



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 Strategic Programs (OSP)
Office of Program and Strategic Analysis (OPSA)
Lean Management Staff (LMS)

Application Period: September 11, 2023 – October 2, 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: Operations Research Analyst

Series: AD-1515

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 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 compensated 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.

The Office of Program and Strategic Analysis (OPSA) is responsible for quantitative and qualitative data analysis, business process analysis and 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.

The Lean Management Staff (LMS) serves as the Center coordinator and focal point to drive cross-organizational operational improvements.

This position is located in the Lean Management Staff (LMS), Office of Program and Strategic Analysis (OPSA) within the Office of Strategic Programs (OSP) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

Duties/Responsibilities

As an **Operation Research Analyst**, the incumbent conduct analyses, evaluations, and implementations of CDER programs and initiatives. This work will have a direct effect on decisions affecting major Center regulatory policies and programs. The incumbent will utilize tools and techniques such as evaluation, management science, and economics.

Band A:

- Assist with complex analyses, selects the appropriate techniques, and participates in the analytical process to collect applicable quantitative and qualitative data, evaluate, and diagnose challenges.

- Observes and synthesizes findings from work group sessions that are held by the Center or Agency in order to gain insight into the root causes and impact of processes and programs.
- Assist with compiling data examine current and historical trends regarding the operation and management of programs, policies, and processes within the Center. Techniques include, but are not limited to strategic analysis, root cause analysis, operations research and analysis, process analysis and improvement, value-stream analysis, risk analysis, or decision analysis.

Band B:

- Meets duties and responsibilities outlined in Band A above.
- Evaluates the customer’s readiness for change (i.e., identifying barriers and strengths) and implements coordinated and thoughtful change management strategies that appropriately address the operational gaps and process changes which are a by-product of various projects. In simpler situations, the analyst manages components of a change management plan (i.e., communication tools, timelines, outputs, etc.) and leverages the proper strategic communications techniques with internal and external customers.
- Participates in researching successful approaches to implementation and shares information to incorporate findings and then develops and implements tools and methodologies for the improvement of current or future programs, initiatives, and processes.

Band C:

- Meets duties and responsibilities outlined in Band B above.
- Assesses and evaluates the customer’s readiness for change (i.e., communication tools, timelines, outputs, etc.) and leverages the proper strategic communications techniques with internal and external customers.
- Monitors and conducts stakeholder analysis, explores, and leverages potential stakeholders and champions of change and participates in the involvement of leadership and their teams who impact or influence the outcomes of ongoing projects and their subsequent implementation efforts.

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 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.

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:

[Operations Research Series, 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 Experience:

Our ideal candidate will possess:

- Ability to apply the principles, concepts, tools, and methodology related to evaluation, implementation, and strategic analysis.
- Ability to identify and collect necessary relevant information to address a routine issue/problem, including both qualitative and quantitative information with an emphasis on experience gathering qualitative data via interviews, focus groups, and surveys.
- Knowledge of techniques used to design and execute change management programs, process improvement efforts, program evaluations, and/or implementation plans.
- Experience participating in workgroups with stakeholders from multiple disciplines and sectors.
- Ability utilizing written and oral communication techniques required to prepare and deliver reports and presentations to a wide range of audiences.

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/Low Risk (A) and Non-Sensitive/ Moderate Risk (B/C).

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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 transcripts by **October 2, 2023**, to:

CDEROSPRecruitment@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”.

Please reference “**Operations Research Analyst OSP/PEIS**” in the subject-line when applying or submitting questions.

Announcement Contact

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

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

FDA is an equal opportunity employer.

