Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Translational Sciences (OTS)
Office of Biostatistics (OB)
Project Management Staff (PMS)

Application Period: August 5, 2024 – August 16, 2024

Area of Consideration: 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

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $117,962

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: up to 25%

Bargaining Unit: 3591

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 mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs,

including biological therapeutics and generic drugs.

The Office of Translational Sciences (OTS) promotes and facilitates scientific collaboration and innovation in drug regulatory review across CDER, assuring the validity of clinical trial design and analysis in regulatory decision-making, overseeing bioequivalence inspections to ensure the availability of safe and effective generic equivalents of investigational drugs, and providing innovative and reliable solutions that improve and strengthen the scientific review process.

The Office of Biostatistics (OB) provides statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs and therapeutic biologics for the American public. OB provides scientific expertise and recommendations to multi-disciplinary regulatory teams across the FDA on advanced statistical, mathematical, and computational theory and practices for the design and review of studies to demonstrate safety, efficacy, and quality of drugs.

The Project Management Staff (PMS) assists in the development of policies, processes, and procedures for the OB and for assigned project teams. In this capacity, the PMS serves as the manager of OB projects throughout the full project lifecycle, including developing, planning, budgeting, and implementing project activities. The PMS builds tools and knowledge management systems to enable scientific and policy analysis; coordinates cross-cutting initiatives to address unmet needs in drug development; and liaises with internal and external stakeholders in support of regulatory review, research, and workload management.

Duties/Responsibilities

As a Regulatory Health Project Manager (RHPM), the incumbent is responsible for the management activities of project teams including scheduling meetings, preparing agendas, and recording meeting action items. The incumbent will assure attainment of project objectives and completion of project activities within established timelines. The RHPM will conceive and develop valid approaches for efficient management of projects, make decisions regarding processes that impact the Office, and recommend standard operating procedures to enhance programs of OB Divisions, the Office, or the Center. The responsibilities include working with all members of the review or project team (scientific, regulatory and management) to establish project plans with milestones and outcomes with associated timelines.

- Directly managing and coordinating the work of the project team members to determine how much progress is being made and if any problems arise.

- Coordinate all activities of OB Working Groups and Committees and serve as the liaison with the Immediate Office.

- Responsible for managing all activities associated with OB-led initiatives and will provide

OB leadership with regular status updates.

- Utilize all available tools to ensure consistent knowledge and workload management across OB and will recommend novel tools, when needed.

- Perform scientific and policy analysis based on information gathered from available tools and resources.

- Monitor and report the status of all activities within the assigned OB projects through interaction with project participants and, if required, supervisors and directors.

- Initiates correspondence regarding action, policy issues, or requests for additional information.

- Identifies activities or situations that may adversely impact the project plan and advise management of the potential impact and, with the team, recommending solutions to problem areas.

- Provides advice to all parties engaged in the review or project process.

- Serves as the point of contact for all communications, within the Office of Biostatistics as well as other relevant offices within CDER such as the Office of New Drugs, Office of Medical Policy, or Office of Generic Drugs, concerning assigned projects and ensures compliance with all legal, regulatory and policy requirements.

- Liaison with other organizations within the Center including, but not limited to, the Office of New Drugs, Office of Generic Drugs, and the Office of Surveillance and Epidemiology. They will also ensure timely and effective communication with pharmaceutical firms.

- Responsible member of the team tasked with overall control, coordination, and analysis of incoming requests for programmatic action or information; research specific information on projects required by the Office for use in preparing for meetings; and serve as primary point of contact for special projects.

- Manage office-wide program management, regulatory and review operations, and quality system management consistent with Center priorities.

- Coordinate and manage, ctivities associated with the development, clearance, and training of OB-initiated guidance or other policy documents.

Supervisory Responsibilities: None.

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.
- One year supervisory 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:

General Medical and Healthcare Series, 0601 Degree: Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied

sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Professional Experience:

- Mastery of the techniques, processes and procedures established within the agency to manage projects and resources, and the ability to use them to meet project goals
- Knowledge of the scientific fields involved in state-of-the-art drug development and approval to judge the expertise of others when determining the need for additional scientific resources for review teams
- Skill in planning and organizing the work of the review or project teams to accomplish a variety of concurrent activities performed in several organizations and to anticipate subtle and difficult issues. Ability to analyze situations, identify problems and suggest courses of action for scientific and regulatory specialists to pursue
- Ability to function within a regulatory environment and problem solve to meet challenging demands
- Skill of and ability to communicate both in writing and orally to present findings and deliver briefings, explain and to justify recommendations
- Establish and maintain effective and diplomatic working relationships with the internal scientific research community and management.

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: Non-Sensitive/High Risk investigation, and the incumbent has access to documents and facilities.

If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a

background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

Equal Employment Opportunity Policy

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

Reasonable Accommodation Policy

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

Applicants should submit a letter of interest (cover letter) and current resume or curriculum vitae by August 16, 2024 to: CDEROTSHires@fda.hhs.gov

Please adhere to the following submission protocol:

- **Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name**
- **Reference 'Regulatory Health Project Manager' in the subject line of the email.**

Announcement Contact

For questions regarding this Cures position, please contact the Office of Translational Sciences recruitment and outreach liaison at CDEROTSHires@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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