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: Assistant Director

Series: 0301

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: Yes

Bargaining Unit: 8888

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 or Office) 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 Assistant Director serves as a technical consultant to the Associate Center Director of Quality Management and Organizational Excellence and Assistant Directors in the Quality Management Staff regarding the development and implementation of quality assurance processes and policies to determine conformity of CDRH core, organizational, and enabling processes to requirements. Effectively negotiates with CDRH leadership, Associate Center Directors, Office Directors, and Assistant Directors to accept and address audit findings where remediation may require extensive changes in established procedures or may be in conflict with current approaches. Designs and develops reports using data in FDA databases to support quality assurance activities, including the assessment of program performance. Advises CDRH leadership on the development and implementation of quality assurance initiatives, key indicators, performance monitoring and analysis. Develops and presents briefings to CDRH leadership and internal and external clients, providing the probable consequences of the various courses of action along with recommendations.

Develops and maintains methods/capabilities to assess (reporting, dash-boarding, data quality) performance of CDRH quality assurance and audit processes and monitors performance of the QMS component of responsibility. Leads the implementation of improvements and programs within their area of expertise as well as across CDRH to assure compliance with Center-wide quality management and operational excellence programs. Develops process improvements to assure the compliance with practices and procedures in support of CDRH's audit quality management programs and Center's ISO 9001:2015 Certified Quality System. Analyzes statistical data and performs objective reviews of the quality assurance and management program to verify adequacy, effectiveness, and compliance with regulations and policies. Oversees development, implementation, and administration of CDRH's audit policies, business processes, standard operating procedures and work instructions that support continuous process improvement (CPI) of the CDRH quality management systems (QMS), CDRH operations and quality activities. Uses CPI as tool or systemic approach to improve the efficiency of the Center products and services within their area of expertise or assigned quality management activity. Identifies opportunities and plans for changes, collaborates with stakeholders to manage change, implements the change, uses data to analyze the results of the change, determines if the planned changes resulted in improvement; acts if the change was successful and implements it on a wider scale to continuously assess results. Conducts audits and analyses of assigned quality assurance activities programs, processes, policies, and procedures to determine compliance with standards; identify weaknesses or deficiencies; and makes recommendations to management for corrective action. Engages in collaboration with CDRH leadership and staff to develop performance measures that are meaningful and representative of CDRH and FDA quality, strategic, and operational goals, and objectives. Uses evidence-based performance measures to evaluate the organization's progress in complying with requirements and identifies opportunities for changes to CDRH products, services, quality management policies, processes, or programs.

The incumbent performs critical reviews of scientific or technical procedures, methodologies, inspections, and investigations in areas that require extensive interpretation. Evaluates the impact of procedures on scientific and regulatory policies and on overall activities and priorities of the quality management program. Supports and helps manage CDRH quality management

efforts and day-to-day operations related to the establishment of CDRH best practices and guidelines in the areas of quality management and operational excellence. Oversees the continual improvement of procedures supporting premarket review, post market surveillance and product compliance.

Supervisory responsibilities: Manages multiple projects and provides supervision and leadership to a team of multi-disciplinary personnel. Assigns work, manages timelines, and provides team-level feedback and concurrence on premarket, post-market and compliance submissions. Manages resources by considering employee expertise and workload in task assignment. Assesses progress on reviews, provides guidance on regulatory and scientific issues, and advises on training and professional development. Plans work to be accomplished by subordinates, sets and adjusts short-term priorities, and prepares schedules for completion of work; assigns work to subordinates based on priorities, selective consideration of the difficulty and requirements of assignments, and the capabilities of employees. Coach and mentor staff and help sustain a strong and dynamic culture across teams in the Division, including organizational agility, staff empowerment and mobility, and collaboration.

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.*

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:

Demonstrated experience with medical device review programs.

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

- Excellent communication skills
- Organizational Awareness and Business Process Improvement skills
- Strong analytical skills and problem-solving 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.

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/Assistant Director-Audits**

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.

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/Moderate Risk* 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

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

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.