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)

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: Regulatory Program Manager

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 $126,233

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 50%

Bargaining Unit: 3591

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 Regulatory Program Manager develops, implements, and evaluates programs and projects; designs, plans, develops and enhances OMPTO projects and programs of high visibility, conducts special studies, meets, and consults with heads of various agency functions and provides consultation and expert advice in the coordination of projects between several different organizations. Additionally, the regulatory program manager:

- Manages activities and resources of cross-functional project teams; establish project plans and monitor project/program milestones and deliverables.
- Develops written project progress reports and oral presentations for internal and external stakeholders.
- Serves as primary point of contact for the up-to-date status of project progress and representing the team activities to management and/or external partners. Proactively advises senior leaders on recommendations for program improvements related to individual and overall project planning.
- Monitors and reports actual status of all activities within the assigned projects through interaction with project participants and, if required, supervisors and directors. Ensures

timelines and deliverables are met and raises any matters or issues to the Associate Director for Advanced Medical Products Manufacturing (AMPM).
- Serves as an ORA contact point for all project communications concerning advanced manufacturing / MCM operational and regulatory policy activities. Ensures ORA's priorities are aligned and reflected in in the overall advancement of modern, emerging, and advance technology through proactive and sustained collaboration
- Leads, manages, and facilitates the work of individual projects collaboratively.
- Interfaces with Center Regulatory Project Managers to ensure advanced awareness of AM/MCM related activities and coordinate operational engagement.

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:

- Knowledge 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.
- Knowledge 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.
- Knowledge 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.
- Knowledge of a wide range of advanced manufacturing and emerging product technologies man 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 technology 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: Regulatory Program Manager, 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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