Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Bioresearch Monitoring Operations (OBIMO)
Consumer Safety Officer (Investigator)

Application Period: December 27, 2022, 2023 – June 1, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Consumer Safety Officer (Investigator)

Series: AD-0696

Location(s): Multiple vacancies in the following locations: El Segundo, CA; Irvine, CA; Long Beach, CA; Ontario, CA; Woodland Hills, CA; Hartford, CT; Maitland, FL; Miami, FL; Tampa, FL; Atlanta, GA; Bannockburn, IL; Chicago, IL; Hinsdale, IL; Lisle, IL; Indianapolis, IN; Baton Rouge, LA; Covington, LA; Metairie, LA; Stoneham, MA; Baltimore, MD; Detroit, MI; St. Louis, MO; East Brunswick, NJ; Parsippany, NJ; Memphis, TN; Nashville, TN; Austin, TX; Dallas, TX; El Paso, TX; Houston, TX; San Antonio, TX; Falls Church, VA; Richmond, VA; Puget Sound, WA; Seattle, WA

Salary: Starting at $74,950

Work Schedule: Full Time

Cures Band(s): Band A

Full Performance Band Level: Band B

Travel Requirements: Up to 50% travel

Bargaining Unit: 3591

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

Join the Food and Drug Administration (FDA) and serve on the frontlines protecting our nation's

public health and safety within the Office of Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 16 laboratories throughout the nation or around the world. Our employees inspect product facilities; investigate criminal violations; analyze lab samples; provide administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. ORA supports the six FDA product centers by inspecting regulated products and manufacturers, conducting sample analyses on regulated products and reviewing imported products offered for entry into the United States. In addition to executing its mission through its federal workforce, ORA also works with the FDA Centers, who develop FDA wide policy on compliance and enforcement and ORA executes the annual commodity work plans. Over 5,000 ORA employees located in district offices, resident posts and laboratories, strategically located throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education and outreach directly to consumers, industry representatives, importers and shippers as well as other stakeholders across the nation. ORA also works with its federal, state, local, tribal, territorial and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

The FDA's Office of Bioresearch Monitoring Operations (OBIMO) is the lead office for conducting inspections and investigations of clinical and nonclinical research performed in support of marketing applications for regulated products, as well as post marketing adverse drug experience reporting and risk evaluation and mitigation strategies for approved products. OBIMO works with all six product centers to develop policies on compliance and enforcement and is responsible for the following: Inspecting foreign and domestic bioresearch monitoring establishments for which FDA has regulatory responsibility, collecting samples for analysis, and preparing reports. These establishments include sponsors, clinical investigators, institutional review boards, and nonclinical laboratories. OBIMO evaluates inspectional and/or analytical findings relative to compliance and recommends appropriate follow-up. OBIMO is responsible for preparing and providing evidence of investigational findings. OBIMO provides dedicated inspectional and investigational support to Headquarters and other divisions, as needed. OBIMO advises ORA and other centers on emerging inspectional, scientific, and regulatory issues related to FDA regulated products. Additionally, OBIMO provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

Duties/Responsibilities

The Consumer Safety Officer (CSO) has demonstrated and is recognized for a high level of competence in the full range of establishments regulated within the OBIMO program such as: clinical investigators, nonclinical laboratory facilities, sponsors, contract research organizations, institutional review boards, post marketing adverse drug experience reporting, and risk evaluation and mitigation strategies.

Assignments involve a combination of scientific and regulatory responsibilities which usually call for several atypical inspectional or intensive investigative approaches to be applied to a wide variety of regulatory functions or scientific evaluations; and include the most difficult and complex sample collections, establishment inspections, unusual or novel special investigations and conducting objective surveys and emergency activities within the assigned area of responsibility. The CSO will also perform international inspections.

Inspections and Investigations

- Assignments cover large, medium, and small firms, complex investigations and inspections of various industry establishments covered by the program such as: clinical investigators, sponsors, contract research organizations, institutional review boards, nonclinical laboratories, post marketing adverse drug experience reporting, and risk evaluation and mitigation strategies. The investigator independently conducts inspections, investigations, and sampling where new or unusual features are present, only limited guidance documents are available; proposed or new regulations must be used to evaluate the industry; or the inspection or investigation may result in considerable attention and review in the media, the Department, Congress, or other forces inside or outside the Agency. Inspections cover all types of products and problems within the area of assigned responsibility.
- Investigates and evaluates the adequacy of complex practices to determine compliance with the regulations.
- Incumbent interacts with and advises various levels of officials representing the establishments subject to regulatory review. The incumbent initiates contact with industry officials to obtain information on regulatory and scientific documents and to discuss the status of investigations.
- Assists the immediate supervisor in planning inspections, investigations, sample collections, and related activities in the area of assigned responsibility; training new personnel and higher graded personnel, as appropriate; training foreign government personnel. Developmental assignments include assisting higher level employees in inspections or other field activities, meetings, and conference calls with regulated industry.

- Incumbent conducts re-inspections to follow up with non-compliant industry establishments on previously noted violations. In situations where compliance is not offered, it is enforced through other methods, including administrative action, informational agency meetings, and legal court actions.

Analysis and Reporting

- The Incumbent will perform analyses and evaluation on data samples and documented information gathered during inspections and investigations to ensure that documentation and practices are in compliance with Federal laws, rules, and regulations. Documents and organizes required evidence, data, and other information to support violations noted during inspections, investigations, and sample collections.
- For team inspections, employee gathers scientific and technical comments from team members, assists with the preparation of reports relevant to the inspection, and contributes to status reports for inspections and investigations under review.
- Prepares final reports, position papers and other written documentation that support investigative findings and recommendations. Reports are developed and well-written in accordance with quality elements.

Supervisory Responsibilities: This is not a supervisory role.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Consumer Safety Series, 0696:

Desired Education: Advanced Degree

Desired Professional Experience:

- Knowledge and skill in applying a wide range of complex professional theories, concepts, principles, standards, and methods to determine, execute, and explain actions that modify standard practices, equipment, devices, processes, and well-known techniques and resolve a wide variety of complications and constraints contained in traditional projects.
- Skill to adapt precedents and existing strategies which allow occupational projects to meet unusual needs or demands and serves as a principal contributor for the assigned specialty areas on team-based projects.
- Ability to coordinate a team project by providing technical oversight and direction for a variety of principal team members representing related professional disciplines, and evaluates and presents plans, designs, reports, and correspondence concerning projects and product issues.
- Knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques to conduct complete and professional inspections and investigations, persuade reluctant persons and officials to provide information or access

to information, and persuade industry representatives to agree to terms needed to achieve compliance.

- Skill in planning and carrying out assignments, resolving most conflicts that arise, coordinating the work with others as necessary, and interpreting policy on own initiative in terms of established objectives. In some assignments, the employee also determines the approach to be taken and the methodology to be used. The employee keeps the supervisor informed of progress and potentially controversial matters.
- Ability to apply judgment in interpreting and adapting guidelines, such as agency policies, regulations, precedents, and work directions for application to specific cases or problems. The employee analyzes results and recommends changes. Skilled in making decisions to assess unusual circumstances, variations in approach, and incomplete or conflicting data.

Additional Requirements of this Position:

- Candidates for this position must complete a statement regarding their physical ability and may be required to undergo physical examination because the position requires:
    - the need to work long and unscheduled hours.
    - exposure to all kinds and extremes of weather and noise.
    - the need to lift heavy objectives up to 50 pounds, walk, bend, stand, stoop, kneel, and climb.
    - the need to meet the vision, hearing, and olfactory requirements necessary to perform the work of this position.
- Travel approximately 50 percent of the time which will often require the Consumer Safety Officer to be away from the duty station for up to two to three weeks at a time.
- The work involves regular and reoccurring exposure to moderate risks, discomforts, and unpleasantness such as:
    - contagious diseases
    - infectious materials, or toxic or irritating chemicals
    - carcinogenic materials
    - noxious fumes
    - flammable liquids
    - radiation, and/or
    - potentially pathogenic bacteria.
- Special safety precautions such as protective clothing and equipment may be necessary.
- While some work is performed in an adequately lighted and climate-controlled office, onsite investigations and inspections may involve exposure to moderate risks or discomforts such as high levels of noise, dust, moving parts of machinery, irritant fumes, etc. Protective clothing and gear, and observance of safety precautions are required.
- Inspection and sample collection duties are performed either inside buildings and other structures, outdoors, or both depending on the type and location of the facility. Consequently, employees are exposed to a variety of environmental conditions including extremes of heat, cold or humidity; excessive noise; excessive dust; uneven

surfaces and slippery floors; and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, etc. During these periods, employees must eat and sleep in primitive conditions with little or no privacy. As Investigators, incumbents must travel into and work in areas that have been the subject of violence and that are otherwise considered unsafe.

- This position requires the incumbent must possess a valid Driver's License to drive a government/privately owned motor vehicle.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an

employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

Additional Information

Incentives: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years.

Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: recruitment, relocation, student loan repayment (for government employees only), PCS and creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

How to Apply

How to Apply: Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position and preferred location(s), detailed resume and bibliography, redacted SF-50 (for federal employees only), and transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through **June**

1, 2023. Candidate resumes may be shared with hiring official within the OMPTO with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please reference **OBIMO Consumer Safety Officer - name of preferred location(s)** in the subject line.

Announcement Contact

For questions regarding this Cures position, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov.

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