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)
Office of Policy and Strategic Analysis (OPSA)

Application Period: September 1, 2021 – September 9, 2021
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 (OPSA Deputy Director)

Series: 1515

Location(s): Silver Spring, MD

Salary: Starting at $163,962.00

Work Schedule: Full Time
Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 5% or less

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 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.

This position is located in the Immediate Office (IO), Office of Program and Strategic Analysis (OPSA) within the Office of Strategic Programs (OSP) in CDER at FDA. OPSA is responsible for quantitative and qualitative data analysis, business process analysis and improvement, decision science support, 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

The incumbent supports the Director's role as Program Manager and Principal Management Official. In this capacity, the incumbent provides expert-level leadership and consultation on strategic and operational plans through the following activities:

Participates with the OPSA Office Director in developing and organizing policies and projects and other related concerns for the management of assigned programs. Serves as expert advisor to the OPSA Office Director in the execution of CDER's strategic performance plan development. Supports the OPSA Office Director in analyzing, planning, and developing programs and projects.

- Explains and interprets applicable laws, rules, regulations, and procedures as to the best solution for handling complicated and unusually complex problems.
- In collaboration with the OPSA Director, evaluates the impact of operations and policies on external stakeholders, including patients, consumers, health care provider, constituents, and regulated industry. Participates in the oversight and management of the Center's User Fee programs.
- Manages change throughout the planning and implementation process of a large portfolio of projects. Consults with management and planning personnel in preparing requirements and criteria for complex or high value projects or programs. Provides guidance and technical advice to program offices in the performance of related assignments and provides consultative advice on assigned projects as needed.

In collaboration with the OPSA Director, evaluates the impact of operations and policies through subordinate staff directors and other employees. Performs full range of second and third-level managerial duties for the Office including providing technical oversight of work products that may include complex analytical, scientific, qualitative, and quantitative components:

- Program Evaluation and Implementation Staff conducts qualitative and quantitative analyses to inform internal strategy and decision making; conducts program evaluation studies, including designing evaluation frameworks, and facilitates development of strategic and operational plans across the Center.
- Economics Staff serves as technical expert and knowledge resource regarding commercial business and economic drug development to inform Center leadership of industry trends used to support decision-making. Conducts economic analyses

and modeling to enable proactive rather than reactive event monitoring.

- Analytics and Data Services Staff supports maintains performance reporting requirement for brand, biologics, generics, and biosimilar drug products in alignment with regulations, policies and program needs.
- Lean Management Staff provides consultation and application of Lean Management concepts and principles are used within the Center; chairs and oversees process governance on behalf of the Center.
- Resource Capacity Planning Staff serves as focal point for resource capacity planning and its interfaces with budget planning, execution, and relevant financial analyses for medical product user fee programs that impact CDER; provides resource capacity planning analysis to human drug user fee and non-user fee program stakeholders to inform resource requests and allocation decisions in all organizational components; oversees activity-based time reporting.
- Decision Support and Analysis Staff serves as the subject matter experts for developing and incorporating decision analysis tools, methods and approaches to support, structure, and effectively communicate Center's drug regulatory decision making, including but not limited to benefit- risk assessment, uncertainty assessment, patient elicitation methods, and other decision framing approaches.

Position Summary: The Deputy Director shares fully responsibility with the OPSA Office Director in managing the office and program work. Assists the Office Director with the development of long-range strategic planning process, including strategic program planning, and coordination with the Office of Commissioner and Department of Health and Human Services long-range planning process. Coordinates, manages, and oversees various projects, programs, and cross-cutting initiatives for the Center. Develops novel methods and approaches in planning,designing, and integrating the policies, procedures, programs, and other related management considerations. Develops strategies for planning and/or implementing agency programs with broad scope and impact on the Centers operations. Administers complex program(s) requiring budget management, human resources allocations, administration, procurement, and other considerations.

The Deputy Director collaborates with the OPSA Director to conduct periodic and comprehensive productivity evaluations of ongoing functions to ensure that the organization meets its stated goals and identifies areas where operational efficiency can be enhanced. Reviews productivity in all areas, monitors problem areas and oversees implementation of solutions that will eliminate them. Makes recommendations and, where appropriate, takes actions necessary to maintain or improve the quality and quantity of operational services that involve the introduction or refinement of automation, reorganization of operating sections, reassignment of personnel, and development of proposals to increase the organization's resources or other actions. Resolves issues in areas where there are high levels of uncertainty and balances conflicting interests of extreme national or international importance.

Supervisory Responsibilities:

Supervises the Immediate Office Acquisition staff; And assists with managing an office, providing leadership and management oversight to 59 subordinates and staff directors. Helps manage and direct a staff of technical and scientific professionals, administrative personnel, and support staff through subordinate supervisors and team leads. Provides occupational-specifically technical, scientific, and administrative direction to subordinate supervisors performing the work and function of the organization twenty-five percent or more of the time. Obtains resources and identifies strategic objectives for the organization.

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. Top Secret Security Clearance is Required for this position.
- A Statement of Understanding is required to be signed by the selected candidate indicating they understand the terms and conditions to this appointment.

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:

Meets Office of Personnel Management Individual Occupational Requirements for Operations Research Series, 1515. For more information please see: OPM Occupational Series Qualification Requirements

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.

Desired Education: Graduate or higher-level degree in a technical or scientific field from an accredited institution of higher learning.

Professional Experience:

- Candidate should have advanced level of demonstrated skill and experience in leading complex facilitations.
- Candidate should have demonstrated experience in leading teams of analysts with a large and diverse portfolio of projects.
- Candidate should have strong communication skills and experience in communicating with audiences at all levels of the organization and should have demonstrated experience in representing their organization in senior-level meetings with internal and external stakeholders.
- The ideal candidate will have experience in financial and operational oversight of large complex programs.

Desired Professional Experience: There is no desired professional experience for this position.

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: Top Secret Security Clearance is Required for this position. This position requires a Top Secret security clearance and the incumbent has access to sensitive, propriety, or financial information, documents and facilities related to national security. 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 reinvestigation or supplemental investigation may be require at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, 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 and transcript by September 9, 2021 to: Brad.Goins@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". For questions please contact Brad Goins, 240-402-3502.

Announcement Contact

For questions regarding this Cures position, please contact Brad Goins at Brad.Goins@fda.hhs.gov.

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