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)

Application Period: March 28, 2023 – April 10, 2023

Area of Consideration: This vacancy is open to current FDA employees only. 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: Division Director

Series: AD- 0601

Location(s): Silver Spring, MD

Salary: Starting at $177,123

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 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 mission of the Office of Surveillance and Epidemiology (OSE) is to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health using four core functions: Pharmacovigilance, Pharmacoepidemiology, Risk Management, Medication Error Prevention and Analysis.

The mission of the respective divisions such as DPV-I in the Office of Pharmacovigilance and Epidemiology (OPE) is to protect the public using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics by detecting, assessing, and evaluating the safety and effectiveness of drugs and biologics using observational methods; and conducting drug and biologic safety and effectiveness surveillance and research using the best available epidemiologic methodologies.

This position is in the Division of Pharmacovigilance I (DPV-I), Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER).

Duties/Responsibilities

As a **Division Director,** the incumbent oversees a highly skilled staff that detects safety signals and assesses safety-related issues for all marketed drug and therapeutic biologic products. In this capacity, the Division uses a variety of surveillance tools and data sources to provide scientific and clinical evaluation. Specific duties include the following:

- Oversees the development and implementation of Division policies and plans and makes critical decisions and provides expert advice and counsel to the Office Director and other OSE leadership concerning approaches and options in relation to Office and Center goals and objectives.

- Addresses and solves unusual and often precedent setting problems associated with the Division programs and carries out the mission of the Division.

- Leads the review and analyses from their division staff on adverse event reports related to marketed drugs in order to detect safety signals, evaluate risk, performs follow-up as appropriate, and recommend regulatory actions.

- Manages the Newly Identified Safety Issue (NISS) process for safety issues led by the Division. Develops and implements internal Manuals of Policies and Procedures and guidance on safety signal detection and drug risk evaluation initiatives. Responsible for the development of best practices for safety signal detection and evaluation.

- Directs the preparations, clearance, and finalization of Division responses to inquiries covering all aspects of the program segment(s), functions, and activities of the Division.

- Serves as senior advisor to the Office Director and provides authoritative advice and assessments on the impact of actual and proposed Administration or Congressional actions on the programs, functions, and activities of the Division.

Supervisory Responsibilities: Counsels and rates immediate subordinates. Identifies employee competency gaps. Responsible for developing policies, strategies, and plans to address cross-cutting population health issues. Provides occupational specific technical and administrative direction and supervision 25% or more of the time to subordinate supervisors, team leads and/or 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 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:
Division Director (General Medical and Healthcare Series) AD-0601
Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for OPM Occupational Series Qualification Requirements.

Desired Education:
Our ideal candidate will possess:
A bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education (https://www.ed.gov/) atthe time the degree was obtained.

Desired Skills and Professional Experience:
Our ideal candidate will possess:
- Experience managing, planning, organizing, monitoring, and providing expert advice and leadership on regulatory program segments, functions, and activities to a highly trained and skilled staff of health professionals, scientists, and/or multidisciplinary professionals in a regulatory program.
- Demonstrated ability applying knowledge of the Food and Drug Administration Amendments Act, and the regulations and policies promulgated under that statute.
- Experience applying advanced knowledge of science (e.g., biology, regulatory science, drug safety, pharmacoepidemiology).
- Demonstrated ability developing networks and build alliances; and collaborating across boundaries to build strategic relationships and achieve common goals. Demonstrated ability working at all levels of the organization and varying levels of domain expertise.
- Demonstrated ability identifying and analyzing problems; weighing relevance and accuracy of information; generating and evaluating alternative solutions; and making recommendations.
- Demonstrated ability to clearly communicate, both orally and in writing, including exhibiting a commitment to communicate in a timely manner. Experience communicating complex scientific materials to diverse audiences such as scientific, legal, and/or management professionals on a wide range of issues related to drugs and biological products.
- Experience planning and organizing large projects.
- Experience managing and leading teams of professional 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 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.

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 accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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

How to Apply: Submit resume with cover by **April 10, 2023** to: OSE-PMAS-Admin-Team@fda.hhs.gov. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Job Reference ID: DivDir-DPVIMar2023.

Announcement Contact

For questions regarding this Cures position, please email OSE-PMAS-Admin-Team@fda.hhs.gov.

The U.S. Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer.