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 New Drugs (OND)
Office of Drug Evaluation Science (ODES)

Application Period: July 24, 2023 - August 4, 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: Deputy Office Director

Series: AD-0602

Location(s): Silver Spring, Maryland

Salary: Starting at $165,000

Work Schedule: Full Time

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 over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

Office of New Drugs (OND) develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process. OND also reviews Investigational New Drug (IND) applications for all classes of drug and therapeutic products for human use with the exception of generic drug applications and recommends appropriate action with respect to safety and effectiveness of clinical trials. In addition, OND evaluates safety and effectiveness and approves New Drug Applications (NDAs) for drug products and Biological License Applications (BLAs) for human use.

Office of Drug Evaluation Science (ODES) supports OND's mission to foster advances in drug development by providing focused scientific expertise on the development and implementation of novel drug development tools, including clinical outcome assessments, and biomarkers. ODES also supports OND's patient focused drug development activities to incorporate the patient's voice in drug development. The office facilitates the development of tools and practices for the robust analysis and interpretation of data to support clinical assessment and decision-making. In addition, ODES is responsible for OND's research portfolio management to promote advancements in regulatory science and foster drug development.

Duties/Responsibilities

As a **Deputy Director** for the Office of Drug Evaluation Sciences (ODES), the incumbent assists the Office Director with managing an immediate office and the Division of Clinical Outcomes Assessment (DCOA) and the Division of Biomedical Informatics, Research and Biomarkers Development (DBIRBD). Together, this Office and its divisions help foster advances in drug development through the qualification of novel tools such as biomarkers or instruments that measures of how a patient functions or feels (clinical outcomes).

- Provides scientific and leadership skills within ODES and through oversight of drug development tool (DDT) committee which involves senior subject matter experts in clinical medicine, pharmacology and toxicology across the OND, and Subject-Matter-Experts in the Office of Translational Science (OTS) and from the Center for Biological Evaluation and Research (CBER). The DDT committee meets regularly to consider submissions to the biomarker or COA qualification program and to determine if, based on scientific merit, scientific evidence provided, and achievable objectives and research plans, that the submissions can be accepted for review by agency scientists and qualified for use by external stakeholders (e.g., industry or academic researchers).
- As the principal advisor to the Director, the incumbent has the direct responsibility for identifying and coordinating the development of standard approaches for safety data analysis as well as enhancing and implementing safety data analysis approaches and tools to provide more effective and efficient evaluations of pre-market data.
- Development with regulations, guidance documents, standard operating procedures, and other policy documents related to the regulation of new drug products with regard

to the application of biomarkers, surrogate endpoints, COAs, and other novel approaches.
- Consultations with OND review divisions and other FDA Centers on COA development, validation, and interpretation as effectiveness endpoints in clinical trials for IND, NDA, and BLA submissions.
- Initiation and support of regulatory science research focused on the development of novel drug development tools (biomarkers and COAs), bioinformatics supporting drug development or review, and safety analytic approaches to regulatory reviews. Supports OND's mission to foster advances in drug development by providing focused scientific expertise on the development and implementation of novel drug development tools, including clinical outcome assessments, and biomarkers.

Supervisory Responsibilities: Manages a multi-disciplinary program, providing leadership and management oversight to subordinate support staff and division directors. Supervise and evaluate 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.

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:

Physician Series, AD-0602

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

Professional Experience:
Our ideal candidate will possess:

- Demonstrated ability and experience in leadership principles and concepts.
- Effective and experienced communicator who can drive collaboration and empower staff.
- Mastery professional knowledge of, and skill in applying theories, concepts, principles, and practices of medicine sufficient to serve as a recognized technical authority and consultant in a specialized technology and broad program that affects national and international interests, including the well-being of the American public.
- Mastery professional knowledge and understanding of current FDA, Center and OND regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Expert written and verbal communications skills to provide advice and guidance to senior management and employees
- and prepare a variety of written reports and documents.
- Experience in drug development, including early phase programs with application of translational research findings to inform drug candidate selection for continued late-stage clinical investigations.

Desired Professional Experience:
Our ideal candidate will possess:

- Experience in drug development programs with the development, application and assessment of biomarkers and clinical outcome assessments and with the application of

research and bioinformatics.
- Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities and spearhead important program initiatives.
- Knowledge of leadership principles and concepts and experience leading diverse, cross-disciplinary teams in addressing complex scientific issues in drug development.

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

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 **August 4, 2023** to Lisa Conrad at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference Job Reference ID: **ODES/IO-ES-23-007** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Wright at Danielle.wright@fda.hhs.gov .

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