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

Application Period: November 14th, 2022 – December 5th, 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: Senior Advisor (Medical Countermeasures Coordinator)

Series: AD-0696

Location(s): ORA district offices in Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Francisco, San Juan, Seattle

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 50%

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 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 multibillion 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.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. Over 5,000 ORA employees strategically located in district offices, resident posts, and laboratories 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).

The Office of Medical Products and Tobacco Operations (OMPTO) has responsibility for inspections, investigations, compliance and enforcement of medical products and tobacco facilities regulated by the Medical Products and Tobacco Centers. The incumbent is expected to have knowledge of ORA inspections of regulated products and manufacturers, provides expert advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Agency leaders on inspectional and compliance operations, training needs and emergency response activities related to advanced manufacturing and medical countermeasure regulated products.

To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values

Duties/Responsibilities

The Senior Advisor serves as the ORA authority with medical countermeasures (MCM) and advanced medical products manufacturing. Recommends operational policy relating to domestic and international program area through the preparation of opinion papers and providing advice and counsel to ORA management corresponding to the specialty area. Additionally, the senior advisor:

- Leads cross-cutting project coordination efforts for enterprise-wide entities as they pertain to agency-level inspectional activities and operational standards across all commodities.
- Collaborates effectively and coordinates throughout ORA and with external partners and stakeholders to gather input, develop recommendations for efficiencies in current work processes and implement changes; maintains appropriate and constructive relationships with Program offices and other components of FDA headquarters; and coordinates with Center compliance, technical and scientific staff to understand technical and regulatory issues with advanced manufacturing to ensure inspectional activities and operational policy keeps pace with industry advancements

- In collaboration with FDA's MCM agency leads, DHHS components and other government agencies:
    - Enhance communications and partnerships with external stakeholders in addressing global supply chain issues.
    - Ensures ORA's priorities are aligned and reflected in the overall advancement of modern, emerging, and advance technology through proactive and sustained collaboration.
- Coordinating with ORA Senior Emergency Response Coordinators (ERCs) and product centers on medical countermeasures preparedness and response activities
- Evaluates a broad range of issues concerning implementing legislation, regulations, policies and/or procedures affecting medical products programs and makes recommendations to the Associate Director for Advanced Medical Products.
- Monitoring emerging threats and data to identify resource needs and gauge Agency preparedness / response level.
- Representing the Agency at executive level meetings and serving as an authority on MCM subject matter
- Evaluates, develops, and maintains the ORA MCM training program, including new MCM priorities and initiatives, in consultation with management and development coordinator.
- Collaborate with OMPTO programs, Office of Training, Education, and Development (OTED), Centers, and Office of Counterterrorism Emerging Threats (OCET) to develop and execute MCM training and preparedness exercises.
- Participates in course advisory groups and/or curriculum committees and acts as training instructor, as appropriate.
- Acts as a liaison with other government agencies, industry groups and professional organizations to evaluate and leverage training expertise from outside FDA.
- Working with ORA/Center POCs s to ensure the development and implementation of standardized MCM procedures throughout agency.

The senior advisor is a field resource in inspections/investigations of the commodities regulated by the FDA. The incumbent serves as an advisor for Advanced Medical Product Manufacturing and ORA Management in the formulation of program goals, objectives and broad operating policies covering the full scope of specialized programs and activities related to medical products regulated by the agency. Provides professional and managerial expertise and leadership in the development and enhancement ORA field science-based regulatory surveillance and compliance programs that support FDA and ORA regulatory compliance goals and participates as a key member of OMPTO's management team in the development of long-range strategic and operational plans, complex cross cutting information collection and analysis and decision-making.

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 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.*

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 at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements

Consumer Safety Officer Series 0696

Professional Experience:

- Mastery of the principles, theories and practices related to advanced manufacturing including regulatory.

- Knowledge of the principles, theories, and practices of related scientific or professional fields that enable the incumbent to carryout tasks related to regulatory activities in medical devices and radiological health products.
- Mastery of inspectional and investigative techniques associated with the regulation of the domestic and international industries within the medical products device and radiological health and advanced manufacturing technologies functional program area.
- Comprehensive knowledge of the FD&C Act and regulations, related acts, laws legislation and precedents, that govern the procedures and guidance materials of ORA and associated organizations.
- Thorough knowledge of the principles and practices of manufacturing technologies in medical devices and radiological products health to serve as a technical authority on current and emerging technologies to provide authoritative advice and assistance to other senior technical experts on extensive and complicated manufacturing processes and operations and training opportunities.
- Mastery of legislation, laws, precedents, and regulations which govern ORA's activities related to Medical Device and Radiological Health Products to serve as a technical authority to interpret and provide advice on all related policies and develop new or revised existing approaches, precedents, and methods.
- Skill in oral and written communications to make clear, convincing presentations; represent the Agency at meetings and conferences; interact with high level officials and representatives from public and private public health organizations.
- Mastery of a wide range of advanced manufacturing and novel product technologies and qualitative and quantitative analytical methods and techniques to provide the Office Program Directors, ACMPTO and other senior staff of ORA with authoritative information, analyses, advice, and assistance in the formulation and solution of major, complex, and sensitive issues, emerging threats and problems which face ORA.

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.

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

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, resume, bibliography, redacted 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 December 5th, 2022. Please reference Job Reference ID: Senior Advisor, AMPM.

Announcement Contact

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

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

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