Title 21 Vacancy
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices & Radiological Health (CDRH)

Application Period: 7/30/24 – 8/27/24

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: Center Director,
Center for Devices and Radiological Health

Series: 0601

Location(s): Silver Spring, MD

Salary: $301,825 - $400,000

Work Schedule: Full-time

Pay Band(s): Band I

Full Performance Band Level: Band I

Travel Requirements: 25%

Relocation Expenses Reimbursement: May be offered.

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote

public health. CDRH ensures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the United States.

Duties/Responsibilities:

- Participates in the senior leadership of the FDA, working with the Commissioner and other members of the senior executive team to advance the agency's mission, inform key strategic and operational decisions, and identify and address risks to further the best interests of the agency and the public that it serves.

- Serves as the agency's scientific and programmatic lead on matters related to ensuring the safety and effectiveness of medical devices and to controlling unnecessary exposures of humans to, and assuring the safe and efficacious use of, potentially hazardous ionizing and non-ionizing radiation.

- As the Center Director, the incumbent provides executive leadership in managing/directing over 2,200 scientific/professional/technical support personnel engaged in developing/executing nationwide programs/activities in the areas of radiological health and medical devices.

- Leads the Center's senior leadership team, setting the vision and strategic priorities for the Center, and measuring success. Provides technical guidance and executive leadership for Center programs. Reviews and evaluates scientific proposals and plans submitted by subordinate components within the Center in terms of substance, sufficiency of project protocols, related priorities, availability of resources and probable benefit from results. Makes decisions and/or recommendations that have major impacts on the Center's scientific and technical activities.

- Provides direction/guidance on policy issues and controversial program matters related to the Center's activities in areas such as: the development of policies and priorities relating to the clinical investigation and premarket approval of new medical devices technologies; the safety, effectiveness, and labeling of all medical devices; the development of research and testing relating to medical devices and to the health effects of radiation exposure; and the development and administration of performance standards for medical devices and radiation-emitting electronic products, as well as guidelines and recommendations concerning medical x-ray usage.

- Provides information/guidance on Center programs designed to increase nationwide awareness among health professionals and consumers in the areas of medical devices and radiation protection, and to generate support and gain acceptance of Center guidelines and recommendations from the professional/education communities.

- Reviews/approves Agency's new/revised/proposed policies involving regulatory responsibilities as they relate to radiological health and medical devices. Provides approval/disapproval decisions and/or recommendations based on findings of fact and application of FDA's statutory standards and regulations. Ensures resolution of

legal/administrative/regulatory problems and issues encountered in the conduct of the Center's surveillance and compliance programs.

- Develops and maintains liaison with national and international organizations to advance the work of the Center. Maintains liaison with international counterparts to advance global harmonization and convergence of medical device regulation and assure the safety of medical devices and radiation-emitting products.

- Maintains liaison with other Federal, State and local agencies with responsibilities concerning health care delivery and provides and/or solicits assistance in order to ensure consistency of standards, guidelines, education and research related to medical device safety and radiation protection practices.

- Represents the Center in meetings, discussions, and conferences with officials of Congress, HHS, PHS, FDA, other Federal, State and local governmental agencies, the scientific and academic community, representatives of regulated industries, and others to present and explain Center activities, plans, policies, and decisions. Testifies to Congress at hearings in area of expertise with or on behalf of the Commissioner.

Supervisory Responsibilities:

- Manages the Center for Devices & Radiological Health (CDRH). Directs the effective and efficient use of Center scientific and technical personnel. Identifies and assists in recruiting/securing high quality personnel for key positions. Encourages and fosters professional and career development of staff and managers.
- The incumbent establishes and directs organizational objectives that encompass the agency's public health mission, operational matters and human capital strategies.
- Provides overall direction and support of Equal Employment Opportunity (EEO) administration and management for the Center. Participates in the development of monitoring systems to review and measure EEO progress included in Senior Executive Service and Merit Pay plans of Center senior staff.

EEO responsibilities:

Exercises leadership to ensure that all programs under his/her direction reflect the principles of equal employment opportunity and workforce diversity in their management and operation in such areas as recruitment and staffing by inclusion of minority groups, women, and people with disabilities; employee development; staff assignments; and communications. In addition to demonstrating personal commitment to the objectives of equal employment opportunity and workforce diversity, the incumbent ensures that subordinate supervisors and managers recognize the importance of their EEO and diversity enhancement responsibilities. Provides reasonable accommodations needed to best utilize qualified people with disabilities. The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to race, color, religion, sex, national origin, age, or disability.

Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Agency in the following:
(1) merit promotion of employees and recruitment and hiring of applicants;
(2) fair treatment of all employees;

(3) encouragement and recognition of employee achievements;
(4) career development of employees; and
(5) full utilization of their skills.

Position requires eligibility for access to Sensitive Compartmented Information (SCI), other intelligence-related Special Sensitive information, or involvement in Top Secret Special Access Programs (SAP).

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 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 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.
- This position is designated as an SES Equivalent position.

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

1. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Title 21 appointments. The FDA Office of Talent Solutions (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 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:

General Medical and Healthcare Series, 0601

Candidates must have the following:
Degree - a doctoral-level degree from an accredited institution of higher learning, such as: Ph.D., M.D., D.V.M., D.D.S., D.N.D., Sc.D., or degree with major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position equivalent to a Ph.D.;

AND

Professional Experience:

- Strong background in public health or medical products regulation including more than fifteen **years related experience** in the scientific, clinical, and/or public health research fields.
- Demonstrated knowledge and understanding in the breadth of science applicable to FDA's medical device and radiological health regulatory programs.
- In-depth knowledge of the Agency's policies, and scientific and regulatory programs as they relate to medical products.
- Demonstrated experience in building partnerships and coalitions with stakeholders in public and private arenas.

Mandatory Managerial/Executive Qualifications:
Candidates must have the ability to bring about strategic change, both within and outside the organization, to meet organizational goals; the ability to lead people toward meeting the organization's vision, mission, and goals:

- Demonstrated executive-level leadership experience directing large diverse and multi-disciplinary organizations, including scientific and regulatory organizations.
- In-depth knowledge of the Federal authorities, policies, scientific and regulatory programs as they relate to medical devices and radiological health.
- Expertise in setting public-health goals and priorities based on risk prioritization and desired public health outcomes.
- Expertise in establishing decision-making frameworks that balance public health, legal, regulatory, scientific, and policy considerations
- Ability to build coalitions internally and with other Federal agencies, State and local governments, nonprofit and private sector organizations, foreign governments, or international organizations to achieve common goals.

Desired Qualifications:
Candidates should have:

- Executive level administrative or managerial experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment.
- Experience indicating the ability to communicate and effectively interact with the scientific/academic and public health communities; medical and other health-related organizations; high level government officials, including members of Congress, principal representatives of counterpart Federal agencies, foreign government officials; CEO-level and other senior representatives from regulated industry; and other research stakeholders.
- Experience establishing organizational policy, including the implementation of new legislative authorities or other significant mandates.
- Experience managing staff allocation and a fluctuating operating budget for a complex program.

- Experience leading a significant scientific organization within government, industry, or academia.
- Extensive knowledge in radiological health and the development and manufacturing of medical devices;
- Familiarity with the application of FDA laws and regulations.
- Training, professional development, and outside activities that provide evidence of initiative, resourcefulness, and potential for effective job performance, such as invitations, presentations, and international activities.
- Receipt of honors, awards, or other recognition for performance or contributions based on managerial experience and/or scientific excellence.

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.

Background Investigation/Security Clearance Requirements:

This position requires a Top-Secret security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top-secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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.

Drug Impact Statement for Top Secret Clearance

The position requires a Top-Secret/Sensitive Compartmented Information (TS/SCI) security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top-secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage.

Testing Designated Position (TDP)

This is a Testing Designated Position. Incumbent must submit to and successfully pass a urinalysis drug screening prior to appointment. The Incumbent will also be subject to unannounced random drug testing for the duration of their time in this position, in accordance with the HHS plan for a Drug Free Workplace.

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 **11:59pm on 8/27/2024** to: CuresExecutives@fda.hhs.gov.

For questions, please contact CuresExecutives@fda.hhs.gov. Please reference Job Reference ID in subject line of email: FDA-CDRH-2024-03

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