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: December 9, 2022 – December 23, 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 for Therapeutics, Quality, and Emerging Regulatory Operations

Series: AD-0696

Location(s): Location determined upon selection

Salary: Starting at $203, 596 (Pay Table 1)

Work Schedule: Full Time

Cures Band(s): Band G

Full Performance Band Level: Band G

Travel Requirements: Nationwide, with the ability to travel to Silver Spring, MD, White Oak, MD, ORA District Offices for senior level meetings or staff meetings, and some international travel. Up to 40% travel is required.

Bargaining Unit: Non-Bargaining Unit Position

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 global 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 globe. 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/aboutfda/office-regulatory-affairs/ora-vision-mission-and-values

Duties/Responsibilities

The Deputy for Therapeutics, Quality, and Emerging Regulatory Operations (Deputy) shares fully with the ACMPTO and the Deputy for Technology and Bioresearch Quality and Support Operations, in the facilitation of office staff coordination between multiple, smaller program offices. The Deputy advises the ACMPTO and other senior managers and staff on program issues and problems. Other responsibilities include:

- Serves as the primary deputy for operational oversight of ORA's Advanced Medical Products Manufacturing program director.
- Provides executive leadership to ORA's global drugs and biologics programs and the respective Program Executives. Ensures that the ACMPTO is briefed on drugs and biologics operational issues of significance.
- Ensures that the ACMPTO is briefed on significant global inspectional activities, enforcement actions, and Center programs and policies impacting the aligned programs.
- Oversees the operational aspects of the International Mutual Recognition Agreements. Advises on the operational and ORA implementation of the agreements.
- Leads ORA efforts in international operations in the medical product arena including Pharmaceutical Inspection Co-operation Scheme (PIC/s) and any international operational issues.

- Provides authoritative policy analysis by evaluating information/initiating research to validate existing policy or to recommend implementing changes or new policy or guidance.
- Responsible for OMPTO budget justifications and User Fee related activities working with the program executives.
- Provide direction and counsel to the Program Executives on significant enforcement cases working with OCC and the Centers.
- Advises the ACMPTO on productivity trends and works with the Deputy for Technology and Bioresearch Quality and Support Operations and Program Executives to develop ways to increase productivity.
- Provides authoritative policy analysis by evaluating information/initiating research to validate existing policy or to recommend implementing changes or new policy or guidance.
- Additionally, the Deputy serves as principal advisor on compliance initiatives efforts in the areas of medical products.

Supervisory Responsibilities: Manages one or more portfolios and provides leadership and direction for multiple program offices in coordination with the ACMPTO. Serves as a deputy and where designated, the delegated authority for the ACMPTO and assist in overseeing program directors in the coordination, interpretation, and evaluation of the OMPTO's mission. Plans, develops, executes, and coordinates the Office's investigations, inspections, and regulatory and compliance activities. The Deputy also oversees and coordinates across programs drugs, biologics, and advanced manufacturing related recalls, consumer complaints, and quality system activities and directs and coordinates ORA's emergency preparedness and response activities relative to OMPTO's global drugs, biologics, advanced manufacturing, and regulatory operations. Plans and assigns work to be accomplished by subordinate supervisors and employees, gives advice and counsel to leaders, interviews and selects candidates for positions, makes promotions and reassignments, hears, and resolves complaints from employees, identifies developmental and training needs for leaders, and finds ways to improve production or increase quality of work.

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.
- Travel is required up to 40% of the 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 Series 0696

Professional Experience: To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. Examples of specialized experience include independently carrying out routine investigations, inspections, entry review, filer audits and sampling; documenting and organizing evidence, data, and other information to support violations, developing and maintaining effective communication with regulated industry, consumer groups and the general public to foster understanding of the Agency's programs activities and regulations and assisting higher level employees in the review and evaluation of inspection reports of products or establishments.

Desired Education: A degree in law, science, public health, management, or other related field from an accredited college/university. Biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

Desired Professional Experience:

- Advanced knowledge of ORA's global footprint and its Medical Products and regulatory operations.
- Executive level experience in budget formulation, capital investments and human resources.
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or imported medical product and drugs, biologics, and advanced manufacturing related activities.
- 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.

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

This position requires a 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 sensitive, 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.

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, detailed resume 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 December 23, 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". Please reference Job Reference ID: Deputy OMPTO

Announcement Contact

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

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