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 & Specialty Laboratory Operations (OMPSLO)
Medical Products & Tobacco Scientific Staff (MPTSS)

Application Period: October 24, 2023 – November 02, 2023

Area of Consideration: Open to current FDA employees. 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: Staff Director

Series: AD - 0403 1320

Location(s): FDA – All U.S. Locations

Salary: Starting at $155,700

Work Schedule: Full Time

Title 21 Band: E, Pay Table 1

Full Performance Band Level: Band E

Travel Requirements: Up to 25% travel

Bargaining Unit: 8888

Incentives: Incentives may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 Policy.

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) is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are 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 multi-billion-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 and abroad.

The mission of the Office of Regulatory Affairs is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

The Office of Regulatory Affairs (ORA) is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 12 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

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

The Office of Regulatory Science (ORS) provides strategic leadership, coordination, and expertise to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy Associate Commissioner for Regulatory Affairs (DACRA) and other ORA senior leaders on scientific issues related to policy and regulations.

The Office of Medical Products and Specialty Lab Operations (OMPSLO) provides oversight on scientific issues and laboratory analysis related to pharmaceutical, tobacco, medical devices, foods, forensic chemistry related to all FDA regulated products, and international mail facilities.

The Medical Products and Tobacco Scientific Staff (MPTSS) are responsible for developing, reviewing, and implementing scientific and regulatory policy, procedures, guidance, criteria to secure conformance with agency and Department compliance and science policy, regulation, and guidance. The MPTSS' ensure that field science-based work products, compliance programs, assignments, guidance impacting field laboratory analyses and outputs are suitable for the intended legal regulatory, compliance or enforcement purpose.

The Staff Director reports to the Deputy Associate Director for The Office of Medical Products and Specialty Lab Operations.

Duties/Responsibilities

The Staff Director serves as the bridge between Center and other ORS regulatory enforcement customers and the laboratories. In that capacity the Staff Director leads a team of chemists and microbiologists that assists in coordinating the assignment of work to the proper OMPSLO laboratories and provides reviews of laboratory work products prior to delivery to the customer. Program work focuses on chemical and microbiological analyses of pharmaceuticals and medical devices, tobacco products, radionuclides in food and pharmaceuticals, and forensic chemistry related to all FDA regulated products. The Staff Director ensures the team of program coordinator reviews and laboratory work products prior to customer compliance reviews. The incumbent is responsible for the strategic planning and management of regulatory/external programs. The Staff Director serves as a scientific program SME to other senior staff within ORA in the formulation of program goals, objectives and broad operating policies covering the full scope of specialized laboratory programs and activities. Develops, implements, and evaluates programs or projects; provides consultation and expert scientific advice in support of ORA programs related to laboratory research and development

activities that improve laboratory capacity in responding to emerging, re-emerging public health, regulatory, and compliance issues. Provides scientific, technical knowledge, managerial expertise, and leadership in the development or enhancement of ORA field laboratory programs.

- Makes recommendations to OMPSLO Directors and Deputy Directors, Office of Regulatory Science, on appropriate chemical or biological/microbiological methods, method performance, quality control and assurance activities, and the appropriate use and limitations of analytical techniques.
- Supervises the development, review, and implementation of scientific and analytical compliance-type publications including the FDA Analytical Manuals, Compliance Programs, Field Assignments, Compliance Policy Guides, ORA Laboratory Manual, Regulatory Procedures Manual, Investigations Operations Manual and other guidance publications.
- Develops, coordinates, and monitors the development of new or modified scientific and analytical compliance policies and regulatory procedures for domestic and imported products regulated by the Agency.
- At the discretion of the Associate Director, Office of Medical Products and Specialty Laboratory Operations, represents the Associate Director, Deputy Associate Director, or Senior Science Advisor, on routine and top-level scientific policy and program matters.
- Identifies goals and objectives for field scientific compliance and regulatory activities; develops policies and procedures as they relate to these activities.

Supervisory Responsibilities:
Supervises a staff of professional employees with backgrounds in chemistry, molecular biology, and microbiology. The incumbent will provide leadership, guidance, and day-to-day direction to subordinate employees. The Staff Director supervises and executes day-to-day scientific compliance and regulatory review activities and provides counsel, leadership, and managerial direction necessary for the effective accomplishment of the functional responsibilities of the staff. Supervision and oversight of personnel and resources requires extensive and significant coordination and integration of scientific and technical programmatic work. The Staff Director regularly makes determinations or major recommendations in a number of areas such as:

- The Staff Director supervises and executes day-to-day scientific compliance and regulatory review activities; provides scientific policy and program direction to Agency units carrying out the objectives of the FD&C Act.
- As an agency technical regulatory review authority, the Staff Director provides expert advice to FDA managers, analysts, investigators, compliance officers, and branch staff to implement agency programs and initiatives in line with specialty disciplines of biology, microbiology, and chemistry.
- Coordinates compliance programs and assignments involving multiple FDA centers and interagency analytical assignments.

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.

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.
    b. ***Qualified*** applies to all candidates for Title 21 appointments.

In order to qualify for this Title 21 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:
Microbiologist - 403: A bachelor's degree or higher in biology, microbiology, or virology.
Chemist - 1320: A bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology.

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.

Professional Experience:
- Experience directly related to the position which has equipped the applicant with the particular knowledge, skills, and abilities to perform successfully the duties of the position.
- Desired experience includes directing laboratory operations, developing, implementing, and providing guidance on laboratory operational science policies and procedures.
- Advanced Degree at a doctorate level is valued.
- Demonstrated supervisory leadership and organizational management skills are valued.
- 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.

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

The United States Government does not discriminate in employment on the basis of race, color, religion, gender identity and sexual orientation, 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 applicants. Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, redacted SF-50 (for federal employees only), and transcripts (with foreign credentials evaluation if applicable) to the ORA Executive Recruitment Team at: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the ORS with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

IMPORTANT: You must reference Job ID in the email subject line: **52-Staff Director, MPTSS, OMPSLO**

Applications will be accepted through Thursday, November 02, 2023.

Announcement Contact

For questions regarding this Title 21 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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