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)
Foreign Cadre Director

Application Period: May 8, 2023 to May 19, 2023

Area of Consideration: Open to current FDA employees only. 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: Foreign Cadre Director

Series: AD-0696

Location(s): ORA district offices in Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Francisco, San Juan, Seattle

Salary: Starting at $132,368

Work Schedule: Full Time

Title 21 Band(s): Band D, Pay Table 1

Full Performance Band Level: Band D

Travel Requirements: 25%

Bargaining Unit: This is a non-bargaining unit position

Incentives: 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 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 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/office-regulatory-affairs/ora-vision-mission-and-values.

The Office of Bioresearch Monitoring Operations (OBIMO) is responsible for onsite inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA regulated research. OBIMO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders relative to BIMO field operations including emergency response activities. The BIMO Program includes Postmarketing Adverse Drug Experience (PADE) and Risk Evaluation and Mitigation Strategies (REMS) inspections.

The OBIMO Foreign Cadre is comprised of FDA investigators (Consumer Safety Officers) who travel internationally for the purpose of contributing to OBIMO's mission of protecting human subjects and verifying the accuracy of safety and efficacy data submitted to the Agency. Given the breadth and variety of this work, it is important to have a dedicated group of skilled people who are ready and willing to go whenever and wherever there is a need.

Duties/Responsibilities

The Foreign Cadre Director (FCD) is responsible for supervising a dedicated cadre of investigators who conduct foreign inspections of bioresearch monitoring establishments for which FDA has regulatory responsibility. Bioresearch monitoring establishments sponsor and/or conduct clinical and nonclinical research on FDA-regulated products including new human and animal drugs, devices, and biological products. The FCD works with all six commodity centers to develop bioresearch monitoring foreign inspection work plan, receive and review foreign inspection assignments and assign equitably to dedicated cadre, India office, and volunteer pool of field division investigators. Annual work plan of foreign bioresearch

monitoring inspections is approximately 350 inspections per year. The FCD will also advise ORA, OBIMO, and centers on emerging inspectional, scientific, and regulatory issues related to FDA regulated products and provide counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

- This position is assigned first level supervisory responsibilities over a staff of employees ranging in grade from a GS-11 to GS-13, at least 90% of whom are Consumer Safety Officers performing foreign bioresearch monitoring inspections.
- Responsible for developing and implementing policies and procedures needed to carry out functional responsibilities.
- Responsible for reviewing work products and ensuring that inspectional or investigational assignments assigned to the bioresearch monitoring program are carried out within established time frames.
- Evaluate field investigational and inspectional capabilities.
- Evaluate regulated firm correspondence associated with inspectional findings.
- Provides technical direction related to conducting bioresearch monitoring inspections related to human and animal drugs, medical devices, and biological products.
- Identifies development and training needs of employees and arranges for needed development and training.
- Evaluates results of inspections against applicable compliance program, regulation, and law to recommend substantive actions or changes as appropriate when there are deficiencies.
- Identifies and resolves investigational problems having national and international significance.
- Provides advice and consultation during meetings within the agency as well as with regulated firms.
- Provides oversight and participates in meetings to handle major investigational assignments having national and international impact.
- The furthering of the organization's equal opportunity goals is a requirement of this position. The incumbent is responsible for applying equal opportunity principles in all individual, team, and workplace activities.

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.
- Males born after December 31, 1959 must be registered with the Selective Service.

- One-year supervisory 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 OPM 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.

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. For more information please see: OPM Occupational Series Qualification Requirements.

Consumer Safety Series, 0696: A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work. The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming. OR: Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Position requirement:

- This position requires the incumbent to have a current Driver's License.
- Able to travel up to 25% to various bioresearch sites across the US and abroad.
- While most work is performed in an adequately lighted and climate-controlled office, onsite 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.
- This position may require the incumbent to successfully obtain and maintain a secret security clearance.

Professional Experience:

- Thorough knowledge of, as well as the intent of, enabling legislation, policies, implementing regulations and procedures, organizational structures, and interrelationships of inspectional/investigative and compliance organizations and programs with each other in relation to area of responsibility.
- 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.
- Knowledge of written and verbal communication practices and principles and skill in preparing and presenting written reports, findings, etc.
- Ability to provide training on inspectional technique of the most complex bioresearch monitoring inspections.
- Skill in developing a team dynamic and fostering open communications across the team to support accomplishment of assigned duties.

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 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.

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.

How to Apply

Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, and SF-50 (social security number and date of birth ***must*** be redacted) to the ORA Executive Recruitment and Scientific Staffing Committee at: ORAExecutiveandScientificRecruitment@fda.hhs.gov and must include position title Foreign Cadre Director in the subject line. Applications will be accepted through May 19, 2023.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAExecutiveandScientificRecruitment@fda.hhs.gov and must include position title Foreign Cadre Direct in the subject line.

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

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