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)
Investigator II

Application Period: January 10, 2024 – July 10, 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

Series: AD-0696

Location(s): Multiple vacancies in the following locations: Birmingham, AL; Alameda, CA; Long Beach, CA; Los Angeles, CA; San Diego, CA; San Francisco, CA; San Jose, CA; Woodland Hills, CA; Lakewood, CO; Hartford, CT; Wilmington, DE; Boca Raton, FL; Jacksonville, FL; Maitland, FL; Miami, FL; Tampa, FL; College Park, GA; Bannockburn, IL; Chicago, IL; Indianapolis, IN; Boylston, MA; Winchester, MA; Detroit, MI; Minneapolis, MN; East Brunswick, NJ; Parsippany, NJ; Jamaica, NY; White Plains, NY; Brunswick, OH; Cincinnati, OH; Columbus, OH; Philadelphia, PA; Pittsburgh, PA; Providence, RI; Nashville, TN; Houston, TX; San Antonio, TX; Salt Lake City, UT; Falls Church, VA; Portsmouth, VA; Richmond, VA; Bothell, WA; Seattle, WA

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

Work Schedule: Full Time

Title 21 Band(s): Band A, Table 1

Full Performance Band Level: Band B

Travel Requirements: Up to 50% travel

Bargaining Unit: This is a bargaining unit position.

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 the 21st Century Cures Act can be found here: 21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animal, tobacco, 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 multibillion 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 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 Investigator II 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 Investigator II 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 II 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.
- Incumbent 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 Title 21 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 Title 21 appointments. The FDA OTS will use the basic requirements defined in the Title 21 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.

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/Experience Requirements: Candidate must meet the following requirements:

Education: The degree must be 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.

To qualify for Band A candidate must have:

- A bachelor's degree and (2) years of comparable experience; or
- A master's degree and (1) year of comparable experience; or
- A Ph.D. with no experience

To qualify for the Band B candidate must have:

- A bachelor's degree and (3) years of comparable experience; or
- A master's degree and (2) years of experience; or
- A Ph.D. and (1) year of experience

OR

Experience: To qualify for Band A without a bachelor's degree, candidate must have at least 4 years of comparable experience. To qualify for Band B without a bachelor's degree, candidate must have at least 5 years of comparable experience.

Comparable experience is defined as 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.

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 incumbent 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. The incumbent 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 to 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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request 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.

Applicants selected for this position will be subject to reasonable suspicion and post-accident drug testing upon hiring. To demonstrate commitment to the HHS goal of a drug-free workplace and to set an example for other Federal employees, employees not in a testing designated position may volunteer for unannounced random testing by notifying their Drug-free Federal Workplace Program Point of Contact upon hiring.

How to Apply

Applications will be accepted by all qualified applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position and preferred location(s), detailed current resume, and college transcript(s) (with foreign credentials evaluation, if applicable) to ORA Investigator Hiring at: ORAInvestigatorHiring@fda.hhs.gov. Applications will be accepted through **July 10, 2024**. Applicants must reference: **8-INV II-OBIMO-A-name of preferred location(s)** in the email subject line.

Announcement Contact

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

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer.