Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
U.S. Food and Drug Administration (FDA)
Office of the Commissioner
Office of Policy, Legislation and International Affairs
Office of Global Policy and Strategy
Office of Global Operations
Europe Office

Application Period: August 11, 2022 – September 01, 2022

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: Director, Europe Office

Series: 0685

Location(s): Brussels, Belgium

Salary: Starting at $168,914

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25%

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency 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 Global Policy and Strategy (OGPS) is to protect and promote the public health of Americans by effectively advancing FDA's public health mission globally. OGPS

performs foreign inspections, and provides executive oversight, strategic leadership, and policy direction on FDA's global engagements including information sharing, international standards development, trade relations, and collaboration activities with partner regulatory authorities or multilateral institutions.

Duties/Responsibilities

- Serves as an agency technical expert in working with senior, policy-level officials and technical specialist at other U.S. regulatory agencies, such as the U.S. Department of Agriculture, and others; which work in areas that impact FDA.
- Works closely with other U.S. agencies including the department of State, the U.S. Trade Representative toward the conception, development and implementation of agreements with foreign countries.
- Represents FDA senior leadership at meetings with international regulatory authorities or other governmental officials, foreign manufacturers, professionals, and collaborating associations involved with regulating, reviewing, evaluating, or developing FDA regulated products.
- Participating fully with the Associate Commissioner for Global Policy and Strategy and the Director of OGO, directs the implementation of new FDA policies, scientific and regulatory programs and activities that impact the mission of the office.
- Stays abreast of new developments in the area of responsibility within the host country or region; monitors and tracks new legislation, guidelines or policy initiatives; procures copies of supplementary legislation, new documents and other materials, and prepares appropriate reports to inform decision making at FDA headquarters.

Supervisory Responsibilities: Supervises the collection, analysis, trending, and dissemination of information surrounding the socioeconomic, geographic, regulatory, and political landscape of countries and regions, distills and reports crucial developments and emerging trends to senior FDA stakeholders to facilitate decision-making related to FDA regulatory activities and enable riskinformed utilization of Agency resources.

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 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. This position requires a Top Secret Clearance.
- This position is temporary and does not provide permanent placement upon completion or termination of the overseas assignment.
- Selectees for temporary/term assignments may begin and remain stateside until all required clearances and trainings (security, medical and applicable trainings) are completed before being deployed to an overseas location.
- A Statement of Understanding is required to be signed by the selected candidate indicating they understand the terms and conditions of this temporary appointment.
- For FDA employees under CURES appointment, the Center/Office has the responsibility of determining a "comparable" position for the employee upon return, if the position of record is backfilled during deployment. If there is no comparable CURES position, it is likely that the employee will not be able to return to a CURES appointment and will be returned under Title 5 at the appropriate grade, step and pay, if there is a comparable position under Title 5.

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 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 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: There is no basic education requirement for this grade/level.

Desired Education: Competitive candidates will have earned an advanced scientific, management, or social science degree.

Professional Experience: Must have one year of specialized experience planning and managing foreign regulatory review operations; Evaluating and analyzing complex public health programs and policies; Advising management on policies, operations, products, and services to improve global public health program and initiatives.

Desired Professional Experience:

- Priority will be placed on candidates with relevant, recent management experiences in driving continual improvement and change management.
- Strong knowledge of FDA policies, procedures, and statutory authorities as well as an understanding of how medical products are regulated by foreign counterparts.
- Demonstrate a deep understanding of global health policy, diplomatic and foreign affairs, and demonstrate an ability to work with the Department of State on the management and administration of offices within U.S. Embassies.

NOTE: Current permanent civilian FDA employees selected for temporary overseas assignments will be given a return assignment to their permanent position, title, series and grade (or a comparable one within the commuting distance, i.e., 50-mile radius), once the appointment is completed. All other candidates, including current permanent Federal civilian employees, DO NOT have return rights to a position within FDA. "This position will be located Brussels, Belgium. The temporary assignments not-to-exceed 2 years, but may be extended up to a total of 6 years. Eligible FDA employees will have statutory return rights to their permanent FDA position series and grade once the foreign assignment is completed.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Top Secret Clearance

This position requires a *Top Secret* security clearance and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of *critical sensitive, top secret* information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request

information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

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

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.

How to Apply

How to Apply: Submit resume or curriculum vitae with cover letter by September 01, 2022 to: Jessica.Lacey@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Office of Global Policy and Strategy with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact Jessica Lacey, 301-796-7462. Please reference Job Reference ID: 22-001T21OGPS

Announcement Contact

For questions regarding this Cures position, please contact Jessica Lacey, 301-796-7462, Jessica.Lacey@fda.hhs.gov.

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