Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Office of Program Operations (OPO)
Multiple Vacancies

Application Period: November 6, 2023 - November 20, 2023

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: Project Manager

Series: AD-0601

Location(s): Silver Spring, MD

Salary:
$78,592-$103,984 (Band A)
$94,199-$127,096 (Band B)
$112,015-$155,978 (Band C)

Work Schedule: Full-Time

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You WILL NOT 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) 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 Drug Evaluation and Research (CDER) mission 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 New Drugs (OND) is a super office within the Center for Drug Evaluation and Research responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Program Operations (OPO) purpose is to support the execution of a wide range of new drug program and business process activities, including ongoing implementation of programs/processes; design and execution of new programs/processes or initiatives; fulfillment of routine program/process performance monitoring and data requests; and continuous program and process improvement.

Duties/Responsibilities:

As a **Project Manager**, the incumbent serves in one of the Staffs of the Office of Programs Operations (OPO), providing support to the OND Director, OPO Director, and Staff Directors by applying project management principles and best practices to various initiatives, programs, meetings, workgroups, and communications that directly support scientific review, regulatory programs, and operational activities across OND and CDER.

Band A:

- Assists with project timelines and regularly reviews project status with senior project manager or supervisor to assist with identifying project risks and mitigations to keep projects on track.
- Schedules meetings and assists senior project manager or supervisor to develop agendas and background materials, facilitate meetings, track and follow-up on action items, and draft written communications.
- Utilizes information technology (IT) tools wherever possible to track and collect project updates to assist senior project manager or supervisor with monitoring project status. Triages, tracks, and facilitates clearance of responses to incoming requests for scientific, regulatory, or new drug review program information from the public, media, Congress, and other government agencies (such as CMS, foreign government regulatory agencies, etc.).
- Tracks and shares key metrics with senior project manager or supervisor to assist in the development of reports and identification of opportunities for improvements in OND's regulatory and user fee programs, as well as OND's scientific review and operational processes.
- Maintains knowledge of relevant operational, scientific, regulatory, and project management principles and best practices to assist with ensuring assigned projects, initiatives, programs, workgroups, and communications are consistent with the Agency's

public health mission.
- Follows established records management principles and CDER's Records Management Policy when creating and archiving documents.
- Assists with scheduling internal OND staff meetings and formal meetings with the sponsor/applicant, assembling relevant scientific and regulatory reviews and communications for background packages, and other basic project management activities associated with Formal Dispute Resolutions of scientific and regulatory decisions appealed to the OND Director level.
- The above responsibilities are applied by project managers across OPO, but with some variation depending on the OPO staff to which the project manager is assigned.

Band B:

- Meet duties and responsibilities outlined in Band A above.
- Participates in project timelines and regularly reviews project status with senior project manager or supervisor to assist with identifying project risks and mitigations to keep projects on track.
- Coordinates with senior project manager or supervisor to identify relevant stakeholders across OND, CDER, and FDA when initiating a new project.
- Participates in scheduling internal OND staff meetings and formal meetings with the sponsor/applicant, assembling relevant scientific and regulatory reviews and communications for background packages, and other basic project management activities associated with Formal Dispute Resolutions of scientific and regulatory decisions appealed to the OND Director level. The above responsibilities are applied by project managers across OPO, but with some variation depending on the OPO staff to which the project manager is assigned.

Band C:

- Meet duties and responsibilities outlined in Bands B above.
- Develops and manages project timelines, anticipating project risks, and coordinating with senior project manager or supervisor to identify and implement mitigations to keep projects on track.
- Identifies relevant stakeholders across OND, CDER, and FDA when initiating a new project.
- Schedules meetings, develops agendas, and background materials; facilitates meetings; create meeting minutes; and drafts written communications.
- The above responsibilities are applied by project managers across OPO, but with some variation depending on the OPO staff to which the project manager is assigned.

Supervisory Responsibilities: N/A

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 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.

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, AD-0601 Series

For more information please see: OPM Occupational Series Qualification Requirements.

Professional Experience:
Our ideal candidate would possess:

- Demonstrated experience in a professional or administrative field supporting decision-making and the development of recommendations for standardized processes, policies, or guidelines.
- Experience applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Experience working independently and proactively identify priorities and complete assignments with minimal oversight.

Desired Professional Experience:
Our ideal candidate would possess:

Band A
- Education, training, or experience pertaining to medical product development or the social sciences or a health-related field.
- Experience identifying problems and gathering information to assist with generating alternative solutions.
- Experience communicating both orally and in writing.

Band B
- Knowledge of operations and the nature of regulations, guidelines, policies, and procedures.
- Education, training, or experience pertaining to medical product development or the social sciences or a health-related field.
- Experience communicating both orally and in writing.

Band C
- Experience with and knowledge of operations and the nature of regulations, guidelines, policies, and procedures.
- Education, training, or experience pertaining to medical product development or the social sciences or a health-related field.
- Demonstrated experience and knowledge with data gathering methods and assisting with assessments of business processes or programs.
- Experience identifying and analyzing problems weighing the relevance and accuracy of information and generating alternative solutions with oversight.
- Experience communicating both orally and in writing with diverse audiences, including scientific professionals.

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/ Moderate Risk (A/B/C)

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 the 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

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

Submit resume with cover letter and unofficial transcripts by **November 20, 2023,** to Lisa Conrad at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference Job Reference ID: **PO-23-014** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Wright at Danielle.Wright@fda.hhs.gov.

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

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