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 27, 2023 - March 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 Director, Division of Risk Management

Series: AD-0601

Salary: Starting at $155,700

Location(s): Silver Spring, MD

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 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.

Office of Surveillance and Epidemiology (OSE) is the Center lead for the review of proposed proprietary names; responsible for the review of proposed product designs, labels, labeling and packaging for their potential to contribute to medication errors; responsible for performing root-cause analysis of post-market medication error reports; and responsible for developing policies, procedures, and guidance in medication error and patience safety initiatives.

The Division of Risk Management (DRM) serves as the scientific lead for all CDER Risk Evaluation and Mitigation Strategies (REMS) activities. DRM provides risk management expertise on development and implementation of programs and initiatives to support the Center's policies related to REMS authorities under the Food and Drug Administration Amendments Act (FDAAA) of 2007. DRM reviews all proposed REMS, REMS modifications, and REMS assessment plans and assessment reports for all products with approved REMS for conformance with current FDA standards.

Duties/Responsibilities

As the **Deputy Division Director**, the incumbent is responsible for but not limited to the following major duties:

- Shares responsibilities with the Director in planning, managing, organizing, and directing all operations, functions, and activities of the Division as carried out by subordinate staff of highly trained and skilled, scientific professionals (e.g., physicians, pharmacists, nurses, and health communication analysts) to meet the goals and mission of the organization.
- Participates fully in discussions and decisions concerning Division plans, programs, and activities, in both strategic planning and in actual determination, allocation, and administration of program segment(s), functions, and activities.
- Serves as senior advisor to the DRM on complex scientific, administrative, procedural, and policy issues that are important to advancing the programmatic goals.
- Oversees the development and implementation of REMS for complex programs that involve the multiple Sponsors and drug products which include new drug applications (NDAs), abbreviated new drug applications (ANDAs), biological licensing applications (BLAs) into a shared system REMS or separate comparable REMS.
- Represents the Division and OMEPRM in dealing and negotiating REMS with individuals and organizations such as Congress; other federal agencies such as Centers for Disease Control and Prevention (CDC), Centers for Substance Abuse and Mental Health Service and Services Administration (SAMSHA), and Centers for Medicare and Medicaid Services (CMS); State, local and foreign governments such as the European Medicines Agency (EMA); the regulated industry; professional and industry organizations; and public interest groups.

Supervisory Responsibilities:

- Provides occupational specific technical and administrative direction and supervision 25% or more of the time to team leads and/or staff performing the work and functions of the organizational unit.
- Provides authoritative and professional expertise in health sciences, including epidemiology, and population health issues related to the regulation of drugs and therapeutic biological products.
- Serves as expert adviser and technical authority on analyzing, advising, and resolving complex and precedent-setting policy and program issues.
- Responsible for developing policies, strategies, and plans to address cross-cutting population health issues. 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 supervisory 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:

Deputy Director, Division of Risk Management (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)

Professional Experience:

Our ideal candidate will possess:

- Experience with design, implementation and assessment of safety and risk management programs, including REMS and quality improvement regarding health care.
- Excellent knowledge of the medication uses system and strong clinical skills.
- Knowledge of laws, regulations and guidance including regulations pertaining to Food Drug Administration Amendments Act (FDAAA) and relevant updates.
- Strong analytical, negotiation, and communication (writing and oral) skills,
- Demonstrated leadership, interpersonal skills, and knowledge of the many scientific areas important to post marketing safety.

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 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 or curriculum vitae with cover letter by **March 10, 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: **02DRMDD23**

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.

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