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 Pharmaceutical Quality Operations (OPQO)
Division of Foreign Pharmaceutical Quality Inspections (DFPQI)
Foreign Pharmaceutical Quality Inspection Branch II (FPQIBI)
Senior Investigator III (Foreign)

Application Period: May 20 to June 24, 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: Senior Investigator III (Foreign)

Series: AD-0696

Location(s): Remote Eligible

Salary: $139,395 to $191,100

Work Schedule: Full Time

T21 Pay Table & Band: Pay Table 1**,** Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25-50% travel

Bargaining Unit: This is a bargaining unit position under National Treasury Employees Union (NTEU 3591).

Relocation Expenses Reimbursement: Will not be paid

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 (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 animals, tobacco and radiation emitting devices safe, and effective.

The mission of the Office of Regulatory Affairs (ORA) 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 Pharmaceutical Quality Operations (OPQO) is specialized to help protect and promote the safety and quality of human and animal products. This program, within the Office of Medical Products and Tobacco Operations (OMPTO) in the 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.

The Division of Foreign Pharmaceutical Quality Inspections (DFPQI) oversees the Foreign Drug Cadres. DFPQI serves as subject matter experts on foreign operations relative to the pharmaceutical quality program on internal cross-Agency committees, workgroups, and task forces. The Foreign Pharmaceutical Quality Inspections Branch (FPQIB) is responsible for inspecting and conducting remote regulatory assessments of foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collecting samples for analysis, performing field examinations, and preparing reports.

Duties/Responsibilities

The Senior Investigator III (Foreign) (SI-3F) serves as a foreign and national authority in inspectional and investigative techniques within multiple functional areas, with an intensive awareness of current and emerging technologies. The SI-3F provides guidance on FDA regulations and procedures to foreign competent authorities, foreign government inspectors/investigators and presents authoritative recommendations, assures consistent and coordinated policy development and implementation, ensures consistency, uniformity, and fairness in the application of law and regulation, and develops innovative ways of conducting business. The incumbent serves as a senior level investigator and is a field resource in conducting foreign inspections/investigations of the commodities regulated by the FDA. The SI-3F serves as an advisor for DFQPI and ORA management in the areas of assigned responsibility. The SI-3F is responsible for the following:

- Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations and prepares reports.
- Identifies and assesses complex investigation issues impacting on nation-wide, regional and district ORA procedures, policies, activities, and resources. In his/her assessments, the incumbent uses expertise in ORA's regulatory business processes and how those processes interact with processes of other FDA Centers and the Office of Chief Counsel.

Applies expertise on how management systems support those regulatory business processes.

- Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow up.
- Advises ORA and OPQO on emerging inspectional, scientific, and regulatory issues related to pharmaceutical products.
- Advises on difficult issues associated with policies, processes, and procedures for the conduct of inspections, investigations, sample collections, and/or sample analysis, methods development, and/ or regulatory case management.
- Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.
- Completes annually an assigned number of multifaceted foreign inspections globally, including complex and high or top priority assignments needing to be completed within very short timeframes and requiring a high level of expertise.
- Ensures written Establishment Inspectional Reports (EIR) and other work products comply with all established policies, and procedures, inter center agreement and work products required no or very minimal changes or revisions.
- Completed EIRs and other work products are submitted within timeframes specified within the organization standards.

Additional duties and responsibilities:

- Provides inspectional technical advice and assistance regarding emerging and novel technologies and advances in the state-of-the-art technologies and methodologies within the specialty area.
- Identifies the need for a policy draft, and provides technical advice, counsel, leadership, and comment in the drafting of ORA policies and practices impacting pharmaceutical facilities and any related compliance activities.
- Leads teams of specialists, investigators, analysts and/or Center personnel to accomplish highly complex projects and assignments.
- Defines and resolves major problems encountered and, as appropriate, either resolves these problems or develops and recommends alternatives as required, to meet the program objectives.
- Meets with hostile or uncooperative industry representatives to exchange information and to provide advice and guidance regarding those aspects of reviews/reports with emphasis on deficiencies.
- As a technical authority, the SI-3F provides on the job training for investigators, supervisors, center personnel and industry regarding technical and scientific matters, inspectional/investigational issues, policies, and laws.
- The SI-3F participates in the Office of Training, Education and Development by training cadres, and various work groups within ORA and the Centers.
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- The SI-3F may be called upon to represent the Agency at international conferences, meetings or workshops as a subject matter expert or participant in his/her area(s) of expertise.

Supervisory Responsibilities: This is not a supervisory position.

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 T21 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 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.

Education/Experience 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.

To qualify for the Band D candidate must have:

- A bachelor's degree and (5) years of comparable experience; or
- A master's degree and (4) years of experience; or
- A doctorate and/or J.D. and (2) year of experience

OR

Experience: To qualify for Band D without a bachelor's degree, you must have at least seven (7) 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.

Experience for Band D: Our ideal candidate will have:

- The incumbent is capable of leading teams of specialists, investigators, analysts and/or Center personnel to accomplish highly complex projects and assignments.
- The incumbent has the expertise to conduct inspections and investigations related to the most complex, controversial, and precedent setting scientific and regulatory problems involving foreign industry practices and products within the specialty areas.
- Expert knowledge of inspectional and investigative techniques with the regulation of the international industries within the functional program areas of expertise including evidence development, case preparation and report writing for a broad range of operational schemes, and the skill to recognize, apply and adapt the appropriate methods.

Position requirements:

- This position requires the SI-3F obtain and maintain the following current License and/or Certification: Valid U.S. driver's license.
- This position requires the incumbent to travel up to 50% or greater and it is expected that up to 100% of the incumbent's operational time is spent conducting inspections in the international arena.

Physical demands:

- The work requires some physical exertion, such as long periods of standing; walking over rough, uneven, or rocky surfaces; recurring bending, crouching, stooping, stretching, reaching, or similar activities; or recurring lifting of moderately heavy items, such as typewriters and record boxes. The work may require specific, but common, physical characteristics and abilities, such as above average agility and dexterity. This position requires: working long, and possibly unscheduled hours; exposure to all kinds and extremes of weather and noise; ability to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel and climb; ability to maintain the vision, hearing, and olfactory requirements necessary to perform inspectional work.

Work environment:

- Professional work is primarily conducted in the international arena and conducted in offices and office areas, or manufacturing locations where there may be occasional exposure to unsafe practices or conditions associated with operations that require normal safety precautions.

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: Recognition of Foreign Qualifications | International Affairs Office (ed.gov).

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 Policy

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 Policy

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

- 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.

- 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

Applications will be accepted from all qualified U.S citizens. Applicants must submit the following documents: 1) a letter of interest, 2) a detailed current résumé, 3) college transcripts (with foreign credentials evaluation if applicable).

IMPORTANT: You must use the following job ID in the email subject line: **3-SI-3F-DFPQI-D.**

Send the above-mentioned documents to the ORA Executive Recruitment Team at: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through **June 24, 2024.**

NOTE: It is your responsibility to ensure the job ID is noted in the subject line and the appropriate documentation is submitted prior to the closing date for your application to be considered.

Announcement Contact

For questions regarding this T21 position, please contact ORAExecutiveandScientificRecruitment@fda.hhs.gov and include the following job reference ID in the subject line: **3-SI-3F-DFPQI-Q**.

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

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