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: 4/15/2024 – 4/24/2024

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: 0301

Location(s): Remote Eligible position

Salary: Starting at $99,200

Work Schedule: Full Time

Telework Eligible: Yes

Cures 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 federal agency responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. 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 public health through the regulation of biological and related products including blood, vaccines, allergenics, human tissues, and cellular and gene therapies. CBER protects and advances the public health by helping to ensure that biological products are safe, pure, and potent. 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 policies and procedures; review-related committees; interaction with offices on review and regulatory issues to facilitate application of statutes, regulations, guidance, and processes. DROP provides strategic oversight of review and regulatory submissions at CBER.

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 (MRP). 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 incumbent serves as the Project Manager for the Regulatory Programs Branch (RPB) in the Division of Regulatory Operations and Programs (DROP) within the Office of Regulatory Operations (ORO). The Project Manager supports the User Fee billing activities and review vouchers and exclusivity assessments for CBER. The incumbent supports leadership with the implementation of policies and procedures for user fee application assessment, waiver evaluation, annual invoicing, and processing of payments. The Project Manager supports review teams and regulatory project managers in the determination of user fee assessment. The incumbent tracks implementation of user fee and other applicable legislation for all types (i.e., biologics, devices, drugs) of CBER-regulated products.

Specifically, the Project Manager will:

- Monitor the User Fee billing policy and procedures, application assessment, waivers evaluation and processing. Track implementation of user fees, legislative and other assigned initiatives within CBER.
- Verify the payment of user fees and monitor submissions when fees are in arrears to ensure resolution with the user fee regulations and requirements, which includes processing of waiver and refund requests and updating CBER systems with user fee payment information.
- Resolve payment discrepancies and arrearages through contacts with applicants, FDA user fee staff, and CBER review staff.
- Serve as Center POC for user fee payment verification and for validating billable and discontinued products to maintain and report information on FDA's internet site, internal CBER Systems, and Sharepoint site to prepare and issue invoices.
- Develop, interpret, and provide recommendations on regulatory program policies, processes, and guidance documents.
- Assist with the management of review vouchers and exclusivity assessments.
- Assist with regulatory review projects. Work collaboratively with all team members, develop project plans and milestones, and assure timely resolution of regulatory review issues. Study the background of the project, research appropriate sources for information, proposes and justifies solutions.
- Assist in planning, programming, development, oversight, scheduling, facilitating, preparing issues-based agendas, tracking status, and overall management for the regulatory review projects.
- Identify and analyze user fee billing, reporting requirements, data systems and evaluate, monitor, and ensure compliance with laws, regulations, policies, standards, and/or procedures for all project deliverables.
- Support the managed review process (MRP) for all CBER regulated products.
- Provide input and make recommendations to leadership for implementation of new or revised policies

and procedures.
- Assist with process engineering/re-engineering, and implementation of all Center-level review policies, procedures, review tools, and regulatory templates for use by CBER reviewers in the MRP.
- Represent CBER on internal and external task forces, working groups, and committees.
- Provide expertise on organizational and review management issues, prepares recommendations, and makes presentations to appropriate officials.
- Performs 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.
- 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: OPM Occupational Series Qualification Requirements

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 knowledge 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.

- Knowledge of regulatory science or drug/device/biologics manufacturing or research to prepare written documents (e.g., Standard Operation Procedures, Job Aids, Templates, etc.).

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.

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), unofficial copies of 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 4/24/24.

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.