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 Strategic Programs (OSP)

Application Period: November 7, 2022, to November 18, 2022

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: Supervisory Operations Research Analyst

Series: AD-1515

Location(s): Silver Spring, MD

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: Non-Bargaining Unit

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 are 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of Strategic Programs (OSP) is responsible for quantitative and qualitative data analysis, program evaluation, business process modernization, decision support services to facilitate effective operations, consultation to Center Offices in developing strategic and operational plans for CDER, cross-center management and coordination of work on Center-wide governance and special initiatives, and the implementation of IT solutions to meet CDER's business needs. OSP provides essential expert support and enabling services for CDER to meet its mission objectives

Office of Program and Strategic Analysis (OPSA) is responsible for quantitative, qualitative data analysis, business process analysis, improvement, and program evaluation to support senior management decisions. OPSA provides consultation services to Center Offices in developing and implementing proposals for key strategic initiatives and priorities, evaluating the impact of operations and policies on external stakeholders, and in conducting evaluation studies to inform Center strategy and policy position on emerging issues in drug regulation.

Duties/Responsibilities

As the **Staff Director** of the Program Evaluation and Implementation Staff (PEIS) in the Immediate Office of OPSA, the incumbent is responsible for providing leadership, strategic, and technical direction to the PEIS.

- Provides leadership and oversight for the staff's preparation of summaries of work, reports, and other products and oral presentations of studies and analyses to Center leadership, internal stakeholders, and external audiences, such as conference and seminars. Plans, executes, and manages the PEIS on how to analyze customer's current state and corresponding strategic goals, and influences them to independently identify and explain how the team could apply OPSA services. These activities can cover a range of business issues and processes such as those for regulatory review of medical products. Periodically reviews staff's work products to ensure the work objectives are met.
- Directs and coordinates the implementation of significant initiatives that can include implementation partners and stakeholders from multiple organizations. Advises Center Commissioner, Center Directors, and Office Directors throughout FDA leadership, senior agency officials, program directors, and scientific and professional personnel on best practices in medical product related program implementation.
- Provides expert insight and guidance on different qualitative and quantitative analytical techniques used to examine and/or uncover current and historical trends regarding the operation and management of medical product related programs within the Center, develop relevant predictions, and solve problems across the Center. Explores and shares novel approaches to collect, review, and analyze complex unstructured, or structured quantitative and qualitative data related to specific medical product related programs/policies/initiatives from disparate sources (i.e., querying tools) and examines it for integrity and validity.
- Monitors and validates the selection of evaluation frameworks (i.e., process, impact, outcome, and summative evaluation) for an evaluation of programs, prediction of

behavior or phenomena, and/or the communication of results, their creation of an evaluation plan (i.e., background, questions, data collection, methodology, metrics, deliverables), and design of evaluation questions based on the customer's objectives and key research.

- Develops and directs analyses for user fee negotiations and provides strategic advice to Center and FDA leadership related to those analyses. Participates in user fee negotiations with regulated industry as needed.

Supervisory Responsibilities: Manages a staff who serve as experts in their field and are responsible for programs of multi-discipline focus within the organization. Provides occupational specific technical and administrative direction 25 percent or more of the time to eight or more subordinate employees performing the work and functions of the organization. Obtains resources, identifies strategic objectives, and establishes goals for the Division.

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: Supervisory Operations Research Analyst, AD-1515

Degree: in operations research; or at least 24 semester hours in a combination of operations research, mathematics, probability, statistics, mathematical logic, science, or subject-matter courses requiring substantial competence in college-level mathematics or statistics. At least 3 of the 24 semester hours must have been in calculus.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Professional Experience:

- Possess a graduate level or higher degree in a technical or scientific field from an accredited institution of higher learning.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to identify the internal and external politics that impact the work of the organization.
- Demonstrated ability to conduct successful formal negotiations with stakeholders within and outside of FDA.
- Established ability to work independently and also as a contributing, collaborative team member.
- Demonstrated ability to perform project management and time management skills (e.g., organizing time effectively and determining priorities).

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 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 an 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.

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

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 **November 18, 2022,** to: CDEROSPRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within 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: PEIS Supervisory Operations Research Analyst.**

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact CDEROSPRecruitment@fda.hhs.gov.

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