Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of the Center Director (OCD)
Quality Management Staff (QMS)

Application Period: June 13, 2024 – July 12, 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: Operations Research Analyst

Series: 1515

Location(s): Anywhere in the U.S. (Remote Job)

Salary: Salary is commensurate with education and experience and starts at $139,395.00

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position requires less than 25% of travel

Supervisory: No

Bargaining Unit: 3581

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 safe, and effective.

The mission of the Center for Devices and Radiological Health (CDRH or Center) is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. The Office of the Center Director (OCD) provides vision, leadership, strategic direction for the

Center regarding the regulation of medical devices and radiation-emitting products. Also provides leadership and direction for Center-level management, planning, and evaluation systems to ensure optimal utilization of personnel, budgetary and financial resources.

Duties/Responsibilities

The OCD's Quality Management Staff is responsible for:

- Providing vison, leadership, and strategic direction for the Center regarding quality management, and organizational excellence.
- Establishing and developing resources to facilitate implementation of quality management and organizational excellence for CDRH.
- Integrating applicable quality management and organizational excellence principles and best practices into key business processes.
- Establishing a foundation for quality, effectiveness, efficiency, and improvement for all products, services, and business processes.
- Supporting CDRH's mission to achieve organizational excellence, efficiency and effectiveness while delivering continually improved products and services to provide the public access to safe, effective, and high-quality medical devices and safe radiation-emitting products.

The Operations Research Analyst will provide expert direction to Center staff and leadership to ensure that regulatory, technical, and operational processes and procedures support effective, efficient, and optimal utilization of personnel, budgetary and financial resources, information technology, and facilities. Will lead studies, analyses programs, and provide expert quality, process improvement and organizational excellence support to facilitate and coordinate the development, clearance and delivery of strategies, processes, and procedures necessary for the implementation of Congressional mandates and strategic initiatives, including development of plans, strategies, materials, and background information for meetings and projects.

The Operations Research Analyst is a recognized improvement expert in medical device technical, regulatory, and administrative processes and procedures, providing information, expert advice, and consultation to FDA centers, the Agency, and private industry on the improvement and implementation of processes and procedures to support addressing unique and complex technical, regulatory, and operational medical device program and process issues. The operations research analyst is also an expert consultant in the planning, monitoring, and administration of CDRH quality management and operational excellence programmatic areas including, for example, the Process Improvement Program, the Audit Program, the CDRH ISO 9001:2015 Certified Quality Management System, and a broad range of projects with significant impact on Center strategic priorities.

The Operations Research Analyst also performs the following duties:

- Serves as an agency authority on the application of quality management and organizational excellence methodologies to technical and regulatory processes.
- Works with Center and other agency senior leaders to develop or oversee the development of process improvement and organizational excellence strategies to support implementation of quality management and organizational excellence across

the Center.

- Collaborates with engineers and medical and healthcare professionals on a wide range of regulatory and policy processes improvement projects.
- Serves as a Center focal point for the identification and resolution of quality and organizational challenges affecting CDRH products and services.
- Assists in developing new concepts and procedures, and in ensuring consistency within CDRH.
- Conducts discussions with stakeholders including scientists, engineers, medical and healthcare professionals, and management officials regarding the impact of quality management and organizational excellence on regulatory policies and procedures.
- Articulates, explains, and defends the CDRH□s initiatives and goals intelligently and accurately, knowing the importance and implications of people and institutions having differing interests and responsibilities.
- Maintains effective working relationships with medical device experts.
- Works closely with officials and technical specialists on areas such as Medical Device User Fee Acts and associated efforts that directly impact the resources available to the Center to perform its mission.
- Works with Center Leadership to develop and evaluate positions and proposals for the solution of complex issues related to quality management, organizational excellence, and process improvement as it applies to medical device regulation; provides authoritative and direct assistance to Center staff and maintains good working relationships while working out substantive disagreements.
- Explains program or project goals, seeks to persuade others to support approaches enhance quality management and organizational excellence, and coordinates and completes projects.
- Develops recommendations and provides advice and consultations regarding quality, organizational excellence, and process improvement issues to the CDRH leadership and other key agency officials.
- Deviates from or extends traditional practices and programs and develops solutions to extremely complex scientific regulatory and technical problems using improvement methodologies. Interprets and applies existing practices, setting precedents that affect CDRH program activities and the marketing of regulated medical device products.
- Uses quality and process improvement methodologies to improve the development and application of processes associated with policies, procedures, guidance, and regulations for medical device products and works with senior and expert subject matters across the FDA and CDRH as appropriate.
- Addresses new and existing standards, regulations, procedures, and policies, and applies quality and process improvement methodologies to help ensure they meet current regulatory and policy requirements.
- Provides leadership and expertise on quality management and process improvement to FDA's technical experts and provides a lead role responsibility in Center Strategic Initiatives applying quality management and process improvement to all activities that further the Center's mission.
- Engages in strategic planning on resource issues related to all the above-mentioned activities (e.g., identifies innovative sources of manpower and dollars to support Center

initiatives).

- Participates directly in the planning and execution of implementation and improvement activities relevant to the oversight of regulatory activities, including agreements in the Medical Device User Fee Act. As a technical authority the incumbent works closely with the Center leadership to develop, evaluate, and gain Center consensus on quality and process improvement projects that directly impact policies, concepts, strategies, negotiating positions, procedures, and other courses of action.
- Through persuasion and leadership, ensures consistency across the Center in both the development and implementation practices and process supporting implementation of new policies.
- Provides leadership and guidance to professionals located in other parts of the Center who are developing and carrying out quality management and process improvement activities.
- Leads and represents the center on task forces, planning groups, or special study groups.

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: A bachelor's degree or higher in operations research, mathematics, engineering, science, economics, statistics, management science, or information technology. The degree must be from an accredited program or institution.

OR

Professional Experience: To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which is equivalent to the following: Comparable work in operations research or related disciplines that use scientific methods and techniques to analyze and optimize operations.

Desired Professional Experience: The ideal candidate will possess the following professional experience:

- Substantive work in planning new programs; reviewing program operations to develop or improve methods, procedures, or controls and bringing about major changes in program operations and procedures.
- Excellent communication skills.
- Ability to work collaboratively with a diverse cadre of customers and stakeholders.
- Ability to build and work effectively within teams.
- Ability to prioritize and make critical decisions.
- Experience leading and planning internal audits **or**
- Experience leading activities and project designed to monitor and improve interaction with customers.

How to Apply

How to Apply: Submit resume or curriculum vitae, with cover letter by **July 12, 2024,** to CDRHRecruitment@fda.hhs.gov**.** Compile all applicant documents into one combined document (i.e., Adobe PDF). Candidate resumes may be shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". Please include the following Job Reference ID in the subject line of your email submission: **CDRH/OCD/Operations Research Analyst-D**

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

Educational 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.

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.
- 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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: This position requires a *Public Trust* security clearance.

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.

Announcement Contact

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

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

FDA is an equal opportunity employer.