Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Pharmaceutical Quality Operations (OPQO)
Investigator II

Application Period: October 11, 2023 – April 11, 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): Telework Eligible

Location Reference Code (LRC)	Openings per LRC	Cities within Location
PHRM1	6	MA: Stoneham MD: Owings Mills NJ: Parsippany NY: Buffalo, Jamaica PA: Philadelphia, Pittsburgh
PHRM2	7	FL: Maitland, Miami GA: College Park NC: Raleigh-Durham PR: San Juan TN: Memphis, Nashville TX: Dallas, Houston
PHRM3	4	IL: Chicago IN: Indianapolis KY: Louisville MI: Detroit, Grand Rapids MN: Minneapolis MO: Maplewood OH: Cincinnati WI: Wauwatosa
PHRM4	8	CA: Alameda, Irvine, Long Beach, Ontario, Woodland Hills CO: Lakewood WA: Bothell

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

Work Schedule: Full Time

Title 21 Band(s): Band A

Full Performance Band Level: Band B

Travel Requirements: 25% to 50% travel

Bargaining Unit: This is a bargaining unit position.

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

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/fdaorganization/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 Pharmaceutical Quality Operations (OPQO) coordinates domestic and foreign inspectional, quality, and investigational activities across the field and at headquarters. In addition, OPQO works closely with the Center for Drug Evaluation & Research (CDER) and the Center for Veterinary Medicine (CVM) on compliance and enforcement activities and to implement policies related to the pharmaceutical program such as the Food & Drug Administration Safety & Innovation Act (FDASIA), Drug Quality & Safety Act (DQSA), Prescription Drug User Fee Act (PDUFA) and the Generic Drug User Fee Act (GDUFA).

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 OPQO program. Assignments involve conducting regulatory inspections and in-depth investigations of various industry establishments, such as manufacturers, re-packers, own label distributors, and importers. Investigations and inspections are necessary to ensure compliance with FDA laws, policies and regulations related to the pharmaceutical programs.

The Investigator II performs analyses and evaluation on data samples and documented information gathered during inspections and investigations to ensure that documentation and practices follow Federal laws, rules, and regulations.

Inspections, Investigations, Analysis, and Reporting:

- Investigator independently conducts objective surveys and emergency activities where precedents are lacking, and inspection program and guidelines are frequently outdated, too broad, or in some other way inadequate.
- Independently plans and conducts regulatory inspections and in-depth investigations of various industry establishments. Assignments are frequently complicated by a variety of diverse products, ingredients, and additives; highly specialized and sophisticated processes and equipment; products that are unstable; complex quality control systems, or uncooperative establishment management.
- 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.
- Assists the immediate supervisor or a team leader by planning inspections, investigations, sample collections, and related activities in assigned responsibility.
- Performs analyses and evaluation on data samples and documented information gathered during inspections and investigations to ensure that documentation and practices follow Federal laws, rules, and regulations.
- Documents and organizes required evidence, data, and other information to support violations noted during inspections, investigations, or sample collections.
- Serves as the compliance and enforcement officer with non-compliant industry establishments on previously noted violations. Enforcement methods include administrative/legal court actions and informational agency meetings.
- Serves as an instructor providing investigation and inspection training to lower graded trainees. Assist in training state and local government officials to ensure compliance with federal laws.
- Interacts with team members in generating scientific and technical data to draft correspondence and reports relevant to recent inspections/investigations.
- Interacts with and advises various levels of officials representing the establishments subject to regulatory review. 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.

- Prepares final reports, position papers and other written documentation that support investigative findings and recommendations.
- Advises supervisor on potentially controversial inspections and investigations that require additional monitoring or legal action.

Supervisory Responsibilities: This is a non-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 later.

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.

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.

Experience/Education Requirement: Candidates must meet the following:

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.

Position requirement:

- This position requires the incumbent to have a valid driver's license to drive a government or privately owned motor vehicle.
- Able to travel up to 50% to various manufacturing sites across the US and abroad which may require Investigator to be away from the duty station for up to two to three weeks at a time.
- Must meet physical demands of assignments conducting physical plant inspection. These assignments will require the climbing of staircases, working on wet floors, working in coolers, working in freezers, working in extreme heat, i.e., around retort cookers, and incidences when working with dangerous cleaning chemicals and unknown compounds.

Desired Education: Advanced Degree

Desired Experience:
BAND A: Our ideal candidate will have:

- 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

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:

- Skill in planning, conducting, and leading highly technical, complex, and multi-faceted inspections and in-depth investigations related to the production, control and testing of pharmaceutical products, and skill in interview and investigation techniques.
- Skills in analyzing and evaluation complex data samples and documented information gathered during inspections and investigations and utilizes novel approaches as needed to ensure compliance with federal laws, rules, and regulations.
- Ability to prepare final Establishment Inspection Report (EIR), investigations memoranda and proposed or final endorsements for inspections and investigations.
- Ability to evaluate and make recommendations on the state of compliance of a firm/individual involved in pharmaceutical, or other FDA regulated product manufacturing.

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 based on 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 may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 years.

Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 Policy.

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, SF-50 (redacted for SSN and birth year, for federal employees only), and college transcript(s) (with foreign credentials evaluation, if applicable) to ORA Investigator Hiring: ORAInvestigatorHiring@fda.hhs.gov. Applications will be accepted through April 11, 2024.

IMPORTANT: Applicants must show this job reference ID in the email subject line: **8-Inv II-OPQO-Location Reference Code(s).** E.g., 8-Inv II-OPQO-PHRM1, PHRM3.

Announcement Contact

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

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