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 Surveillance and Epidemiology (OSE)
Office of Pharmacovigilance and Epidemiology (OPE)

Application Period: July 28, 2023 – August 10, 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-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $177,123

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band(s): Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Will NOT be paid.

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 are safe, and effective.

The Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotional activities; review, monitoring and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Surveillance and Epidemiology (OSE) within CDER works to detect, assess, prevent, and manage the risks of medications so that they can be relied on to treat disease and improve health. OSE participates in the safety analysis of drugs before they are marketed to patients and consumers and utilize risk assessment tools to identify and assess adverse events and medication errors that did not appear during the drug development process.

The Office of Pharmacovigilance and Epidemiology (OPE) is responsible for identifying and evaluating safety concerns for drugs and therapeutic biologics and for using epidemiologic evidence to assess the effectiveness of drugs and the therapeutic biologics. OPE recommends actions to improve patient safety and protect and promote the public health. The Drug Safety Team (DST) supports the therapeutic areas anesthesia, addiction, pain, and psychiatry. The mission is to evaluate the safety of marketed drugs.

Duties/Responsibilities

The **Deputy Office Director** participates fully with the Office Director and Super Office Director in planning, managing, organizing, and directing all of the post-market operations, program, functions and activities of the staff as carried out by subordinate supervisors/team leaders and a highly trained and skilled staff of health professionals, medical doctors, epidemiologists, pharmacists, social science researchers and health writers/communicators, organized into subordinate organizations. The Division of Epidemiology-II (DEPI-II) and the Division of Pharmacovigilance-II (DPV-II) reports to the Deputy Office Director.

- Assists the Office Director in reviewing office requests for funds and personnel, evaluates budget estimates and justifications, and makes appropriate recommendations to the OSE Director. Directs budget for staff, which includes medical, scientific, administrative, and support personnel assigned to the divisions.
- Provides clinical, scientific, technical, and administrative direction and supervision 25% or more of the time to subordinate supervisors, team leaders and staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives for the organization. Provides authoritative and professional expertise in health sciences, including epidemiology, and population health issues related to the regulation of drugs and therapeutic biological products; and serves as expert adviser and technical authority on analyzing, advising, and resolving complex and precedent-setting policy and program issues. Is responsible for developing policies, strategies, and plans to address cross-cutting population health issues.

- Serves as scientific lead and leads special projects and initiatives, for example signal identification and guidance development.
- Participates plans, manages, and directs all postmarket operations, programs, functions, and activities of the staff as carried out by subordinate supervisors, team leaders, and highly trained and skilled staff of health professionals, physicians, epidemiologists, pharmacists, and other multi-disciplinary health care professionals organized into subordinate divisions. The OPE divisions are responsible for management and research of drug safety analysis and drug safety data bases including FDA Adverse Event Reporting System (FAERS) and external databases. In conjunction with other CDER offices, OPE divisions are also responsible for disseminating postmarket information to the public and other health professionals.
- Along with the OPE Office Director, provides critical reviews in the study design and methods of epidemiological study protocols relevant to the assessment of post-marketing drug safety submitted by the pharmaceutical industry. Additionally, the incumbent reviews and analyzes epidemiological study reports and datasets relevant to the assessment of post-marketing drug safety that are submitted to the FDA.

Supervisory Responsibilities: As Deputy Office Director, the incumbent supports the Office Director, providing executive leadership and direction to the Office's subordinate Divisions.

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.
- 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, candidate 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 Health Science Series AD-0601 Series

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

Professional Experience:
Our ideal candidate will possess:

- Ability to understand, review and synthesized data from a variety of sources (e.g., FAERS, observational studies, clinical trials).
- Identification and assessment, understanding of risk management and epidemiology.
- Background/experience in epidemiology; public health preferred.
- Knowledge of Agency Procedures, related regulations of the Food Drug and Cosmetic (FD&C) Act, and the Regulatory Procedures Manual.
- Strong clinical and leadership skills, and a collaborative spirit.
- Ability to communicate scientific information orally and in writing.
- Highly organized.
- Healthcare professional licensure (e.g., MD, DO, PharmD, Nurse Practitioner (NP), Physician's Assistant (PA).

Desired Professional Experience**:**
Our ideal candidate will possess drug safety experience.

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 based on 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 10, 2023** to OSE-PMAS-Admin-Team@FDA.HHS.gov. Candidate resumes may be shared with hiring officials 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: OMEPRMDOD0823** on the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact OSE-PMAS-Admin-Team@FDA.HHS.gov.

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