TITLE 21 DETAIL 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)

Position: Deputy for Therapeutics, Quality, and Emerging Regulatory Operations (DTQERO), Office of Medical Products and Tobacco Operations (OMPTO)
This announcement is for a 120-day detail as the Deputy, OMPTO

Series: AD-0696

Location(s): Location determined upon selection

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.

Application Period: December 9, 2022 – December 16, 2022

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

Who may apply: Open to current ORA employees. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service.

Conditions of Employment: 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.

Special Notes: This detail is available immediately. Temporary promotion will be considered.

Additional information on 21st Century Cures Act can be found here.

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/about-fda/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 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.
- 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 requires up to 40% travel.

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.

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

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.

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 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 products 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.

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.

How to Apply:

Applications will be accepted from all qualified internal applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, detailed resume and 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, ORAExecutiveandScientificDetails@fda.hhs.gov. Applications will be accepted through December 16, 2022. Please reference Job Reference ID: Deputy, OMPTO Detail

Announcement Contact:

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

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

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