Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of the Center Director (OCD)
Counterterrorism and Emergency Coordination Staff (CTECS)

Application Period: November 27, 2023 – December 15, 2023

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: Staff Director

Series: AD-0601

Location(s): Silver Spring, MD

Salary: $155,700 – $219,523

Work Schedule: Full Time (Telework Eligible)

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

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) 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 Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter and prescription drugs,

including biological therapeutics and generic drugs.

The Office of the Center Director (OCD) provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. The Counterterrorism and Emergency Coordination Staff coordinate Center activities related to emergency situations involving CDER-regulated products or facilities and provide consultation on the development and availability of safe, effective, and quality medical countermeasures (MCMs) for chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases.

Duties/Responsibilities

As Director **of the Counterterrorism and Emergency Coordination Staff**, the incumbent serves as a recognized authority within the Center, responsible for the oversight and representation of varied scientific and regulatory matters. Participates fully in planning, managing, organizing, and directing all the operations, program segments, functions, and activities of CTECS including the formulation and establishment of policies and goals, determination of organizational staff, and budget requirements, preparation of the budget, and allocation of resources necessary to accomplish the mission of CTECS. Serves as the subject matter expert for briefing Congress, White House, press, professional organizations, patient groups, and other stakeholders.

- Provides direction, coordination, and leadership to staff responsible for critical missions such as: facilitating the development of medical countermeasures (MCMs) for chemical, biological, radiological or nuclear (CBRN) threat agents and emerging infectious diseases; working with strategic stockpiles – the Strategic National Stockpile (SNS) under the Assistant Secretary for Preparedness and Response (ASPR) and states - for the availability of MCMs; and coordinating public health responses for emergencies related to CDER-regulated products and facilities.
- Serves as personal scientific advisor and consultant to the Deputy Center Director for Regulatory Programs, and higher-level agency officials on functions, programs and problems of functional areas covered by the Office.
- Establishes and coordinates MCM policy and program objectives to staff, within overall program objectives of the Center, the Agency, the Department, and other governmental agencies. Provides consultation on Center's use of emergency authorities, including Emergency Use Authorization.
- Maintains a Top Secret (TS) national security clearance to allow for discussions with TS level colleagues in FDA, HHS, DoD, and other federal agencies on CDER regulated products as well as MCMs and CBRN threats
- Directs, through subordinate staff, the Animal Model Qualification Program, a Drug Development Tool identified in the 21st Century Cures Act, used to support, obtain approval or licensure under the Animal Rule for a drug or therapeutic biologic by any sponsor.
- Plans and develops overall activities, policies, and procedures involving interpretation and adaptation of the CDER Incident Management Plan, which provides a framework for the Center to prepare for, prevent, respond to and assist the agency and country in

recovering from domestic events.

- Notifies the Principal Deputy Center Director, Deputy Center Director and Center Director when issues with CDER-regulated products and/or facilities occur and need coordination at the CTECS level. Such issues include emergencies related to the safety of a CDER-regulated product like natural disasters that impact CDER regulated firms which could lead to shortages.
- Participates in or delegates other staff to participate in FDA Incident Management Groups that are formed to coordinate and manage public health emergencies that involve CDER-regulated drug/biologic product issues.
- Represents the Center and FDA on committees and at professional meetings, both national and international, making commitments, suggestions, and recommendations concerning programs, policies, and evaluation of activities within his or her areas of responsibility. Helps prepare testimony to Congress and other outside bodies.
- Directs and oversees staff providing assistance to scientific researchers and drug sponsors early in MCM drug development to prepare for formal regulatory meetings with CDER's review divisions
- Oversees the coordination of the individual Office COOP plans within CDER. Follows the lead of the FDA COOP Coordinator for program changes and updates at the agency level.
- Serves as a Facility Manager in collaboration with the Office of Management with responsibility for the on-site suitability of buildings, occupants, and equipment in the event of a public health emergency, natural disaster, or crisis. Assists in identifying and eliminating un-safe conditions. Responsible for applying quality control systems and quality assurance methods to determine risks and compliance standards for work and implements associated risk mitigation actions.

Supervisory Responsibilities:
Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate supervisor, team leads and staff that perform the work and functions of the organizational unit.

Ensures the programs goals, objectives, work plans, and products are in accordance with the organization's strategic plan, mission, vision, and values. Obtains resources, identifies strategic objectives, and establishes goals for the program.

Establishes priorities and administers Counterterrorism and Emergency Coordination operations. This includes rendering guidance on policy and administrative matters and taking responsibility for the productivity and quality of work products within the staff.

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.

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.

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:
General Medical and Healthcare Series, AD-0601

Desired Education:
Our ideal candidate should possess:

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained

Professional Experience:

Our ideal candidate will possess:

- Proven ability in providing effective leadership and promoting maximum potential of a large organization with a multicultural workforce.
- Demonstrated previous senior leadership experience, strong interpersonal skills, and sound judgement.
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or import activities.
- Expert knowledge of agency-wide occupational safety and health program policies and procedures that address the wide range of hazardous and high-risk activities within the FDA.
- Expert knowledge necessary to develop and implement practices/procedures or engineering controls to minimize or eliminate safety hazards, and potentially hazardous risks.
- Ability to function within a regulatory environment and problem solve to meet challenging demands.
- Ability to establish an organizational vision and to implement it in a continuously changing environment.

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: Top Secret Level

The incumbent has access to documents and facilities. 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. Applicants are also advised that all

information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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

Submit resume or curriculum vitae with cover letter by **December 15, 2023,** to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact Crystal Coulter, Management Analyst, Crystal.Coulter@fda.hhs.gov.

Please reference Job ID: 'OCD CTECS Director' in email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Crystal Coulter, Management Analyst, Crystal.Coulter@fda.hhs.gov

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

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