Title 21 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)
Immediate Office of the Director (IOD)
CBER Surveillance Program Staff

Application Period: July 9, 2024 – July 22, 2024

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: Project Manager*
*Multiple selections can be made from this announcement

Series: Misc. Administrative and Program (0301)

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

Salary: Starting at $99,200 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy.

Title 21 Band: Band B

Full Performance Band Level: Band B

Travel Requirements: 25% or less

Bargaining Unit: 3591

Note: 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 Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission 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. CBER protects and

advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The mission of the Office of Biostatistics and Pharmacovigilance (OBPV) involves evaluating the safety and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, statistics, medicine, risk analysis, public health, genomics, and other scientific areas.

The OBPV CBER Surveillance Program Staff works collaboratively with OBPV and CBER staff to identify key post-market safety and effectiveness questions for biologics to be addressed by Sentinel studies. CBER Surveillance Program Staff coordinates and formulates the design of appropriate studies and analytic plans. The CBER Surveillance Program Staff builds the infrastructure for an active surveillance system of biologics using large-scale administrative claims and electronic health record data from a variety of sources.

Duties/Responsibilities

The incumbent serves as a Project Manager for the CBER Surveillance Program Staff in the Immediate Office of the Director (IOD) within the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to the CBER Surveillance Program Staff Lead. The CBER Surveillance Program Staff Project Manager serves as a focal point for information, operations, program policy, surveillance projects, and implementation issues that require management and coordination for the Biologics Effectiveness and Safety (BEST) Initiative. The CBER Surveillance Program Staff Project Manager works with the CBER Surveillance Program Staff to manage all CBER Surveillance Program Staff projects throughout the full project life cycle, including the planning, budgeting, requirements development, design, development, risks and risks mitigation strategies and implementation phases.

Specifically, the Project Manager will:

- Work with CBER staff in developing strategies for implementing/planning for major information, operations, surveillance, and management projects, especially the implementation and operations of the BEST Program.
- Work with CBER program staffers to identify the project scope, requirements, deliverables, and document project risks. Implement, coordinate, administer, and monitor the project plan. Formulate business practice procedures for information, operations, surveillance projects, and management within CBER. Collaborate with other BEST project managers on cross cutting projects.
- Facilitate CBER Surveillance Program Staff meetings and work with the project leads to prepare agendas, recordings, and track meeting outcomes including decisions and action items. Update CBER Surveillance Program Staff and senior management on project status.
- Serve as technical liaison between the BEST Contractors and the Contracting Officers by monitoring the Contractor's performance of work, assuring technical proficiency and compliance of technical provisions and requirements of the contract, providing status updates, resolving problems as they arise, and confirming delivery of the final products and/or services under the contract.
- Review and evaluate the Contractor's progress related to expenditures and recommends approval/disapproval for payment as appropriate. Assist with the development of contract documents such as requests for proposals, requests for information, statements of work, independent government cost estimates and review of contract proposals.
- Develop implementation plans for recommendations and conduct follow-up activities as appropriate to ensure that program commitments are fulfilled, and deadlines are met. Recommends and justifies changes desired in scope and/or technical provisions of the contract.
- Facilitates interactions between various federal agencies and private stakeholders and develops and maintains a working knowledge and understanding of the issues relevant to the program.
- Assist in developing communication plans to include tailored messages for multiple stakeholder groups regarding program objectives based on current communication channels and best practices.
- Perform other duties as assigned.

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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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.

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 Transcripts

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

Desired Professional Experience, Skills, or Education:

- Strong project and self-management skills – ability to get things done and deliver in a complex environment (high visibility with accelerated timelines).
- Experience or education in allied health or life sciences.
- Expertise in meeting deadlines in a fast-paced environment while managing multiple priorities.
- Expertise in communicating best practices, principles, methods, theories, and techniques.
- Strong oral and written communication skills, and the ability to develop a variety of documents.

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: 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), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CURES CBER/OBPV/IOD/CSPS Project Manager"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **July 22, 2024.**

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.