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 and Specialty Laboratory Operations (OMPSLO)
Detroit Laboratory

Application Period: January 12, 2024 – January 31, 2024

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: Laboratory Director

Series: AD-1320

Location(s): Detroit, MI

Salary: Starting at $163,964

Work Schedule: Full Time

Title 21 Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 25% travel

Bargaining Unit: This is a non-bargaining unit position.

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 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.

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, 15 laboratories, and 3 satellite laboratories throughout the United States and ports of entry. 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.

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. 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 Laboratory Operations (OMPSLO) advises ORS on scientific issues related to medical products, tobacco, drugs, electronic product radiation, medical devices, pharmaceuticals, radiopharmaceuticals, radionuclides in food, biological and microbiological safety of radiopharmaceuticals, and forensic chemistry.

The fundamental mission of the Detroit Laboratory (DETL) is to utilize the resources of the DETL to protect the public health by helping to assure the safety of foods, drugs and other FDA regulated products. Furthermore, DETL specializes in the testing of pharmaceutical based samples. The laboratory staff has unique expertise in the areas of drug analysis, chromatography, spectroscopy, environmental screening, and microbial analysis. In addition to scientific analysis, the laboratory staff supports the Investigations Branch in conducting pre-approval, compliance, and for cause, and surveillance inspections.

Duties/Responsibilities

The incumbent serves as the Laboratory Director within OMPSLO, ORS, ORA, and as such, the incumbent reports directly to the Deputy Associate Director, OMPSLO, and is a member of the program's management team. Additionally, the incumbent brings to bear current scientific knowledge in analytical forensics and related technologies in making substantive decisions concerning the scientific process and work of the DETL staff and serves as the subject matter expert for ORA in the analysis and testing of pharmaceutical based samples and medical products, and the

regulation of food and cosmetics.

- Advises the Deputy Associate Director, OMPSLO, and ORA leaders on new or emerging problems and trends, future program needs and priorities, manpower, equipment, financial needs, and long-range planning.
- Serves as the principal spokesperson for the DETL, the incumbent will represent the DETL as the senior scientist with both internal and external constituencies and provides executive leadership and managerial direction to the DETL scientists and support personnel.
- Responsible for developing, maintaining, and applying state of the art expertise in drug analysis and research as it applies to Agency needs, as well as providing expert advice to Agency officials as well as testimony regarding drug analysis and research issues.
- Develops and maintains the capability to respond immediately to all tampering/terrorism and other incidents, including rapid development of required new methodology, analysis of samples and critical evaluation of results.
- Designs and conducts experiments to demonstrate the physical and chemical effects of poisons on food and drug products and studies the effects of the food and drug products on the stability and toxicity of the poisons.
- Develops procedures that can be used to establish chemical profiles of poisons and other deleterious substances that might be in foods and drugs**.**
- Ensures that program evaluation reviews, quality assurance and quality management systems, strategies, measures, and economical operating practices are in place to promote the effective execution of work plans, conformance to policy and safe working practices.
- Develops physical, chemical, and molecular/microbiological analytical procedures that can be used to further investigations and to provide evidence in cases of fraudulent activities involving foods, drugs and other FDA regulated products.
- Develops analytical procedures that can be used to further investigations and to provide evidence in cases of fraudulent activities involving pharmaceutical products. Provides strategic leadership and support for high quality, collaborative, scientific activities, and research that advance regulatory science and address important public health issues concerning FDA regulated products, including their evaluation, quality, safety, and effectiveness. Coordinates with other Agency components (e.g., Center for Drug Evaluation and Research) on ORA scientific programs to assure a cohesive approach to public health protection.

Supervisory Responsibilities: The Laboratory Director serves as a second-level supervisor and is responsible for the effective utilization of available resources and for providing leadership, guidance, and technical direction necessary for full and effective program accomplishments of the laboratory functions. The Laboratory Director is responsible for managing all phases of laboratory analyses in connection with samples of FDA-regulated commodities assigned to the laboratory for testing and analysis. The Laboratory Director supervises a staff of professional scientists, technicians, and support positions and is responsible for the functions of the Laboratory, including: planning, scheduling, and controlling laboratory operations; and formulating, implementing, and coordinating laboratory work plans.

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 Title 21 position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Outstanding and Qualified 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: A bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

Position's Desired Skills, Experience, or Education:

- Experience with analytical problem solving, FDA law and associated criminal and civil enforcement is desired.
- Experience with technology transfer and public private partnerships is valued.
- Demonstrated networking skills including scientific collaboration with industry and academic partners is desired.
- Advanced Degree at Ph.D. level is valued.
- Demonstrated supervisory leadership and organizational management skills are valued.

- This position may require the incumbent to successfully obtain and maintain a secret security clearance.

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, 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 applicants. Please email letter of interest addressing your experience in the major duties and responsibilities of the position, résumé, transcript (with foreign credentials evaluation, if applicable), and current SF-50 (redacted for birth year and SSN; applies to current federal employees only) to the ORA Executive Recruitment and Scientific Staffing Committee: ORAExecutiveAndScientificRecruitment@fda.hhs.gov.

IMPORTANT: You must reference this Job ID in the email subject line: **52-Laboratory Director, DETL**

Applications will be accepted through **January 31, 2024**.

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.
FDA is an equal opportunity employer.