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 Executive Programs (OEP)
Immediate Office (IO)

Application Period: October 7, 2024- October 28, 2024

Area of Consideration: Open government-wide. You must be a current or former federal employee to apply.

Position: Deputy Office Director

Series: AD-0301

Location(s): Silver Spring, MD

Salary: $176,300

Work Schedule: Full Time Full-time (Telework eligible)

Cures Band(s): Band F

Full Performance Band Level: Band F

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 and prescription drugs, including biological therapeutics and generic drugs.

The Office of Executive Programs (OEP) coordinates the operations of the Office of the Center Director, ensuring that the goals and priorities of the Center Director are carried out.

Duties/Responsibilities

As **Deputy Office Director,** the incumbent shares fully in the duties and responsibilities of the Director, OEP. Incumbent provides technical advice and assistance concerning policy and administrative matters pertaining to the quality, safety, and effectiveness of drug products for human use; performs special studies; and coordinates activities of advisory committees.

- Serves as the OEP Director's personal representative and spokesperson to various individuals and groups that interact with the Center. Represents the Director and Center's senior leadership on task forces and committees mandated by Congress, HHS, FDA, and the Center on drug review and regulatory issues. Exercises the authority to make commitments on behalf of the OEP Director, Deputy Center Directors, and Center Director.

- Supports the implementation coordination of major center-wide programs and new legislation, including steering committees for user fee program implementation and other public health initiatives.

- Assists the OEP Director in providing coordination for all executive operations and support for the Center Director, including Executive Secretariat function of the Center.

- Provides leadership to ensure that the goals and priorities of the Center Director are carried out, and provides advice and guidance on regulatory, technical and policy matters as well as management of CDER programs, which includes CDER's leadership and organizational development program.

- Provides leadership to OEP's multidisciplinary workforce, including executive support for the Center Director and deputy center directors, in ensuring OEP Director and Center Director priorities are carried out. Ensures continuous organizational improvement and enhances the Center's processes for identifying future leaders and managers and strengthening skills for staff already in leadership or management roles.

- Assists OEP Director in providing oversight of the Advisory Committee function of the Center, managing the use of scientific advisors, consultants and committees; developing and implementing policies and procedures for the use of these resources by CDER. Includes the oversight and adjudication of complex conflict of interest cases. Assists the OEP Director in providing oversight to the Special Project Staff and Legislative Affairs Staff, in support of Center-wide cross cutting initiatives.

- Assists the OEP Director with the coordination of Ombudsman and formal dispute resolution activities for the Center, including disputes and complaints between regulated industry and CDER, as well as managing formal and informal dispute resolution within CDER, responding to consumer and industry inquiries and investigating complaints, receiving and assessing feedback on CDER programs and advising CDER Director about problems and proposed solutions.

Supervisory Responsibilities: Assists in managing a multi-disciplinary program, providing leadership and management oversight to 140+ subordinate support staff and division directors. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate supervisors and staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives of the organization. Hears and resolves complaints from subordinate staff, referring group grievances and more serious unresolved complaints to a higher-level supervisory authority. Provides employees with resources and information that ensure a safe and healthy work environment. Recommends employee promotions and recognition. Approves leave, within-grade increases, extensive overtime, and/or employee travel. Implements performance modifications and takes corrective actions as appropriate.

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.

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:
Miscellaneous Administration and Program, AD-0301 Series: There is no minimum educational requirement for this series. For more information, please see: **OPM Occupational Series Qualification Requirements.**

Desired Professional Experience:
Our ideal candidate will possess:

- Superb communications skills, including written and verbal communication.
- Ability to produce high-quality results by analyzing problems, calculating risks, and applying technical knowledge.
- Build coalitions internally and with other federal agencies, state and local governments, nonprofit and private sector organizations, foreign governments, and/or international organizations to achieve common goals.
- Ability to interface regularly with Executives and leadership within FDA and Industry.
- Ability to navigate organizational complexities in a regulatory environment with diverse stakeholders.
- Experience and or knowledge of drug development/regulatory science.
- Ability to identify and analyze problems, weigh relevance and accuracy of information, generate and evaluate alternative solutions, and make recommendations.
- Ability to communicate and work with staff at all levels of the office or organization, represent the office in a variety of settings, and communicate policy positions in a timely manner.
- Ability to identify the internal and external politics that may impact the work of an organization.
- Ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Ability to align and link administrative strategic plans and objectives to mission's plans.

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: Non-Sensitive- High Risk
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 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

Submit resume or curriculum vitae with cover letter by **18 Oct 2024**, 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”.

Announcement Contact

For questions, please contact CDER-OCD-OEP-Hires@fda.hhs.gov.
Please reference Job ID: **OEP Deputy Office Director** in the email subject line.

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