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)
Immediate Office (IO)

Application Period: July 17, 2024- August 16, 2024

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: Associate Director for Rare Disease Strategy

Series: AD-0301/0602

Location(s): Silver Spring, MD

Salary: Starting at:
$213,491 (AD-0301)
$235,000 (AD-0602)

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) 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.

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 the Center Director (OCD) Immediate Office (IO) provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

Duties/Responsibilities

As the **Associate Director (AD) of Rare Disease Strategy,** the incumbent will serve as the director of strategic coalitions for the new joint integrated model between CDER and CBER, whereby a new "hub" will be developed to enable and accelerate development of potentially useful treatments across different modalities, including drugs, cell, gene therapies, and other biologics. The hub will enhance and build on existing cross-center collaborations to support FDA's new paradigm to assure closely integrated and enhanced internal collaboration and external communication and understanding with respect to rare disease product development. The Associate Director of Rare Disease Strategy will report to the CDER Center Director, work directly with both the CDER Center Director and CBER Center Director, and will serve as a cross-cutting role across both Centers to facilitate development and implementation of the integrated model.

- Oversees this new integrated model between CDER/CBER and focused on enhancing shared knowledge and skills between centers and improved integration of efforts and approaches. Particularly when programs in each center are addressing the same or similar rare diseases, and shared outreach can be leveraged to maximize commitment and resources of stakeholder groups; especially patient, family, and disease-focused scientific organizations.

- Responsible for developing and implementing a rare disease strategic agenda action plan that will be organized around the need for more effective engagement with the rare disease communities and that meets the needs of both external and internal stakeholders. In developing such a plan, they will work closely with the CBER and CDER Center Directors, leadership of the CDER Accelerating Rare disease Cures (ARC) program, and comparable CBER programs initiatives to assure appropriate integration and alignment across each Center.

- Coordinates and facilitate engagement with stakeholders and to assure that learnings from these external engagements are considered in programmatic and policy decisions.

- Serves as the single point of connection and engagement with stakeholder organizations on behalf of the Hub , including patient and caregiver groups, trade organizations, and scientific/academic organizations, on cross-cutting rare disease-related issues working with staff in CBER and CDER who collaborate together.

- Identifies the key needs of stakeholder groups and work to meet these needs, such as sharing perspectives with FDA , hearing from with FDA scientific experts and gaining a greater understanding of FDA approaches and policies,.

- Develops approaches to arranging appropriate FDA staff involvement or appropriate settings for further stakeholder engagement.

- Coordinates with ongoing scientific, regulatory policy and communication efforts at the CDER and CBER level, assuring close partnership with the relevant program within CDER/CBER, and where appropriate, within the Center for Devices and Radiological Health, Oncology Center of Excellence, and the Office of the Commissioner. With multiple different centers and offices across FDA involved in rare disease policy, outreach, programs, and research, a key role of this position is to assure that communication and outreach to and from the Hub is fully aligned and integrated with communication and outreach efforts across FDA.

Supervisory Responsibilities: **N/A**

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:

Education: A law degree, specifically a LL.M. or J.D. The degree must be from an accredited programor institution.

OR

Experience: Comparable regulatory experience focused on interpreting laws, rules, regulations, or policies; or develop or analyze regulations and policies for regulated products.

Physician, AD-0602 Series:

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct

service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and

fellowship programs that are approved by accrediting bodies recognized within the United States or Canada.

Desired Professional Experience:

- Superb communications skills, including written and verbal communication.
- Detailed understanding and knowledge of FDA's regulatory framework and scientific initiatives to be able to represent the agency on the national and international stage

regarding rare disease drug and biologic development initiatives; prior FDA experience will be preferred.

- Sufficient background in medical product development, especially those for rare diseases, to understand key approaches, current limitations, and ongoing efforts across scientific and stakeholder organizations to address these gaps.
- Ability to identify, articulate, address, and resolve unique, far-reaching and/or previously unresolved and precedent-setting problems and complex issues.
- Demonstrated ability to bring together different individual staff and organizational units to work collaboratively to develop solutions for critical problems.
- Demonstrated ability to develop and implement a strategic agenda.
- At least 2 or more years of prior experience in rare disease product development working with rare disease communities and stakeholder groups.

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 **August 16, 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: **Associate Director for Rare Disease Strategy** in the email subject line.

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