Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Pharmacovigilance (DPV)

Application Period: July 17, 2023 – September 17, 2023

Area of Consideration: The Public.
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: Physician
*Multiple selections may be made from this announcement

Series: Physician (0602)

Location(s): White Oak Campus, Silver Spring, MD

Salary: Starting at $165,000 and is set to commensurate with education and experience.

Telework Eligible: Yes – as determined by the agency policy.

Work Schedule: Full Time

Cures Band: Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers.

The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

The Office of Biostatistics and Pharmacovigilance (OBPV) provides comprehensive statistical, pharmacovigilance, and epidemiological evaluation of data submitted to the Center in support of regulatory requirements. Collaborates with other Center components to provide reviews and assessments of regulated biological products. Represents the Center within the Food and Drug Administration (FDA), the Public Health Service, the Department, and elsewhere regarding initiatives relating to the statistical and/or epidemiological evaluation of medical products, including the evaluation of product safety. Contributes to the development of regulatory policy in areas relevant to the disciplines of biostatistics, pharmacovigilance, and epidemiology, such as post-marketing surveillance and the design, conduction, and analysis of studies to evaluate medical products. Conducts independent research relating to statistical, pharmacovigilance, and epidemiological methods for assessing the efficacy and safety of biological products, and for assuring the quality and consistency of their manufacture.

The Division of Pharmacovigilance (DPV) perform pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies, and Risk Evaluation and Mitigation Strategies (REMS) under the Food and Drug Administration Amendment Act (FDAAA). DPV reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

Duties/Responsibilities:

The Physician will:

- Monitors the post market safety of CBER regulated biological products to inform regulatory decisions.
- Develops and implements systems for the acquisition of data concerning clinical experience and use trends of biological products.
- Develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts. Coordinates the Center adverse event reporting systems.
- Performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post marketing requirement (PMR) studies and Risk Evaluation and Mitigation Strategies (REMS) under the Food and Drug Administration Amendment Act (FDAAA).
- Reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.
- Performs reviews of other safety data analyses submitted by regulated industry.
- Provide advice and guidance regarding those aspects of the application which fall within the incumbent's area of review expertise.

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.

In order 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:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

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.

Desired Education, Experience, or Skills:

An ideal candidate would possess an active medical license in at least one state or U.S. federal jurisdiction.

Security Clearance Requirements:

Background Investigation/Security Clearance Requirements: 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.

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:

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period). In describing your experience, please be clear and specific. No assumptions will be made regarding your experience. A copy of your unofficial transcripts (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CBER/OBPV/DPV Physician Cures Announcement"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **September 17, 2023.**

Announcement Contact:

For questions regarding this Cures position, please contact CBERHumanCapital@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke-free environment.

FDA is an equal opportunity employer.