Title 21 Detail 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: June 20, 2023 – June 26, 2023

Area of Consideration: Open to current employees. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service.
Please see below criteria

Position: Cross Discipline Safety Advisor (Physician) **Series:** AD-0602

Not to Exceed Date: 120 Days

Location(s): Silver Spring, Maryland **Work Schedule:** Full Time

Cures Band: Band C

Travel Requirements: 25% or less

Relocation Expenses Reimbursement: Will NOT be paid.

This detail (no change in pay) is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act.

a. Details from a Cures position to another Cures position are permitted.
b. Details from a non-Cures position to a Cures position are permitted except for: Title 42 (g) employees that are Visiting Associates and Visiting Scientists, 42 U.S.C. § 217 (a) Advisory Committee Members (and Consultants).
c. Employees being compensated under Cures will retain their current rate of pay under this authority.
d. Non-Cures employees will retain their current rate of pay under the authority to which their pay is currently set in their permanent position of record. Please contact your HR POC for additional information on 21st Century Cures Act.

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 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) 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

As a **Cross Discipline Safety Advisor (Physician)**, the incumbent will serve as part of the Drug Safety Team (DST), in the Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE). Each Cross Discipline Safety Advisor (CDSA) is responsible for a portfolio of drugs and therapeutic areas aligned with a Drug Safety Team (DST) for which they co-chair.

CDSAs coordinate and facilitate the integration and synthesis of relevant safety information and activities from all sources across OSE, such as during evaluations for a Newly Identified Safety Issue (NISS). The incumbent will support and is an integral part of the drug safety surveillance and review process within OSE with duties that include:

- Serving as the lead point of contact responsible for the integration and synthesis of relevant safety information and activities from all sources across OSE to the DST within CDER assigned therapeutic areas/portfolios of drugs throughout a drugs a product's lifecycle. Each DST is assigned a portfolio of drugs that mirror the OND therapeutic area office, and the therapeutic alignments may change over time based on volume.
- Co-Chairing the Drug Safety Team (DST) for the assigned drug portfolio (i.e., hematology, oncology, etc.) and providing guidance to Newly Identified Safety Signal (NISS) evaluation

teams established by the DST.

- Facilitating discussions, ensuring stakeholder input, supporting collaborative working and consensus, and ensuring integration of cross disciplinary outputs of post market safety issues.
- Collaborating with review teams across the Center on providing guidance and recommendations regarding the implementation of the DST, Pharmacovigilance Strategy (PVS), Periodic Safety Reports (PSR) and Integrated Safety Assessment (ISA) initiatives.
- Working with the OND Deputy Director for Safety (DDS), Team Leaders (TLs), Regulatory Project Managers (RPMs), and reviewers to facilitate interdisciplinary collaboration within review teams participating in the phased implementation of the DST, PVS, and ISA to enable robust and efficient decision making based on the totality of evidence.
- Presenting the DST, PVS, PSR, and ISA initiatives to internal FDA stakeholders across divisions and offices both within and external to OND and OSE. The results of these presentations will support collaborative integrated assessments to enable regulatory decision making.

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.
- 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.
- 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.

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.

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:

Medical Officer (Physician), AD-0602 Series:

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

Professional Experience:

Our ideal candidate will possess:

- Ability to understand, review and synthesize 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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 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.

How to Apply

All qualified candidates should submit their resume with cover letter by **June 26, 2023** to OSE-PMAS-Admin-Team@FDA.HHS.gov. Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

Please reference Job Reference ID: **OSECDSAC062023D** 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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