Title 21 Cures Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of the Center Director (OD)
Policy Staff (PS)
Regulatory and Policy Staff (RPS)

Application Period: January 20 – February 2, 2023

Area of Consideration: FDA-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: Senior Regulatory Health Project Manager (Rare Diseases) **Series:** 0601

Location(s): White Oak Campus, Silver Spring, MD. **Salary:** Starting at $132,368

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Band D **Full Performance Band Level:** Band D

Travel Requirements: Less than 25%

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 Regulatory and Policy Staff (RPS) is responsible for Center oversight and leadership in the development,

clearance, and implementation of regulations, guidance, policies, procedures, and other documents affecting the regulation of biological products and other products regulated by CBER. The staff collaborates with all CBER offices and with other FDA offices on policy issues related to CBER-regulated products. RPS develops policies to address emerging or existing issues which affect the products and firms regulated by the CBER and coordinates with the Office of the Chief Counsel on policy matters.

Duties/Responsibilities

The incumbent serves as a Senior Regulatory Health Project Manager (RHPM) and reports directly to the RPS Staff Supervisor. The Senior RHPM provides senior level regulatory policy and project management expertise concerning biological products regulated by the CBER and intended for use in rare diseases. Having a mastery of the laws and regulations concerning orphan drugs and other medical products for rare diseases, the Senior RHPM is an expert knowledge manager for CBER's Rare Disease Program and leads relevant regulatory health projects, stakeholder outreach, and authoritative project management to carry out the regulatory health policy mission of the Office.

Specifically, the Senior Regulatory Health Project Manager will:

- Serve as a recognized regulatory health policy expert authority for scientific and biologics programs, studies, and issues primarily related to rare diseases for the Center.
- Provide policy expertise concerning the regulation of biologics which are complex in nature in terms of their scientific and regulatory policy implications.
- Serve as a key contact and expert authority for Agency-level staff, other Federal agencies, industry, and academia on rare disease issues, represent the Center on internal and external committees, and working groups, and present Center rare disease policies and procedures in public forums. Facilitate intra- and interagency interactions to develop and implement rare disease strategy and policies that require coordination and negotiations among stakeholders.
- Review and prepare regulatory advisory opinions and comments in response to requests from other parts of the Agency and from external stakeholders, including but not limited to Congressional staff.
- Lead and contribute to the development and distribution of relevant policy documents, such as rare disease guidance, Federal Register notices and material.
- Maintain a thorough awareness of the health, scientific, and legislative activities of and challenges faced by various organizations in fields of importance to FDA's mission and promote rare disease scientific programs.
- Recommend agency actions in response to significant developments and independently establish effective mechanisms for action. Present recommendations to top level agency management.
- Work with the CBER Rare Disease Liaison in CBER's Policy Staff in the Office of the Director in leading and coordinating the CBER Rare Disease Program.
- Oversee and ensure implementation and reporting of key Rare Disease Program efforts including those that are Congressionally mandated such as user fee commitments.
- Consult with review and policy staff from relevant CBER Offices throughout implementation of user fee and other statutory requirements for rare disease drug development, and other Rare Disease program efforts.
- Facilitate the development, recommendation, coordination, and implementation of program improvements and new procedures designed to enhance program performance on rare disease drug development activities broadly throughout CBER and across FDA.

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:

- Experience and knowledge of FDA regulations and laws, historical and legal precedents, regulations, guidelines, policies, and procedures pertaining to medical product development for rare diseases.
- Experience with applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Ability to work independently, proactively identify priorities and complete assignments with minimal oversight.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that

requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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), and letter of interest with ***"CURES CBER/OD/PS/RPS* Senior Regulatory Health Project Manager (Rare Diseases)"** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **February 2, 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.