Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)

Application Period: August 19, 2024 – September 19, 2024

Area of Consideration: All Sources. 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: Deputy Super Office Director for Operations

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $213,491

Work Schedule: Full-Time

Cures Band(s): Band G

Full Performance Band Level: Band G

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 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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a super office within the Center for Drug Evaluation and Research responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

Duties/Responsibilities

As a **Deputy Super Office Director for Operations**, the incumbent will oversee offices within OND that manage the regulatory, business process, and administrative operations, providing leadership and supervision on developing and implementing relevant processes and procedures, and assuring that key challenges that arise—related to staffing or regulatory or administrative operations are fully and efficiently addressed. The role is responsible for evaluating the effectiveness of the various regulatory, business process, and administrative programs in OND and assuring that they are meeting established goals and objectives. Also, manages staff in the OND offices that focus on regulatory program operations, business processes, and administrative work. This individual must assure that these organizations are properly staffed, and that the staff are properly trained and are working efficiently and effectively to meet their goals and objectives. OND is looking for a leader with a commitment to scientific excellence and innovative thinking to help lead a dynamic and diverse organization. The incumbent works closely with the Office of New Drugs Super Office Director and other OND Super Office Deputy Directors to formulate policies, set and implement operational strategies and priorities, and provide executive level leadership and direction in the execution of the organization's regulatory, business process, and administrative operations.

Business Operations

- Provides oversight and supervision of financial systems and budgets, working with these staffs to assure financial reporting, appropriate budget setting, and budget modifications required by CDER and FDA. Works to optimize OND's use of allocated budget
- Assures that business processes and regulatory operations are conducted in an efficient manner, with consistent processes across the organization. Works to identify relevant differences in regulatory, business, or administrative functions and then to modify them towards assuring appropriate consistency.
- Supports the resiliency of the OND organization by assuring that staff in a particular discipline are appropriately trained so that they can provide support across the organization for that discipline.
- Provides direction and supervision to assure that key OND review, and scientific functions are provided optimal administrative support
- Provides direction and supervision to assure that business processes are optimized and smoothly implemented to support OND's regulatory operations

Strategic Planning:

- Works collaboratively with the Office Director and other OND leaders to formulate and set the Office's strategic directions.
- Leads Office coordination and requirements gathering efforts among organizational units in the formative stages of program initiation, project design, project implementation, and management of ongoing program.
- Ensures strategic plans and performance metrics align with the regulatory programs and plans appropriately.
- Considers the complex nature of the Office's regulatory portfolio in meeting established goals and objectives across CDER and FDA Offices.

Program Effectiveness and Oversight

- Provides executive level leadership and direction for evaluating the effectiveness of regulatory and program operations in meeting established goals and objectives.
- Collaborates with other CDER functions and OND business process staff in supervising the capture, reporting, and analysis of statistical data relating to the organization's operations and directs studies or projects, as appropriate
- Provides oversight and supervision for the organization reporting to this individual to ensure Office-wide performance metrics are achieved in support important Office, Center, and Agency priorities.
- Directs the execution of programs and processes that enhance review management practices and principles.
- Provides direction and leadership for updating, as needed, and implementing programs and processes necessary for the operational and regulatory management of IND, NDA, and BLA programs within OND.
- Provides direction and leadership for updating, as needed, and implementing programs and processes, including the updating and implementation of IT programs, to support regulatory review activities.

Quality Management

- Directs and oversees the organizations quality management program, system, and initiatives in accordance with FDA's quality standards and expectations; ensures Agency contract requirements are maintained and modified as needed.
- Oversees efforts for ensuring robust, efficient, and effective quality systems related to the Office's regulatory and program operations through effective leadership.
- Supports and enables a culture that strengthens continuous improvements. Acts as a champion and change agent for leading and managing continuous improvement processes while promoting a culture of accountability.

Supervisory Responsibilities: Supervises and evaluates staff who serve as experts in their field. 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 for the

organization.

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:

General Medical and Healthcare, AD-0601 Series:

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

Desired Education and Professional Experience:
Our ideal candidate will possess:

Graduate/higher level degree: degrees in Pharmacy (e.g., Pharm.D), in public health (e.g., MPH), or in a related medical or biological field (e.g., a master's degree or Ph.D. in biological or medical sciences), or in organizational management (e.g., an MBA degree along with a bachelor's degree, as described below).

Individuals with a bachelor's degree with major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position are also eligible with at least 10 years of experience in organizational leadership and management in a health care organization.

Degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the at the time the degree was obtained.

Desired Skills:
Our ideal candidate will possess:

- Executive leadership experience with an established track record in leading organizations of significant size and complexity.
- Effective communicator who can drive collaboration, empower staff, and is committed to the Public Health mission.
- Demonstrate the ability and experience coordinating complex work and priorities and building coalitions
  with partners in other organizations.
- Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program
  activities, and spearhead important program initiatives.
- Knowledge of leadership and organizational management principles and of operational management.
- Detailed understanding of drug development and a detailed understanding of US drug regulation.
- Ability to manage and lead a diverse interdisciplinary staff.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High Risk

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 the 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 **September 19, 2024,** to: CDER-OND-Leadership-Employment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference Job Reference ID: **OND-DSOD-001** in the subject line of the email.

Announcement Contact

For questions regarding this Title 21 position, please contact CDER-OND-Leadership-Employment@fda.hhs.gov.

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