Title 21 Vacancy Announcement
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 Medication Error Prevention and Risk Management (OMEPRM)

Application Period: April 19, 2024 – May 3, 2024

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

Position: Supervisory Associate Director for Risk Evaluation and Mitigation Strategies

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $163,964

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

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 compensated 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 the Center for Drug Evaluation and Research (CDER) works to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health. All medicines have risks as well as benefits; the risks of medicines are the chances that something unwanted or unexpected could happen when consumers use them. OSE participates in the safety analysis of drugs before they are marketed to patients and consumers.
This position is in the Office of Medication Error Prevention and Risk Management (OMEPRM), in the Division of Mitigation Assessment and Medication Error Surveillance (DMAMES). The Division of Mitigation Assessment and Medication Error Surveillance (DMAMES) is responsible for reviewing risk evaluation and mitigation strategies (REMS) Assessment plans, methodologies and REMS assessment reports for all products with approved REMS.

Duties/Responsibilities

As the **Supervisory Associate Director for Risk Evaluation and Mitigation Strategies**, the incumbent serves as a senior advisor to Division Director and Deputy Director on complex scientific, administrative procedural, and policy issues that are related to the REMS assessments to support the Center's policies related to REMS authorities under the Food and Drug Administration Amendments Act (FDAAA) of 2007. In this capacity, the incumbent provides critical leadership in short and long-term planning program development, policy and program analysis, and the implementation of REMS program initiatives and projects that support DMAMES and OMEPRM. The incumbent's research identifies problems and issues in depth, carries out studies, consults with other professionals both within and outside the Office, and the Federal government as necessary.

- Provides supervisory oversight for REMS assessment activities conducted by clinicians and scientists in collaboration with others in Division leadership. Initiates decision making processes and documents, and participates in discussions and decisions concerning Division, Office, and Center plans programs, and activities related to REMS.

- Advises the DMAMES Director on methodologically challenging and/or controversial postmarketing safety issues. Concentrates on complex, long range, and emerging problems as applied to the programs for which the Division is responsible. Incumbent keeps fully abreast of the crucial and precedent setting REMS policies and practices pertinent to the Division and briefs senior leadership on all interpretations and evaluations when necessary.

- Provides authoritative resource on the review of REMS assessment and methods for conducting evaluations of drug safety-related issues and activities related to the REMS of medical products to Division and Office staff and other Center-wide programs. This responsibility requires close personal contact with the "state of science" to inculcate

advancing theories and practices in the scientific field into the Division and Office programs.

- Provides critical guidance in the application of risk management principles, methods, and the research process of DMAMES's drug safety regulatory research/investigation program. Advises Office staff about program evaluation approaches, methodologies, monitoring and contributes to developing guidance documents for Industry, including developing tools, processes, and best practices to improve the efficiency of the review of proposed REMS assessment plans, methodology, and assessment reports.

- Leads complex review programs, projects and processes relating to commitments under the user fee programs throughout the Office and coordination within CDER for meeting the commitments under PDUFA VII including modernization and improvement of REMS assessments. Responsibilities include analysis and resolution of complex issues to resolve difficult problems, operational changes, updates to guidance's, policies and procedures, new review performance goals, and new performance review goals for REMS methodologies and Assessment reports.

- Serves as a subject matter expert, possessing scientific knowledge on different data systems utilizing both past and present, to monitor the effectiveness of different components of REMS which support the development of comprehensive REMS assessment plans. Responsible for maintaining knowledge on the procurement process sufficient to access fundable data systems and support the assessment process.

Supervisory Responsibilities: Provides occupational administrative direction and supervision 25% or more of the time to subordinate staff performing the work and functions of the organizational unit. Applies knowledge of administrative and program management principles and skills to carry out the mission of the Division as well as addressing and solving unusual and often precedent setting problems associated with Division programs. Seeks and develops the most cost effective and fiscally responsible methods to conduct these programs and to solve problems. 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.
- 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 Health Science Series AD-0601 Series

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

Desired Professional Experience:
Our ideal candidate will possess:

- Demonstrated knowledge of the Food, Drug and Cosmetic (FD and C) Act, Code of Federal Regulations, and other Agency Guidelines and policies pertaining to review of drug and therapeutic biologic applications.
- Demonstrated experience applying expertise in advanced professional theories, principles, concepts, standards, and methods of medication use process and/or drug regulatory process sufficient to serve as expert to resolve difficult problems and issues.

- Ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Ability to interpret and apply appropriate guidelines to address REMS evaluation related concerns.
- Experience developing networks and building alliances; collaborate across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability and experience in identifying and analyzing problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.
- Demonstrated experience managing and leading teams of professional staff.
- Experience organizing time effectively, determining priorities, and accomplishing goals.

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.

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 with cover letter by **May 3, 2024** to: OSE-PMAS-Admin-Team@fda.hhs.gov. Resume 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”.

Please reference Job Reference ID: **DMAMESSUPVAD0424**

Announcement Contact

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

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