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: February 22, 2023 - March 17, 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: Associate Director for Medication Error and Risk Management Initiatives

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $155,700

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 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.

The Office of Surveillance and Epidemiology (OSE) works to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health. OSE participates in the safety analysis of drugs before they are marketed to patients and consumers. After the drugs are marketed, we utilize risk assessment tools to identify and assess adverse events and medication errors that did not appear during the drug development process as well as to understand better those risks observed in clinical trials. OSE also provides expertise on risk mitigation strategies to prevent medication errors, to improve the safe use of products, and to manage the risks associated with medicines after they are marketed.

The mission of the Office of Medication Error Prevention and Risk Management (OMEPRM) is to increase the safe use of drug products and improve public health by minimizing use error related to the naming, labeling, packaging, or design of drug products; and developing effective and efficient Risk Evaluation and Mitigation Strategies (REMS) for certain drug products that ensure the benefits outweigh its risks.

Duties/Responsibilities

As the **Associate Director (AD) for Medication Error and Risk Management Initiatives** in OMEPRM, the incumbent works closely with the Office Director to ensure the advancement of OMEPRM's programmatic initiatives, including but not limited to:

- Provides subject matter expertise, technical input, and strategic direction on approaches to implement the Risk Evaluation and Mitigation Strategies (REMS) Assessment Modernization effort across the Office.
- Works with other CDER offices to develop options to resolve difficult and highly complex issues including implementation of policies and procedures to address pharmaceutical companies' REMS program compliance issues.
- Applies the latest advanced concepts, theories, principles, practices, and techniques of risk management to manage, coordinate, review and provide solutions to a broad array of problems related to the management of drug/biologic product risks.
- Serves as OMEPRM lead on complex review programs, projects and processes relating to commitments under the various user fee programs.
- Coordinates clearance of responses to internal and external inquiries and other requests as needed regarding OMEPRM's programmatic initiatives.
- Provides authoritative advice in the review and clearance of internal reviews, manuscripts, abstracts, and presentations prepared by Office staff at relevant Center level and Advisory Committee meetings, Task Forces, Work Groups, and national and international meetings.

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 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:

General Medical and Healthcare Series, AD - 0601

Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for General Health Series (0601) https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-

standards/0600/general-health-science-series-0601/

Professional Experience:
Our ideal candidate will possess:

- Experience applying expertise in advanced professional theories, principles, concepts, standards, and methods of pharmacy and/or drug regulatory process sufficient to serve as expert to resolve difficult problems and issues, as well as plan, design, monitor and evaluate complex projects.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; make recommendations.

Desired Professional Experience:
Our ideal candidate will possess:

- Experience applying knowledge of the Food, Drug and Cosmetic (FD& C) Act, Code of Federal Regulations, and other Agency Guidelines and policies pertaining to review of drug and therapeutic biologic applications.
- Possession of experience working on initiatives related to medication error prevention or the design and implementation of REMS.

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.

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

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

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

How to Apply: Submit resume with cover letter by **March 17, 2023,** to: OSE-PMAS-Admin-Team@FDA.HHS.gov. Candidate resumes may be shared with hiring official 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: OMEPRM0223AD.**

Announcement Contact

For questions regarding this Cures position, please contact 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.