TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Regulatory Science (ORS)
Office of Medical Products, Tobacco, and Specialty Laboratory Operations (OMPTSLO)

Position: Deputy Associate Director for Medical Products, Tobacco, and Specialty Laboratory Operations (DADMPTSLO)

Series: 401, 403, or 1320

Location(s): One position to be located in one of the following locations: Atlanta, GA; Winchester, MA; Cincinnati, OH; Irvine, CA; Jamaica, NY; Philadelphia, PA; San Juan, PR; Rockville, MD; Detroit, MI

Travel Requirements: Able to travel up to 25% to various FDA sites across the US

Application Period: September 4, 2020 to September 18, 2020

Salary: Title 21 (AD) Band F, starting at $162,339

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 the authority.

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 effective.

Serve on the frontlines protecting our nation's public health safety within the Office of Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the nation or around the world. Our employees conduct inspections; investigate criminal violations; analyze lab samples; provide administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

FDA's Office of Regulatory Affairs is the lead office for all agency regulatory inspection 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 collaboratively with the Centers in developing 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).

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

The Office of Regulatory Science (ORS) provides a focal point for all aspects of ORA Field Laboratories and serves as the Office of Regulatory Affairs' headquarters for scientific and technical staff. ORS foster partnerships, within and outside of the Food and Drug Administration and provides convincing and prevailing scientific research and analytical basis for regulatory decisions to protect and promote public health.Office of Medical Products, Tobacco, and Specialty Laboratory Operations (MPTSLO) provides oversight on scientific issues and laboratory analysis related to pharmaceuticals, tobacco, medical devices, radiochemistry, and forensic chemistry to eight laboratories and associated programmatic staff. This Office Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources.

Position Summary:

The DADMPTSLO shares fully with the Associate Director, OMPTSLO (ADMPTSLO) in the facilitation of office staff coordination and communications between multiple program offices/laboratories and includes oversight of research, streamlining the review process, and oversight for the activities related to regulatory science within the super office to improve efficiency, make timely decisions, and ensure consistency.

Supervisory responsibilities: The DADMPTSLO assists in managing a Super Office (>500 full-

time employees) and provides leadership and direction for multiple, smaller program offices in coordination with the ADMPTSLO.

Duties/Responsibilities:

- Provides oversight to the development and implementation of policies and procedures for the components of the MPTSLO.

- Provides managerial guidance and oversight for all pharmaceutical laboratory operations.

- Initiates and/or leads management and operations change processes; creates commitment and drive among key stakeholders; discusses problem areas, identifies need for and initiates studies to develop practical and economic approaches; takes steps to remove barriers or accelerate changes; and demonstrates a commitment to innovation and continuous improvement of laboratory operations.

- Develops plans and makes recommendations to resolve problem areas involving scientific, regulatory and compliance procedures and methods. Ensures that appropriate work measurement, review, accountability, and quality procedures are in place in the conduct of work.

- Oversees the day to day operations of the MPTSL organization and program areas, including oversight of the laboratories performing testing on pharmaceutical products.

- Provides oversight to the MPTSL Directors regarding budget, personnel, facility, inventory, work planning and the quality management system.

- Assists in the overall planning in all discipline-specific areas, e.g., microbiology, biology, chemistry, pharmacology, engineering and other physical medical sciences oriented to laboratory analysis of regulated medical products, devices, tobacco products and their components, and the forensic analysis of products regulated by the FDA.

- Assures that safety policies are adhered to and monitored for compliance in MPTSL field and satellite laboratories.

- Together with the Associate Director, plans, develops, executes and coordinates the ORA's analytical activities. Additionally, and in cooperation with the ORS Office of Research Coordination and Evaluation (ORCE), implements applied analytical method development and research activities.

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 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.

Key requirements will include:

Candidates must possess the required individual occupational requirements to qualify for the Biological Sciences series, 0401; Microbiology Series, 0403; or Chemistry Series, 1320. Please use the following link to review the required qualifications: 401, 403, 1320.

Professional Experience/Desirable Qualifications:

The U.S. Food and Drug Administration is a highly visible, collaborative and impactful organization. As such, this individual must be flexible to operate in a driven culture and capable of exercising good judgment, leadership and decision-making capabilities in times of ambiguity.

- Recognized scientific authority in specialized programs associated with Medical Products, Tobacco and/or Specialty Laboratory projects and their components.
- Able to travel up to 25% to various FDA sites across the US. Initial travel may be greater, as onboarding requires familiarization with headquarters and laboratory facilities.
- Regulatory laboratory experience subject to ISO/IEC 17025 standards.
- Exceptional analytical skills, able to interpret and apply scientific instructions, policies, procedures and guidelines.
- Proven professional experience and stature in their area of expertise, commensurate with the duties of the position being filled.
- Demonstrated ability to approach assigned duties in a highly organized, detailed and accurate manner.
- Ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.
- Excellent written and oral communication and influence skills, with the ability to inspire confidence and work successfully with diverse audiences.
- Demonstrated strength with organizational management, leadership and team-building.
- Creativity in problem identification and resolution and a relentless drive to accomplish company goals and objectives. A can-do attitude is a must.

Desirable Qualification/Experience:
Degree in one of the following: biological sciences, chemistry, physical sciences, or related scientific fields that provide knowledge directly related to OMPTSLO responsibilities and experience as stated above.

Conditions of Employment:

Security Clearance:

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.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Applicants must submit a current résumé, a current SF-50 redacted for complete SS# and birth year (for federal employees only), proof of degree or transcripts (with foreign credentials evaluation if applicable), and a brief (one-page or less) statement explaining your interest and qualifications for this position to the ORA Executive Recruitment Team at: ORAExecutiveRecruitment@fda.hhs.gov by September 18.

For questions please contact Kathleen Davis at Kathleen.Davis1@fda.hhs.gov.

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

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