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 Medical Device and Radiological Health Operations (OMDRHO)
Investigator II/Senior Investigator I

Application Period: January 22, 2024 through July 22, 2024

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: Investigator II/Senior Investigator I

Series: AD-0696

Location(s): Telework Eligible

Location Reference Code (LRC)	Openings per LRC	Cities within Location
OMDRHO1	1	IN: Indianapolis NJ: Parsippany NY: Jamaica PA: Philadelphia MD: Owings Mills OH: Brunswick
OMDRHO2	5	MN: Minneapolis WI: Wauwatosa (Milwaukee) NC: Raleigh GA: Atlanta TN: Memphis
OMDRHO3	3	CA: South San Francisco, Alameda, Irvine TX: Dallas

Salary:
Starting at $82,764 (Band A)
Starting at $99,200 (Band B)

Work Schedule: Full Time

Title 21 Band(s): Band A/B

Full Performance Band Level: Band B

Travel Requirements: 25-50% travel

Bargaining Unit: This is a bargaining unit position.

Relocation Expenses Reimbursement: Will not be paid

This position is being filled under a stream-lined hiring authority, Title 21 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072 and the Consolidated Appropriations Act of 2023, Section 3624. 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

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured, packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The mission of the Office of Regulatory Affairs is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs

The Office of Regulatory Affairs (ORA) is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 12 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

The Office of Medical Products and Tobacco Operations (OMPTO) oversees four program directors in the coordination, interpretation, and evaluation of the Agency's overall field inspections and compliance efforts in the areas of medical products and tobacco. OMPTO is led by an Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) who reports directly to the Associate Commissioner for Regulatory Affairs.

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 devices and radiological health program operations, including emergency response activities. OMDRHO collaborates with the agency's Center for Device and Radiological Health (CDRH) on all FDA-regulated medical devices and radiation-emitting products.

Duties/Responsibilities

The Investigator/Senior Investigator has demonstrated and is recognized for a high level of competence in the full range of establishments regulated within the OMDRHO program such as: inspections and investigation of manufacturers, specification developers, contract manufacturers, sterilizers, initial importers, and distributors.

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.

Inspection and Investigation

- Independently plans and conducts regulatory inspections and in-depth investigations of various industry establishments, such as manufacturers, specification developers, contract manufacturers, sterilizers, initial importers, and distributers. Assignments are frequently complicated by a variety of diverse products, highly specialized and sophisticated processes and equipment, products that are misbranded or adulterated or unapproved, complex quality control systems, or uncooperative establishment management. The Investigator conducts inspections and investigations (domestic and/international) of facilities where 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, Congress, or other forces inside or outside the Agency.
- Incumbent performs various activities including domestic sample collections, establishment inspections, unusual or novel special investigations, remote regulatory assessments (RRAs), recall audit checks, and emergency activities of moderate difficulty within the incumbent's assigned area of responsibility.
- Incumbent interacts with and advises various levels of management officials representing the regulated industry, associations, state, local and foreign governments including those which may be contentious and require special skills to moderate conversations.
- The incumbent initiates contact with industry officials to obtain basic incomplete or missing information on regulatory and scientific documents and to discuss the status of investigations.
- Assists the immediate supervisor or a team leader by planning inspections, investigations, sample collections, and related activities in the area of assigned responsibility, trains new personnel and providing training for personnel, trains State and local government personnel and when required, conducts international inspections.
- Performs investigations involving complaints of illness, injury, or death attributable to products regulated by the FDA.
- Judgment must be used to make field decisions on the nature and extent of investigations and inspections. Incumbent conducts re-inspections to follow up with non-compliant industry establishments on previously noted violations.

Analysis and Reporting

- Incumbent performs analyses and evaluation on potentially complex data samples and documented information gathered during inspections and investigations, utilizing novel approaches as needed to ensure compliance with Federal laws, rules, and regulations. Documents and organizes required evidence, data, and other information to support violations noted during inspections, RRAs, investigations and sample collections. Interacts with and advises various levels of officials representing the establishments subject to regulatory review. Initiates contact with industry officials and manufacturers to obtain basic, incomplete, or missing information on regulatory and scientific documents, to discuss the status of investigations, and to attend meetings and conference calls.
- Prepares final EIR, investigations memoranda, and proposed or final endorsements for inspections and investigations conducted. 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 Title 21 position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. Outstanding candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.
    b. ***Qualified*** applies to all candidates for Title 21 appointments.

In order to qualify for this Title 21 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.

Basic Requirements:

Applicants must meet one of the following requirements.

Education: A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

OR

Experience: Comparable experience with FDA, a state or federal partner agency, or in an FDA-regulated industry or organization providing investigative or compliance services to an FDA-regulated industry, focused on evaluating or ensuring compliance with FDA or related public health laws and regulations. To qualify for Band A with no degree, you must have at least 4 years of comparable experience. To qualify for Band B with no degree, you must have at least 5 years of comparable experience.

Desired Professional Experience:
Band A: Our ideal candidate will have:

- Ability to apply the principles, concepts, tools, and methodologies related to inspections, investigations, and analysis of federal laws, rules, and regulations.
- Working knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Broad knowledge of various scientific and technical disciplines necessary to carry out tasks related to the regulation of the medical device industry.
- 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.
- Skill in determining the approach to be taken and the methodology to be used for inspections and investigations.
- Demonstrated knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations; develop analyses that are used for presentations.

Band B: In addition to the skills/experience listed for Band A, the ideal candidate for Band B will also have the following skills and experience:

- Recognized for a high level of competence in the full range of medical device inspection types with expertise in conducting Current Good Manufacturing Practices (cGMP) utilizing the Quality System Inspection Technique (QSIT) for inspections and investigations such as manufacturers, specification developers, contract manufacturers, sterilizers, initial importers, and distributors.

- Skill in planning, conducting, leading highly technical, complex, and multi-faceted inspections and in-depth investigations related to the production, control, testing, inspection, servicing, and installation of medical device products, and skill in interview and investigation techniques.

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 25-50 percent of the time which will often require the Investigator 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. 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 U.S. 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: student loan repayment (for government employees only), creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

How to Apply

Applicants must submit (1) letter of interest that includes the state(s)/city(s) for which you are interested; (2) a detailed current résumé; (3) transcripts (with foreign credentials evaluation if applicable); (4) for federal employees only, redacted SF-50 (redact birth year and last for digits of SSN only).

Send the above documents to the ORA Executive Recruitment and Scientific Staffing Committee, ORAInvestigatorHiring@fda.hhs.gov.
IMPORTANT: The application must show this job reference ID in the subject line: **8-OMDRHO-MD Investigator-Location Reference Code(s).** *E.g., 8-Investigator-OMDRHO1, OMDRHO2*

Applications will be accepted through **July 22, 2024**. Candidate resumes may be shared with hiring official within the Office of Regulatory Affairs with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAInvestigatorHiring@fda.hhs.gov.

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FDA is an equal opportunity employer.