

- **The Veterans Employment Opportunities Act of 1998**, as amended (VEOA) provides preference eligibles and certain eligible veterans the opportunity to compete for certain positions announced under an agency's merit promotion procedures. It applies only when the agency is filling a permanent, competitive service position and has decided to solicit candidates from outside its own workforce. It allows eligible veterans and preference eligibles to apply to announcements that would otherwise be open to so called "status" candidates, i.e., "current competitive service employees and certain prior employees who have earned competitive status."

- Disabled Veterans Enrolled in a VA Training Program - Disabled veterans eligible for training under the VA vocational rehabilitation program may enroll for training or work experience at an agency under the terms of an agreement between the agency and VA. While enrolled in the VA program, the veteran is **not a Federal employee** for most purposes but is a beneficiary of the VA.

13. What does veteran's preference mean? I will be discharged in 6 months and want to know if I qualify for veterans' preference.

Answer: *Please refer to USA Jobs.gov to access information needed to determine the type of veterans' preference that may apply to you.*

https://www.fedshirevets.gov/job-seekers/veterans-preference/

Further Explanation:

Veterans' Preference *gives eligible veterans preference in appointment over many other applicants. Veterans' preference applies to all new appointments in the competitive service and many in the excepted service. Veterans' preference does not guarantee veterans a job and it does not apply to internal agency actions such as promotions, transfers, reassignments and reinstatements.*

There are basically three types of preference eligibility, sole survivorship (0 point preference eligible), non-disabled (5 point preference eligible) and disabled (10 point preference eligible). Please reference USA Jobs Veterans' Preference for detailed information.

Understanding how veterans' preference works can be a challenge. In accordance with title 5, United States Code, Section 2108 (5 USC 2108) veterans' preference eligibility can be based on dates of active duty service, receipt of a campaign badge, receipt of a Purple Heart, or a service-connected disability. Please know that not all active duty service may qualify for veterans' preference.

Only veterans discharged or released from active duty in the armed forces under honorable conditions are eligible for veterans' preference. This means you must have been discharged under an honorable or general discharge. Under the VOW (Veterans Opportunity to Work) to Hire Heroes Act of 2011, an individual who has reason to believe s/he will be entitled to veterans' preference upon discharge may apply for a position in advance of the discharge, and receive consideration as a preference eligible, if the service member is able to provide a certification that s/he is expected to be discharged or released from active duty under honorable conditions not later than 120 days from the date of the certification; the circumstances of the discharge are verified at the time of actual appointment.

If you are a "retired member of the armed forces" you are not included in the definition of preference eligible unless you are a disabled veteran OR you retired below the rank of major or its equivalent.

The Office of Regulatory Affairs

The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts.

ORA's Mission

Protecting consumers and enhancing public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.

ORA's Vision

"All food is safe; all medical products are safe and effective; and the public health is advanced and protected."

ORA's Quality Commitment

ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

ORA Culture/Values

- ***A**ccountability - We take personal responsibility for meeting individual, team, and organizational commitments.*
- ***C**ommitment to Public Health - We demonstrate our commitment to safeguarding the public health in our actions.*
- ***C**ommunication - We provide information that is accurate and clear, and in our interactions with others, we actively listen to understand other points of view.*
- ***D**iversity & Inclusion - We embrace each individual's uniqueness and seek out their ideas and perspectives.*
- ***I**ntegrity and Respect - We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions.*
- ***Q**uality - We set high standards of excellence for our work and take the necessary actions to continuously improve.*

ORA Offices

ORA includes nine offices under the Office of the Associate Commissioner for Regulatory Affairs (ACRA). These offices are:

- Office of the Associate Commissioner for Regulatory Affairs (ACRA)
- Office of Criminal Investigations (OCI)
- Office of Communications and Project Management (OCPM)
- Office of Enforcement and Import Operations (OEIO)
- Office of Human and Animal Food Operations (OHAFO)
- Office of Management (OM)
- Office of Medical Products and Tobacco Operations (OMPTO)
- Office of Partnerships and Operational Policy (OPOP)
- Office of Regulatory Science (ORS)
- Office of Training, Education and Development (OTED)

ORA Laboratories

The Office of Regulatory Affairs (ORA) operates 13 high-throughput field laboratories, located strategically across the continental United States and Puerto Rico, to support FDA's mission to protect the public health and to create new knowledge in the field of regulatory science.

Human and Animal Food Labs

- Arkansas Lab (ARKL) - Jefferson, Arkansas
- Denver Laboratory (DENL) - Denver, CO
- Kansas City Laboratory (KCL) - Lenexa, KS
- Northeast Food and Feed Laboratory (NFFL) - Jamaica, NY
- Pacific Northwest Laboratory (PNL) – Bothell, WA
- Pacific Southwest Food and Feed Laboratory (PSFFL) – Irvine, CA
- San Francisco Laboratory (SANFL) – Alameda, CA
- Southeast Food and Feed Laboratory (SFFL) – Atlanta, GA

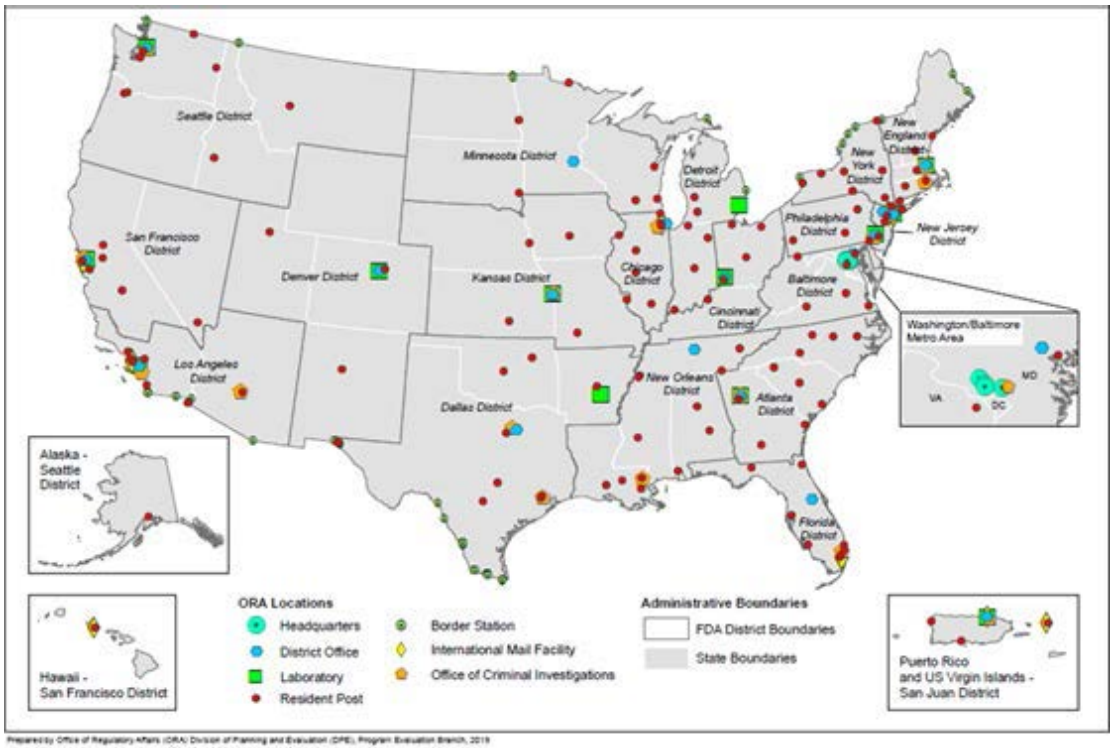
Medical Products, Tobacco and Specialty Labs

- Detroit Laboratory (DETL) – Detroit, MI
- Forensic Chemistry Center (FCC) – Cincinnati, OH
- Northeast Medical Products Laboratory (NMPL) – Jamaica, NY
- Pacific Southwest Medical Products Laboratory (PSMPL) – Irvine, CA
- Philadelphia Pharmaceutical Laboratory (PHIL) – Philadelphia, PA
- San Juan Pharmaceutical Laboratory (SJNL) – San Juan, PR
- Southeast Tobacco Laboratory (STL) – Atlanta, GA
- Winchester Engineering Analytical Center (WEAC) – Winchester, MA

ORA Districts

There are 19 district office locations in the Office of Regulatory Affairs. There are also Resident Posts and Border Stations associated with these offices, for a total of 231 ORA locations.

1. Atlanta – Atlanta, GA
2. Baltimore – Baltimore, MD
3. Chicago – Chicago, IL
4. Cincinnati – Cincinnati, OH
5. Dallas – Dallas, TX
6. Denver – Denver, CO
7. Detroit – Detroit, MI
8. Florida – Maitland, FL
9. Kansas City – Lenexa, KS
10. Los Angeles – Irvine, CA
11. Minneapolis – Minneapolis, MN
12. New England – Stoneham, MA
13. New Jersey – Parsippany, NJ
14. New Orleans – Nashville, TN
15. New York – Jamaica, NY
16. Philadelphia – Philadelphia, PA
17. San Francisco – Alameda, CA
18. San Juan – San Juan, PR
19. Seattle – Bothell, WA



ORA Program Areas

Under ORA's new program-based management model, there are seven key programs for operations Each program has a unique number of program divisions for a total of 28 operational divisions.

1. **Biological Products**
   The Office of Biological Products Operations (OBPO) conducts inspections, investigations, and compliance activities for blood and tissue products as well as vaccines and other biological products covers a wide range of products such as allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins

2. **Bioresearch Monitoring**
   The Office of Bioresearch Monitoring (BIMO) Operations is responsible for cross-center activities ensuring the protection of subjects involved in clinical research for FDA-regulated products and that non-clinical research is conducted according to Good Laboratory Practices (GLP) requirements.

3. **Human and Animal Food**
   The Office of Human and Animal Food Operations (OHAFO) oversees all field inspection and compliance operations related to human and animal food and other products regulated by Center for Food Safety and Nutrition and the Center for Veterinary Medicine.

4. **Medical Devices and Radiological Health**
   The Office of Medical Device and Radiological Health Operations (OMDRHO) coordinates, directs and assists with medical device and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations.

5. **Pharmaceutical Quality**
   The Office of Pharmaceutical Quality Operations (OPQO) coordinates domestic and foreign inspectional, quality and investigational activities of pharmaceutical products, as well as providing technical assistance regarding pharmaceutical investigational operations.

6. **Tobacco**
   Tobacco Operations, a program within the Office of Regulatory Affairs' (ORA) Office of Medical Products and Tobacco Operations (OMPTO), is a rigorous compliance and enforcement program aiming to ensure that the tobacco industry follows the law and regulations designed to reduce the health burden of tobacco use.

7. **Import Program**
   The Office of Enforcement and Import Operations (OEIO) provides direction, assistance, management and oversight of field import operations, including investigational and compliance activities and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems.

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About the Office of Bioresearch Monitoring Operations

A specialized office to ensure the protection of subjects involved in clinical research for FDA-regulated products

The Office of Bioresearch Monitoring Operations (OBIMO), a program within the Office of Regulatory Affairs (ORA),. In addition, OBIMO ensures the quality and integrity of data in clinical and non-clinical studies that support the research and marketing applications submitted for review.

OBIMO oversees all domestic and foreign agency field inspectional operations related to the Bioresearch Monitoring (BIMO) Program, including all clinical and nonclinical research conducted in support of preapproval, licensing, premarket and marketing clearance applications submitted to the agency for products regulated by all FDA product centers.

OBIMO's Director manages the day-to-day operations and coordination with FDA centers and ORA's Office of Strategic Planning and Operational Policy (OSPOP). OBIMO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders relative to BIMO field operations including emergency response activities. The office includes two divisions — the Division of Bioresearch Monitoring Operations I and II — but does not have compliance branches. OBIMO also includes the Bioresearch Monitoring Operations Staff. The BIMO Program includes Post marketing Adverse Drug Experience (PADE) and Risk Evaluation and Mitigation Strategies (REMS) inspections.

ORA's program division directors, formerly district directors, are the most senior FDA officials in their geographic area and continue to be the point of contact for local staff, the public, and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials continues to be managed by district state liaisons. Contact OBIMO at **engageORA@fda.hhs.gov**.

For more information, visit:

a. Office of Regulatory Affairs
b. Office of Good Clinical Practice

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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About the Office of Biological Products Operations

A specialized office to help protect and promote the safety and quality of biological products

The Office of Biological Products Operations (OBPO) consists of a specialized workforce that conducts inspections, investigations, and compliance activities for blood and tissue products as well as vaccines and other biological products regulated by the Center for Biologics Evaluation and Research (CBER).

OBPO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders on field operations and emergency response activities related to products regulated by the Center for Biologics Evaluation and Research (CBER). OBPO coordinates, directs, and conducts CBER-regulated product investigative activities and supports the development of policy and guidance for investigations and compliance for biological products.

OBPO investigators and compliance officers participate as subject matter experts in the design, implementation, and presentation of biologics training programs. OBPO, with CBER, creates, reviews, and/or facilitates issuance of field assignments. OBPO coordinates emergency activities with, and provides assistance to, department components and other external stakeholders in the event of a natural disaster or other emergency.

The OBPO's subject matter experts serve on external and internal cross-agency biologics program committees, workgroups, and task forces related to field operations. OBPO also develops and maintains cooperative relationships with state, local, and other federal agencies. OBPO staff serve on interagency councils and engage with international regulatory authorities to increase competency and consistency in inspections of biological products.

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For more information, visit:

- Office of Regulatory Affairs
- Center for Biologics Evaluation and Research

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About the Office of Medical Device and Radiological Health Operations

A specialized office to help protect and promote the safety and quality of medical devices and radiation-emitting products.

The Office of Medical Device and Radiological Health Operations (OMDRHO), a program within the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding medical device and radiological health program operations, including emergency response activities. OMDRHO collaborates with the agency's Center for Devices and Radiological Health (CDRH) on all FDA-regulated medical devices and radiation-emitting products.

OMDRHO coordinates, directs and assists with medical device and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations. ORA and CDRH 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.

The Director oversees OMDRHO's day-to-day operations and coordination with CDRH. The office structure includes the Foreign Medical Device and Radiological Health Inspection Staff, Medical Device and Radiological Health Operations Staff, and Divisions of Medical Device and Radiological Health Operations I, II, and III, with responsibility for oversight of staff conducting inspections, managing compliance activities, recalls, and partnerships.

ORA's Program Division Directors, formerly District Directors, are the most senior FDA official in their geographic area and continue to be the point of contact for local staff, public and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials will continue to be managed by district state liaisons. Contact OMDRHO at **engageORA@fda.hhs.gov**.

For more information visit:

- Office of Regulatory Affairs
- Center for Devices and Radiological Health

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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About the Office of Pharmaceutical Quality Operations

A specialized office to help protect and promote the safety and quality of human and animal drug products

The Office of Pharmaceutical Quality Operations (OPQO), a program within the Office of Medical Products and Tobacco Operations in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding pharmaceutical products field operations and emergency response activities. OPQO collaborates with the agency's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM) on all FDA-regulated pharmaceutical and biopharmaceutical products.

OPQO coordinates, directs, and assists with pharmaceutical product investigative activities, including conducting investigations and inspections of pharmaceutical products, as well as providing technical assistance regarding pharmaceutical investigational operations. As part of FDA's implementation of the Prescription Drug User Fee Act, Medical Device User Fee and Modernization Act, and the Generic Drug User Fee Amendment, ORA, CDER, and CVM partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations.

The Director of OPQO manages day-to-day operations and coordination with CDER and CVM. The office structure includes a Division of Pharmaceutical Quality Programs, Division of Foreign Pharmaceutical Quality Inspections, and four Divisions of Pharmaceutical Quality Operations whose staff conduct investigations and manage compliance activities, recalls, and partnerships in ORA's 20 district offices.

ORA's program division directors, formerly district directors, are the most senior FDA officials in their geographic area and continue to be the point of contact for local staff, the public, and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials continues to be managed by district state liaisons. Contact OPQO at **engageORA@fda.hhs.gov**.

For more information, visit:

- Office of Regulatory Affairs
- Center for Drug Evaluation and Research
- Center for Veterinary Products

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About the Office of Human and Animal Food Operations

A specialized office to help protect and promote the safety and quality of the nation's domestically produced and imported human and animal foods and cosmetics

The Offices of Human and Animal Food Operations – East and West (OHAFO), a program within the Office of Human and Animal Food Operations (OHAFO) in the Office of Regulatory Affairs (ORA), provides advice and counsel to ORA and FDA leaders regarding human and animal food products, field operations, and emergency response activities. OHAFO collaborates with the agency's Office of Foods and Veterinary Medicine (OFVM), Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM) on all FDA-regulated food products.

OHAFO oversees all field inspection and compliance operations related to human and animal food and other products regulated by CFSAN and CVM. As part of FDA's implementation of the Food Safety Modernization Act, ORA, OFVM, CFSAN, and CVM partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations.

OHAFO's Director manages the day-to-day operations and coordination with CFSAN and CVM. The office structure includes an Office of Human and Animal Food Operations–East (Vinetta Howard-King, acting) and an Office of Human and Animal Food Operations–West (Joann Givens). These offices conduct investigations and manage compliance activities, recalls, and partnerships in ORA's 20 district offices.

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For more information, visit:

- Office of Regulatory Affairs
- Center for Food Safety and Applied Nutrition
- Center for Veterinary Medicine

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About Tobacco Operations

A specialized staff providing assistance to take action against tobacco product retailers and businesses for violations of the Tobacco Control Act

Tobacco Operations, a program within the Office of Regulatory Affairs' (ORA) Office of Medical Products and Tobacco Operations (OMPTO), is a rigorous compliance and enforcement program aiming to ensure that the tobacco industry follows the law and regulations designed to reduce the health burden of tobacco use.

The Program does not have any program divisions, and compliance functions are supported by the Center for Tobacco Products.

The program collaborates with CTP on the implementation of the Family Smoking Prevention and Tobacco Control Act by:

- Supporting contracts with states and territories to inspect places where tobacco is sold,
- Conducting domestic and foreign inspections of manufacturing and clinical-trial facilities in all states and territories, and
- Conducting investigations at events where tobacco product manufacturers distribute free samples.

ORA's program division directors, formerly district directors, are the most senior FDA officials in their geographic area, and they continue to be the points of contact for local staff, the public, and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials continue to be managed by district state liaisons. Contact the Tobacco Operations Staff at **engageORA@fda.hhs.gov**.

For more information, visit:

- Office of Regulatory Affairs
- Center for Tobacco

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About the Office of Enforcement and Import Operations

A specialized office that serves to protect public health through risk-based enforcement strategies designed to ensure the safety and suitability of regulated products destined for the US marketplace.

The Office of Enforcement and Import Operations (OEIO) provides direction, assistance, management and oversight of field import operations, including investigational and compliance activities; and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems. OEIO establishes field uniformity for import activities through adherence to procedural policy and managing automated systems operations, and establishes import quality control program. OEIO coordinates agency import activities with U.S. Customs and Border Protection, including the development and institution of joint regulations, procedures, policies, and operations; and coordinates activities with other federal agencies and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships. With the addition of the Division of Food Defense Targeting (DFDT), OEIO will liaise with law enforcement agencies to obtain and respond to intelligence concerning potentially hazardous human and animal food products destined to be offered for import into the United States. It will continue to provide subject matter expertise and direction for the development of import policies and new import procedures and regulations, as well as support and direction for designated compliance and recall operations that cut across programs. Under Program Alignment, existing port of entry import staff will remain in their current locations and be organized into five areas of responsibility to include the Northeast, Southeast, Southwest, Western and Northern Border Divisions.

The enforcement component within OEIO provides a quality assurance function in compliance casework across programs, permitting the agency to manage, measure, and improve the quality of its work products in coordination with Quality Management staff. OEIO provides management and oversight of the Agency's debarment program relevant to FDA compliance. It serves as the clearance point and coordinator for all administrative warrants and actions, and liaises with ORA and Centers to ensure coordination of evidence. OEIO also oversees all ORA recall operations and the health fraud enforcement activities.

The Director that manages the Office of Enforcement and Import Operations has responsibility for managing operations related to imports, data systems, recalls, and enforcement issues. Contact OEIO at **engageORA@fda.hhs.gov**.

For more information visit:

- ORA Office of Enforcement and Import Operations
- Office of Regulatory Affairs

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
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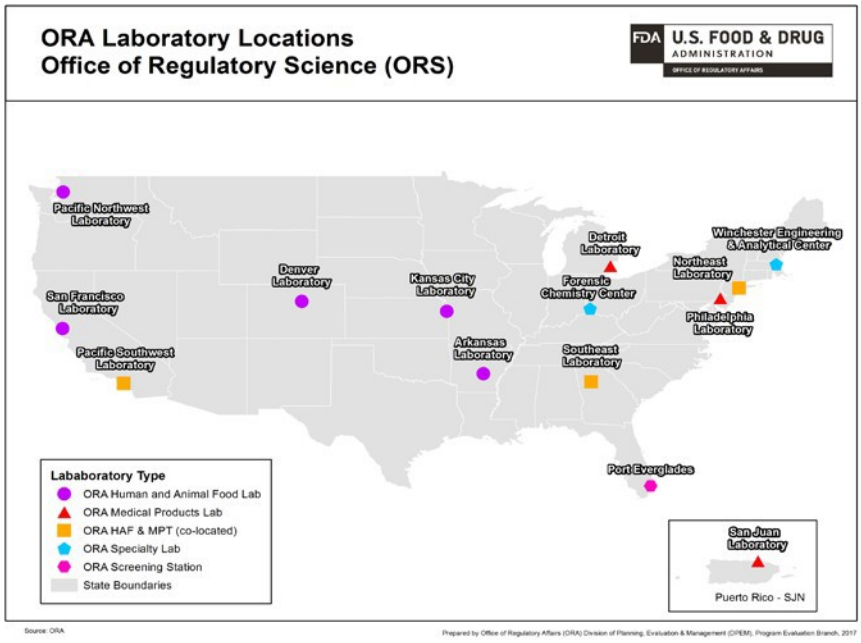
FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

About the Office of Regulatory Science

A nationwide network of laboratories that protect public health by producing data that enables FDA to make science-based regulatory decisions.

The Office of Regulatory Affairs (ORA) operates 13 regulatory laboratories, located strategically across the United States, to support FDA's mission to protect the public health and to create new knowledge in the field of regulatory science. The labs specialize as Human and Animal Food (HAF) Labs or Medical Product, Tobacco, and Specialty (MPTS) Labs, as shown in the figure below.

Approximately 1000 scientists and support staff are assigned to ORS. These individuals work in headquarters and labs across the United States to develop and execute compliance and surveillance programs, analyze samples, strengthen laboratory operations, ensure lab safety, and produce quality data that is the foundation for regulatory decisions. As a direct result of this work, FDA is able to prevent distribution of products found to be in violation of the Food, Drug and Cosmetic Act. The success of FDA activities to protect the public health often depends on the ability of the agency's laboratories to quickly and accurately analyze samples.



The Director oversees the day-to-day operations of the Office of Regulatory Science. He is based in Arkansas and reports directly to ORA's associate commissioner for regulatory affairs.

ORS includes four offices: the Office of Business and Safety Operations (which includes the Lab Work Planning and Metrics Staff and the Safety and Risk Management Staff), the Office of Research Coordination and Evaluation (which includes laboratory quality management oversight), the Office of Human and Animal Food Laboratory Operations (which includes the specialized HAF labs), and the Office of Medical Products, Tobacco, and Specialty Lab Operations (which includes the MPTS labs).

Office Contacts:

FDA-regulated industry should contact staff in the immediate office of the Office of Regulatory Science using the ORA Directory. To share feedback related to performance quality contact the Associate Director, Research Coordination and Evaluation.

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