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)

Application Period: November 28, 2022 - December 16, 2022

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, DMEPA I

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: This is a non-bargaining unit position

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 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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the respective divisions in 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 that is 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.

The Divisions of Medication Error Prevention and Analysis I (DMEPA I) is responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, product design and Human Factor Studies to identify, evaluate, and minimize the potential for medication errors and use errors for CDER-regulated products.

Duties/Responsibilities

DMEPA I is responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, product design and Human Factor Studies to identify, evaluate, and minimize the potential for medication errors and use errors for CDER-regulated products.

As **Deputy Division Director,** the incumbent shares responsibility with the Director in planning, managing, organizing, and directing all operations, functions, and activities of the Division as carried out by Associate Directors, team leaders and staff with professional, medical, and scientific skillsets such as, physicians, pharmacists, nurses, engineers, and social scientists, serving in the roles of safety evaluators and human factors (HF) specialists 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.

The Deputy Director:

- Provides day to day management, oversight, and direction to Associate Directors and other staff involved in providing medication error risk assessment support. Ensures the mission and strategic goals are communicated to all staff and are appropriately integrated into the work of DMEPA I.
- Serves as senior advisor to the DMEPA I Director on complex scientific, administrative, procedural, and policy issues and serves as the alter ego to the Division Director, when delegated. Serves as a Center Point of Contact for Division and provides expert advice as a technical authority on complex and precedent-setting policy and program issues.
- Provides authoritative and professional technical expertise throughout the respective division; applies advanced professional theories, principles, concepts, standards, and methods of drug regulatory process to assess the safety and effectiveness of drugs and biologics; demonstrates mastery of the analysis and application of regulatory policies, procedures, and guidelines; provides tertiary evaluation of relevant reviews.
- Develops and implements Division policies and plans, makes critical decisions, and provides expert advice and counsel concerning approaches and options that are sound and feasible.

- Develops, assesses, drafts, and provides advice and recommendations on the impact of proposed administrative or congressional actions; Directs and implements new laws and regulations which impact the Division.
- Prepares and presents complex scientific data and materials to diverse audiences. This may include activities such as contributing to the develop of guidance documents pertinent to the areas of medication error prevention and analysis.
- Represents the Division or Office in Agency or Center level workgroups or external organizations and provides subject matter expertise in order to collaborate with other scientists/policy experts on original research projects, best practices, guidances, legislative initiatives, and SOPs related to DMEPA -I program areas.

Supervisory Responsibilities:
Provides occupational specific technical and administrative direction and supervises associate directors, team leaders, and professional staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives of the organization. Hears and resolves complaints from subordinate staff, referring group grievances and more serious unresolved complaints to a higher-level supervisory authority. Provides employees with resources and information that ensure a safe and healthy work environment. Recommends employee promotions and recognition. Approves leave, within-grade increases, extensive overtime, and/or employee travel. Implements performance modifications and takes corrective actions as appropriate.

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:

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/

Desired Education: 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/) at the time the degree was obtained.

Professional Experience:

- 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.
- Experience applying expertise in advanced professional theories, principles, concepts, standards, and methods of drug regulatory process using human factors evidence to assess the safety and effectiveness of drugs and biologics, sufficient to serve as expert resolving highly complex problems and issues.
- Demonstrated ability to communicate 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.

- Demonstrated mastery and application of the Food and Drug Administration Amendments Act, regulations, policies, and procedures related to the regulation and evaluation of drugs and biologic products.
- Exhibited ability to develop networks and build alliances and collaborate across boundaries to build strategic relationships and achieve common goals.
- Experience in developing new policy or advancing existing policy to further programmatic goals
- Experience leading teams and managing projects.

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

Submit resume with cover letter by **December 16, 2022** 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”.

Announcement Contact

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

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