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 31, 2023 – April 28, 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: Pharmacist

Series: AD-0660

Location(s): Silver Spring, MD

Salary: Starting at $112,015- $155,978

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

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) 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.

The Division of Medication Error Prevention and Analysis (DMEPA) is primarily responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, and Human Factor Studies to identify, evaluate, and minimize the potential for medication errors for CDER-regulated products. DMEPA serves as the scientific and policy lead for CDER's proprietary naming and human factors programs. DMEPA also leads the review of and designates nonproprietary name suffixes for all CDER biological nonproprietary names.

DMEPA conducts review and analysis of post marketing medication errors submitted to CDER. Based on these evaluations, regulatory action may include changing the drug name, labels and labeling, packaging design, and/or communicating the error to the public via an FDA Drug Safety Communication, ISMP Medication Safety Alert newsletter, or other publication. DMEPA also works closely with federal partners, patient safety organizations (e.g., Institute for Safe Medication Practices [ISMP]), standard setting organizations (e.g., United States Pharmacopeia [USP]), and foreign regulators to address broader product safety issues. The position is located in the Office of Surveillance and Epidemiology (OSE), Division of Medication Error Prevention and Analysis (DMEPA) within CDER.

Duties/Responsibilities

As a **Pharmacist,** the incumbent serves as an integral part of the drug safety surveillance and review process within OSE with duties that include:

- Review the proposed proprietary names, product designs, labels, labeling and packaging for their potential to contribute to medication errors
- Conduct surveillance of FAERS database and other relevant sources to identify emerging safety signals.
- Prepare written and oral deliverables in collaboration with team members that inform regulatory decisions pertaining to medication error prevention.
- Apply knowledge and understanding of applicable laws, regulations, guidance, policies and procedures, best practices, and internal standard operating procedures pertaining to medication safety.

Supervisory Responsibilities: None

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:
Pharmacist, AD-0660 Series:

Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for Pharmacist (0660). For more information, please see: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-

standards/0600/pharmacist-series-0660/

Licensure
Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Professional Experience:

Our ideal candidate will possess:
Knowledge of the use of clinical effects, and composition of medications, including chemical, biological, and physical properties, including:

- Dispensing medications prescribed by health practitioners and providing information to the public about proper usage of medications and side effects.
- Knowledge of failure modes effects analysis (FMEA), and experience in performing root-cause analysis (RCA) of medication errors is desired
- Expertise and experience in medication error prevention and patient safety initiatives is desired
- Establishing medication-handling procedures for the storage and preservation of medications.

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 qualifications 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 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

Submit resume with cover by **April 28, 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".

Please reference **Job Reference ID: 23DMEPA04182023**.

Announcement Contact

Questions regarding this Cures position, please contact ose-pmas-admin-team@fda.hhs.gov.

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