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)
Divisions of Pharmacovigilance (DPV)

Application Period: April 22, 2023 – May 3, 2024

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 Range: $117,962 - $164,260

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: 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 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 mission of the Office of Surveillance and Epidemiology (OSE) is to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health using four core functions: Pharmacovigilance, Pharmacoepidemiology, Risk Management, Medication Error Prevention and Analysis.

The successful candidate will join a multidisciplinary team in the Divisions of Pharmacovigilance (DPV) responsible for the surveillance of adverse events associated with drugs and biological products regulated by CDER. Clinical pharmacists have the unique opportunity to influence patient care on a population level, not found in typical pharmacy practice settings. DPV teams use postmarketing data sources to detect serious adverse events that were not identified during the drug development program and apply a risk-based approach to evaluate more than 2 million adverse event reports submitted every year to the FDA Adverse Event Reporting System database. In addition to adverse event reports, pharmacists use a variety of other data sources, surveillance tools, and clinical knowledge to provide scientific evaluation of safety issues. Safety evaluations may lead to various regulatory actions, such as labeling changes and public communications to promote safe use of the product.

This position is in the Divisions of Pharmacovigilance (DPV), Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER).

Duties/Responsibilities

A **Pharmacist** is responsible for the major duties as follows:

- Conducts surveillance of the FAERS database, medical literature, and other relevant sources in assigned therapeutic area(s) to identify emerging safety signals. Considers the public health impact of the potential or actual risk, the severity of the potential risk, the potential for risk mitigation, and the value and impact of any potential regulatory action.
- Applies expert clinical and scientific judgement to determine the adequacy of clinical documentation, the severity of the adverse event, and the possible causal relationship between specific medications and the adverse event.
- Reviews data collected from various sources (e.g., surveys, study groups, social media, best practices) to consider the public health impact of the potential or actual risk, the severity of the potential risk, the potential for risk mitigation, and the value and impact of any potential regulatory action.
- Serves as a Subject Matter Expert (SME) and works with the appropriate internal and external stakeholders to obtain additional clinical information on adverse events considered to represent potentially significant safety problems.

- Prepares written and oral deliverables in collaboration with team members that convey relevant scientific data and clinical information to inform regulatory recommendations.
- Maintains and applies knowledge and understanding of applicable laws, regulations, guidances, policies and procedures, best practices, and internal standard operating procedures pertaining to postmarketing safety.
- Keeps abreast of new developments in drug and therapeutic biological products in the assigned therapeutic area(s) to anticipate possible safety and reporting problems.
- Serves as scientific advisor on adverse events associated with assigned products to internal and external stakeholders.

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:

Pharmacy Series – AD-0660

Degree: A doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE), or from an educational program from an accrediting body recognized by the U. S. Department of Education at the time the degree was obtained.

For more information please see: OPM Occupational Series Qualification Requirements

Licensure Requirements:

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.

Desired Skills and Professional Experience:

Our ideal candidate will possess:

- Preference is given to candidates who have completed a PGY2 residency, a Master of Public Health degree, or have evidence of scholarship, such as authorship in peer-reviewed journals.
- Knowledge and understanding of applicable laws, regulations, guidances, policies and procedures, best practices, and internal standard operating procedures pertaining to postmarketing safety.
- Skills and ability to apply knowledge of policies on matters related to drug safety and scientific regulatory policy, and familiarity with the Food, Drug, and Cosmetic Act.
- Skills and ability to apply knowledge of several scientific disciplines such as pharmacokinetics, clinical pharmacy and therapeutics, pharmacoepidemiology, pharmacology, and clinical knowledge in a variety of different areas.
- Ability to communicate in writing effectively to a diverse audience.
- Skills in oral communication techniques to make presentations. Demonstrated experience in talking to others to convey information effectively.
- Skills in time management to include prioritizing, organizational, planning, and problem solving.
- Ability to develop strategic contacts and outreach to external members of the healthcare community, including other federal agencies, members of professional organizations, and patient safety groups.
- Ability to identify and analyze problems; generate and compare alternative solutions; and make recommendations to program changes.
- Skills and ability persuading others and gaining cooperation to accomplish 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/Moderate 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 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

How to Apply: Submit resume with cover by midnight on **May 03, 2024,** 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”.

Job Reference ID: **DPVI-PharmApr2024**.

Announcement Contact

For questions regarding this Cures position, please email 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.