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 Regulatory Operations (ORO)
Division of Regulatory Operations and Programs (DROP)
Regulatory Programs Branch (RPB)

Application Period: 08/07/2024 – 08/21/2024

Area of Consideration: Government-Wide
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

Series: 301

Location(s): Remote

Salary Range: $117,926 - $164,260 and is set commensurate with education and experience.

Work Schedule: Full Time

Cures Band: Band C

Full Performance Band Level: Band C

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 (FDA or Agency) 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 safe, and effective.

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 Office of Regulatory Operations (ORO) is responsible for managing the review process and associated activities used to

support CBER in facilitating the regulation and review of biological products, drugs, devices, and combination products. These responsibilities include development and governance of regulatory business processes; data standards; regulatory data analysis; program evaluation; resource utilization; user fee management; electronic submission management; and special initiatives. ORO manages CBER's Information Technology investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

The Division of Regulatory Operations and Programs (DROP) oversees CBER's Managed Review Process (MRP) and governance of regulatory operations. These responsibilities include the review of policy and procedures; review-related committees; interaction with offices on review and regulatory issues to facilitate application of statutes, regulations, guidance, and processes. DROP initiates and oversees strategic of review and regulatory processes and submissions.

The Regulatory Programs Branch (RPB) is responsible for policy formulation, process engineering/re-engineering, and implementation of all Center-level review policies, procedures, review tools, and regulatory templates for use by CBER device reviewers in the managed review process. These responsibilities include managing the User Fee billing policy and procedures, application assessment, waivers evaluation and processing; tracking the implementation of user fees, legislative and other assigned initiatives within CBER; managing CBER regulatory pediatric programs including Pediatric Research Equity Act (PREA) and Pediatric Review Committee; policies and procedures development; interactions for Combination Products; review vouchers and exclusivity assessments.

Duties/Responsibilities

The Project Manager will lead implementation of programs, policies, and procedures that support the Managed Review Process at CBER.

Specifically, the Project Manager will:

- Serve as the lead on multiple projects across CBER programs performing functions to:
    - Develop program implementation plans and supporting documents in collaboration with working group or committee members both within CBER and across FDA centers. Conduct follow-up activities to ensure program commitments are fullfulled and deadlines are met.
    - Track project milestones and action items in collaboration with the program team members.
    - Identify and track program issues and risks, status, execution of mitigation strategies, and final decisions.
    - Provide solutions; advise the chairperson, program team members, supvervisor, managmenent, and senior Center leadership, as appropriate.
    - Draft and coordinate issuance of all program-related communications to appropriate stakeholders, including CBER-wide communications.
    - Communicate technical program and project information and present program status and issues to senior management.
    - Manage integration between multiple programs and projects (e.g., CBER pilot programs).
    - Conduct or support the development of appropriate training for CBER Staff to support the implementation of regulatory programs.
- Lead working groups and committees related to regulatory and scientific review and related documents, reference guides, and collaborative workspaces.
- Lead and support working groups in preparing standard operating policies and procedures (SOPP) and related job aids, references, and templates to adhere to business practices for managing regulatory programs, submissions, reviews, and other projects.

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 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 Education:

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, biology, chemistry, health sciences or allied sciences appropriate to the work of the position.

Desired Professional Experience:

- Experience managing regulatory, scientific, or technical projects or programs.
- Knowledge of project management tools (e.g., OneNote, Teams, JIRA) and collaborative workspaces, such as SharePoint Online.
- Expert knolwedge of Microsoft Office Applications (e.g., Excel, Word, Power Point) and Adobe Acrobat.
- Experience preparing a variety of comprehensive status reports, management summaries, and briefing papers which identify problems, assess the overall condition of work completed or in progress and outlines issues, solutions, and recommendations.
- Ability to plan, organize, and carry out assignments; resolve technical conflicts; coordinate with others; and apply established policy and guidelines to achieve objectives.
- Experience identifying and proposing solutions to critical problems and the need to develop new regulatory approaches or methods that impact operating programs.

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: 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.

Additional Information

If you are serving, or have served in the last 5 years (from 12/01/2023**) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*

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 PMAP (if applicable), copy of your unofficial transcripts (if applicable), and letter of interest with ***"CURES CBER/ORO/DROP/RPB Project Manager*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **08/21/24**.

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.