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 Executive Programs (OEP)
Special Project Staff (SPS)

Application Period: September 16, 2024- October 3, 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: Research Program Manager

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $139,395

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: 25% or less

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) 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 Executive Programs oversees a variety of Center-wide programs, including executive project management, the Center's executive secretariat function, scientific advisory committees, training and development, CDER's ombudsman, and program and administrative management.

The CDER Special Projects staff manages various projects and initiatives for the Center. Typically, these projects involve novel strategies, high profile, and complex and sometimes controversial issues. In addition, this staff manages projects that cut across Center programs or involve CDER and other Agency offices or Centers. Some projects involve facilitating and coordinating external collaborations and partnerships. Others may involve preparing for Congressional oversight hearings for particularly difficult and complex issues.

Duties/Responsibilities

The **Research Program Manager** plays a critical role in ensuring the effectiveness and safety of the Center for Drug Evaluation and Research's (CDER) research programs. As a key member of the Special Projects Staff (SPS), this position is responsible for implementing and managing CDER's research and lab safety programs. The primary purpose of this position is to ensure that CDER's research activities are conducted safely, efficiently, and in compliance with all relevant regulations and policies. Specific duties are as follows:

- Leads the development and implementation of CDER's research and lab safety program strategic vision, policies, and procedures. Establishes and maintains effective communication channels between center offices, councils, and related groups to provide targeted policy information. Engages with CDER staff, research councils, and safety committees to ensure clarity and understanding of procedures and requirements.

- Develops, implements, and maintains policies, procedures, and guidance documents for CDER's research and lab safety programs. Collaborates with the CDER Research Governance Council to support the development of guidance on reporting and review requirements for new initiatives. This includes updating and maintaining documents such as CDER's Manual of Policies and Procedures and other relevant FDA guidelines.

- Creates and manages tracking systems and dashboards to assess and report CDER compliance with Food and Drug Administration (FDA) research policies and training needs. Ensures CDER compliance with all training and policy requirements for research activities, including but not limited to Occupational Safety and Health Administration (OSHA) and other Federal Regulations. This includes overseeing compliance for activities involving Human Subjects Protections/Institutional Review Board (IRB), Animal Research, Radioactivity, Human-Based Adaptive Tests (HBAT), Dual Use Research of Concern (DURC)/ePPP, and General Laboratory Safety.

- Manages complex projects by leading project teams, scheduling meetings, preparing agendas, and recording official minutes. Represents CDER's viewpoint independently in

Agency and Interagency committees, task forces, or working groups related to Special Project Staff (SPS). This may include participation in groups such as the CDER Research Governance Council or cross-functional teams focused on improving regulatory and scientific processes.

- Serves as the primary point of contact for coordination between FDA and other government stakeholders on SPS projects. Provides timely updates to Center Management on project status and resolves administrative and policy issues to ensure project goals are met. This includes engaging with the Center Director, Deputy Center Directors, Office Directors, and other key Center staff.

- Collaborates with the CDER Research Governance Council to develop and implement research and lab safety benchmarks and impact metrics to assess progress and outcomes. This includes evaluating the effectiveness of regulatory processes and assessing compliance with regulatory requirements.

- Analyzes current and future policies to formulate strategies addressing gaps and issues in science and research programs. Develops action plans and implements follow-up mechanisms to ensure Agency compliance with applicable laws, regulations, policies, and standards. This includes ensuring compliance with public availability requirements for results of FDA-funded research.

- Evaluates research and lab safety programs to identify and implement innovative process improvements with significant organizational impact across CDER. Standardizes business requirements to facilitate systems development in CDER. This may involve working with the Office of Translational Sciences (OTS), Office of Pharmaceutical Quality (OPQ), and other CDER super offices engaged in research.

- Builds and maintains strategic relationships to enhance communication for research project review and prioritization activities. This includes working with internal stakeholders such as CDER staff and external stakeholders such as industry representatives and other regulatory bodies.

- Coordinates responses to all research-related inquiries from various stakeholders, including Agency leadership, Office of Inspector General, Congressional offices, and Government Accountability Office. Ensures responses align with the organization's mission and vision.

- Keeps Center leadership and other officials informed on scientific programs and resources related to CDER's research and lab safety program. Identifies potential vulnerabilities and proposes solutions for CDER leadership to evaluate and determine appropriate actions. This includes preparing comprehensive reports, such as Annual Reports on research activities and outcomes.

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: 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.

Desired Skills and Experience:

- A Master's degree or higher is preferred.
- A minimum of 4 years of progressively responsible experience in research program management, regulatory affairs, or a related field, with at least 2 years of experience in a leadership or project management capacity.
- Experience in managing complex research programs, including developing and implementing policies, procedures, and guidance documents related to research and lab safety. This includes conducting assessments, analyzing compliance, and identifying areas for improvement.
- Proven track record of successfully coordinating and overseeing research projects, utilizing strategic planning, risk management, and effective communication to ensure project goals are met.
- Comprehensive knowledge of FDA research policies, relevant regulations (e.g., OSHA requirements, human subjects' protection, animal research regulations), and agency-wide research initiatives. Ability to provide authoritative interpretations and policy advice based on FDA regulatory information and scientific publications.
- Experience in collaborating with senior leadership, cross-functional teams, and external stakeholders to review and enhance research processes and policies.
- Excellent communication and interpersonal skills for developing and presenting clear, concise, and persuasive materials on research program activities to diverse stakeholders, including senior management, researchers, regulatory bodies, and industry representatives.
- Strong analytical and problem-solving abilities to identify, prioritize, and address research program challenges effectively.
- Proficient in project management, including triaging, tracking, and reporting on multiple research projects, and overseeing the development and maintenance of guidance documents and tracking systems.

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

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

Submit resume or curriculum vitae with cover letter by **October 3, 2024**, to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions, please contact CDER-OCD-OEP-Hires@fda.hhs.gov. Please reference Job ID: **Research Program Manager** in the email subject line.

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

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