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 Therapeutic Products (OTP)
Office of Review Management and Regulatory Review (ORMRR)
Division of Review Management and Regulatory Review 1 & 2 (DRMRR1 & DRMRR2)

Application Period: 04/17/2023 – 05/01/2023

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: Regulatory Health Project Manager*
*Multiple selections can be made for Regulatory Health Project Manager positions within DRMRR1/DRMRR2.

Series: 0601

Location(s): White Oak Campus, Silver Spring, MD. 24145-0031.

Salary: Band A starting at $78,592
Band B starting at $94,199

Work Schedule: Full Time

Cures Band(s): Bands A & B

Full Performance Band Level:
Band A FPBL: Band B

Travel Requirements: 0%

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.

Duties/Responsibilities

The incumbent serves as a Regulatory Health Project Manager for a Regulatory Review Branch (RRB) within the Division of Review Management and Regulatory Review 1 (DRMRR1) OR the Division of Review Management and Regulatory Review 2 (DRMRR2). This position falls under the Office of Review Management and Regulatory Review (ORMRR) within the Office of Therapeutic Products (OTP). This position reports to the Branch Chief of the applicable RRB. OTP is a newly established Super Office within CBER which is responsible for the continued safety, purity, potency, and effectiveness of cellular, tissue, hematologic and gene therapies and other products regulated by OTP. As the Regulatory Health Project Manager, the incumbent collaborates with similar or higher graded staff to plan, facilitate, implement, and coordinate the Branch/Division/Office project activities.

Specifically, the Regulatory Health Project Manager will:

- Perform regulatory review activities as a team member, to include facilitating meetings, preparing issue-based agendas, and drafting, finalizing, and providing meeting summaries, in addition to issuing communications (e.g., memos, emails and letters).
- Provide analysis and evaluation on the implementation of projects.
- Provide routine case problem-solving services on specific problems and projects to the management.
- Manage the product review process for routine classes of biologics from initial submission to the time of approval, termination, or withdrawal.
- Work to resolve scientific and regulatory conflicts or problems to avoid delays in achieving goals.
- Partner with other members of the review team to develop project plans, including establishing time frames, milestones, and endpoints.
- Monitor the progress and report the status of all activities within the assigned projects through interaction with review team members and their management.
- Analyze review status to identify adverse activities or modification from the project plans, determine any impact on established project goals and recommend solution to review team.
- Identify discrepancy of resource needs, availability and scheduling.
- Serve as a liaison between sponsors, applicants and FDA review team.
- Keep abreast on current technology, international issues, biologic products policy, guidance, and regulations as well as changes in Center and Agency policies and procedures.
- Provide authoritative advice and counsel to all parties engaged or interested in the FDA product review process concerning the assigned product classes. Opinions are often precedent setting and conveyed decisions may have major public health and/or economic consequences.

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.
- 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.

Desired Professional Experience:
- Knowledge and skill when applying a wide range of routine health science theories, concepts, principles, standards, and methods
- Ability to work as a team member on various complications and constraints contained in traditional projects
- Knowledge regarding the techniques, processes, and procedures established within the FDA to work on projects
- Skilled at maintaining constructive working relationships
- Ability to analyze situations, identify problems, probe causes, and suggest courses of action for scientific and regulatory specialists to pursue

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.

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 transcripts, and letter of interest with ***"CURES CBER/OTP/ORMRR/DRMRR 1 & 2 Regulatory Health Project Manager"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through May 1, 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.