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
Office of Pharmaceutical Quality Operations
Division of Foreign Pharmaceutical Quality Inspections

Application Period: December 4 to December 22, 2023

Area of Consideration: Open to all qualified United States Citizens. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Investigator

Series: AD-0696

Location: Any U.S. FDA Location

Salary: Starting at $132,368

Work Schedule: Full Time

T21 Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25%

Bargaining Unit: This is a bargaining unit position.

Relocation Expenses Reimbursement: 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.

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 pharmaceutical 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 and OPQO's foreign inspection activities. DFPQI serves as subject matter experts on foreign operations relative to the pharmaceutical quality program on internal cross-Agency committees, workgroups, and task forces. DFPQI manages and evaluates resources to assure pharmaceutical program accomplishments, including foreign pharmaceutical program activities. DFPQI provides management support for foreign pharmaceutical program and operational activities, including all phases of personnel management, financial management, property, and supplies, as well as serves as operational liaison for pharmaceutical products foreign inspection programs to FDA's foreign and other offices.

Duties/Responsibilities

The Investigator 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 Investigator serves as team lead in DFPQI and provides guidance on FDA regulations and procedures to foreign authorities, FDA and foreign government inspectors/ investigators and presents the most 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 Investigator is responsible for the following:

- Reviews, evaluates, and classifies investigative reports and recommending the full range of regulatory actions in accordance with Agency policies and the Federal Food, Drug and Cosmetic Act.
- The cases handled may involve complicating factors including the following: (1) a wide range of issues; (2) unclear sections of that law; (3) lack of definitive court precedent.
- Reviews foreign human and animal medical product (i.e., pharmaceutical) inspectional and investigative reports for conformance to the Agency's policies and management expectations and determines the final investigations branch classification and recommends the final Agency classification.
- Evaluates the adequacy of evidence documented in medical product (i.e., pharmaceutical) inspectional and investigative reports and other pertinent records relative to applicable laws, regulations, policies, procedures, programs, and instructions, established precedents, and current science.
- Tracks recommended regulatory actions to monitor timely follow-up or to determine if additional information should be provided to support the recommended action.
- Provides constructive feedback on foreign human and animal medical products (i.e., pharmaceutical) inspectional and investigative reports.
- Recommends regulatory action and/or compliance follow-up when appropriate.
- Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations and prepares reports.

Additional duties and responsibilities: Utilizes Agency enterprise software and databases, for example, ORA's Quality Management System (QMS), eNSpect, Firm Management Services (FMS), Compliance Management System (CMS), ORADSS, FACTS, and docuBridge in his/her day-to-day duties.

- Updates data in Agency enterprise software and databases directly or makes recommendations to have data updated.
- Collaborates and engages with representatives from within ORA, and across Centers and other intra-Agency organizations to develop innovative, investigative and compliance strategies for reducing risk to the public health resulting from or potentially resulting from regulated industry practices, processes, products, and emerging problems.
- Participates in the development of formal and informal Agency training programs and conferences concerning compliance activities, policy, programs, procedures, and instructions.
- Consults with appropriate units within OPQO and ORA, the Office of Global Policy and Strategy (OGPS), the Center for Drug Evaluation and Research (CDER) and Center for Veterinary Medicine (CVM) and other Agency units to provide consistent, accurate and timely responses to inquiries from internal and external parties.

- Provides timely, complete, and accurate responses to inquiries from internal and external parties, for example, the FDA's Ombudsman's Office and Government Accountability Office.
- May assist Investigators on various matters (e.g., technical, logistical) during the conduct of foreign human and/or animal medical product (i.e., drug program) inspections; this may involve prompt follow-up within the ORA or the relevant program Center in a timely manner during a foreign inspection.
- May assist with foreign pharmaceutical inspection activities, including workplanning and communications within the Agency and with other competent authorities.

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 Title 21 qualifications 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 or Experience Requirement
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 D with no degree, you must have at least 7 years of comparable experience.

Position requirements:
- This position requires the incumbent to have a current U.S. Driver's License to drive government vehicles.
- The Investigator conducts at least 1 foreign trip annually directly assigned to him/her to inspect facilities that manufacture medical products (i.e., pharmaceuticals); the assignments are typically complex in nature and of high or top priority needing to be completed within very short timeframes and requiring a high level of expertise.
- This position requires up to 25% travel.
- This position may require additional travel to participate in Agency or external trainings and/or conferences.

Desired Professional Experience:
- 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.
- Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques. The incumbent must be an expert in terms of

inspectional/investigative procedures and developing evidence when situations are encountered that may result in regulatory action.
- 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.

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: 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.

How to Apply

Applications will be accepted from all qualified U.S citizens. Applicants must submit the following: 1) a letter of interest (in pdf format), 2) a detailed current résumé, 3) college transcripts (with foreign credentials evaluation if applicable) 4) for current federal employees only, a current SF-50 with year of birth and last four digits of social security number redacted.

IMPORTANT: You must use the following job ID in the email subject line: **3-IFCTL-OPQO-D.** Send the above-mentioned documents to the ORA Executive Recruitment Team at: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through ***December 22, 2023***

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-IFCTL-Q**.

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

FDA is an equal opportunity employer.