Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Medical Devices and Radiological Health Operations (OMDRHO)

Application Period: August 22, 2022 – September 4, 2022

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: Deputy Director, OMDRHO

Series: 0696

Location(s): Nationwide, with the ability to travel to Silver Spring, MD, White Oak, MD or ORA District Offices for senior level meetings or staff meetings.

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25%

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) is a Federal, science-based regulatory agency with the legislated responsibility to promote and protect the health of the nation's 265 million consumers, in their use of foods, food additives, human and animal drugs, biological products, cosmetics, medical devices, tobacco products and radiation-emitting products and substances. FDA's programs are global in scope and effect, and its activities directly affect and heavily impact on multi-billion-dollar industries, assuring honest and fair dealing in the marketplace, while protecting the public health.

To view our ORA Vision, Mission, and Values please visit:
https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.
FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. ORA supports the six FDA product centers by inspecting regulated products and manufacturers, conducting sample analyses on regulated products and reviewing imported products offered for entry into the United States. In addition to executing its mission through its federal workforce, ORA also works with the FDA Centers, who develop FDA wide policy on compliance and enforcement and ORA executes the annual commodity work plans. Over 5,000 ORA employees located in district offices, resident posts and laboratories, strategically located throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education and outreach directly to consumers, industry representatives, importers and shippers as well as other stakeholders across the nation. ORA also works with its federal, state, local, tribal, territorial and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

Duties/Responsibilities

Functional duties and responsibilities:

The position functions as a Deputy who assists the Program Director and is empowered to exercise full authority in the absence of the Program Director. This involves the advancing of regulatory programs, promoting an understanding of FDA's responsibilities for enforcing regulatory standards to protect and promote public health, actions and activities related to FDA programs, and resolving complex policy questions and issues that arise. The Deputy, along with the Program Director, is directly responsible for providing leadership to employees who are engaged in inspectional and compliance activities related to the program area.

The Deputy participates fully with the Director in planning, managing, organizing, and directing all the activities of the organization through subordinate supervisors and/or team leaders and a highly trained and skilled staff of professional supervisors and subject matter experts in a variety of professional, administrative, and support staff occupations organized into subordinate organizations. The incumbent shares the Director's responsibility for assuring the efficient operation of the Office, including adequacy of on-the- job training, assignments, and performance of personnel.

In conjunction with the Director, the Deputy serves as the agency's authoritative consultant and focal point for ORA and personnel of state, local, tribal, and international regulatory agencies in planning and implementing necessary efforts related to a specific program. As delegated, the Deputy represents and speaks for the Director and, at times, the Associate Director for the Office of Management in meetings with agency and state officials in matters related to education and training administered by ORA.

The Deputy represents ORA in joint monitoring of the execution of the program work plan and, in consultation with the Program Director, negotiates on behalf of ORA any necessary adjustments required throughout the year. Monitors performance for adherence to plans. Negotiates modifications to plans and agreements for ORA with the Center as needed and assures all impacted ORA parties are informed of changes in a timely manner. Monitors and tracks regulatory actions and works with the Center to assure adequate coordination between the ORA, Office of the Chief Counsel (OCC) and the Center. Works closely with all ORA headquarters components to assure seamless interface between the

Center and ORA.

Supervisory Responsibilities: Manages a multi-disciplinary program, providing leadership and management oversight to 300+ including technical investigators, compliance and other subject matter experts and staff supporting the medical device program and division, investigations and compliance directors.

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.

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.*

Consumer Safety Series, 0696

Individual Occupational Requirements

Education Requirement: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education (external link) at the time the degree was obtained.

Applicants must meet one of the following requirements.

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work. The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Desired Education: An advanced degree in law, science, public health, management or other related field from an accredited college/university.

Professional Experience:

- Advanced knowledge of Medical Products and Tobacco.
- Demonstrated strength with organizational management, leadership and team building and the ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.
- Executive level experience in managing a diverse and geographically disbursed organization, including budgeting, capital investments and human resources.
- Executive level experience in developing and implementing an organizational vision for a large complex and diverse organization that integrates broad program goals, priorities, and balances change and continuity.
- Experience establishing operational policy, including the implementation of new legislative authorities or other significant mandates.
- Experience collaborating with top level officials within the organization as well as officials from federal, state, or city governments, professional health organizations, the regulated industry, consumer organizations, etc. to accomplish goals.
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or imported medical product and tobacco

activities.

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: 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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.

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

How to Apply: Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, CV and bibliography, SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through September 4, 2022. Candidate resumes may be shared with hiring official within the OMPTO with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov. Please reference Job Reference ID: Deputy Director, OMDRHO

Announcement Contact

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

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