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)
Forensic Chemistry Center (FCC)
Laboratory Branch Director, Inorganic Branch

Application Period: April 28, 2023 – May 22, 2023

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 Branch Director, Inorganic Branch, Forensic Chemistry Center

Series: 0401, 0403, 1320

Location(s): Cincinnati, OH

Salary: Starting at $132,368

Work Schedule: Full Time

Title 21 Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25% travel required.

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

Hiring Incentives: Incentives may be authorized; however, this is contingent upon funds availability. 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 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072 and the Consolidated Appropriations Act of 2023, Section 3624. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.

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 animal, tobacco, 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 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.

The mission of the Office of Regulatory Affairs (ORA) 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 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.

The Forensic Chemistry Center (FCC) is a Specialty Laboratory located within and the Office of Medical Products, Tobacco and Specialty Laboratory Operations (OMPTSLO), Office of Regulatory Science (ORS), ORA, FDA. The core functions of the FCC laboratory involve essential laboratory analyses and research services involving FDA-regulated commodities to protect the public health and safety. The FCC is FDA's crime laboratory, is accredited, and provides national and international support of investigations supporting public health. Criminal evidence and regulatory sample submissions to the FCC are primarily medical products but include all FDA-regulated commodities.

Duties/Responsibilities

This position serves as the Laboratory Branch Director (LBD) of the Inorganic Branch, FCC. The LBD is responsible for providing leadership, guidance, and technical direction necessary for full and effective program accomplishments and the effective utilization of available resources. The LBD manages all phases of laboratory analyses assigned to the FCC branch for testing and research to develop and refine methodology used in the analysis of samples and to explore new systems of laboratory analysis. The LBD is responsible for planning and implementing scientific programs, criminal and regulatory analysis, and scientific research associated with the chemical,

biological and microbiological examination of regulated products. This position is responsible to the Laboratory Director, FCC, for the effective utilization of available resources and for providing leadership, guidance, and technical direction necessary for full and effective program accomplishments. Incumbent brings to bear current scientific knowledge in the field of specialty and related technologies in making substantive decisions concerning the scientific process and work of the laboratory staff under the direction of the incumbent.

Directs a program segment that performs highly technical, forensic, and professional work. The program segment and work directed typically have nationwide coverage. The program segment(s), functions, and activities of the unit directly and significantly impact the work of the regulated industry; other Federal agencies, State, local, and foreign governments; industry and professional organizations; public interest groups; and the general public. The unit is frequently called upon to assist state, local, other federal agencies, and other governments with forensic analysis. The unit collaborates with other federal agencies and other governments on research programs that have national and international impact. The unit is involved with national counter-terrorism activities.

This position plans and schedules forensic analytical work, which is unpredictable and requires rapid response daily, or direct research assignments of longer duration. Independently adjusts staffing levels or work procedures within the organizational unit to meet challenges presented by requests for forensic analytical services from other field offices, other FDA Centers, or outside state, federal or local law enforcement entities. Identifies new equipment needs and justifies the purchase of new equipment. Often develops new and innovative work methods and procedures used to produce work products. Oversees the development of technical data, estimates, statistics, suggestions, and other information useful to higher level managers in determining which goals and objectives to emphasize. Decides the methodologies to use in achieving work goals and objectives, and in determining other management strategies

Supervisory Responsibilities: This position is a second level supervisor in the Inorganic Branch, FCC over a unit of GS-14 Supervisory Interdisciplinary Scientists. The supervisor is recognized as the authority in the program segment(s), functions, and activities of the unit supervised. The products/regulatory issues with which the supervisor deals are legally/scientifically difficult and sensitive and involve matters associated with criminal investigations. The supervisor is responsible for the technical and administrative supervision of support staff and of first level supervisors who oversee the work of all unit employees (including Chemists, Biologists, and Microbiologists, etc. up to and including GS-14 level employees). The supervision includes planning, assigning, reviewing, and evaluating the work and performance of employees.

Performs the administrative and personnel management functions relative to staff supervised. Establishes guidelines and performance expectations for staff, which are clearly communicated through the formal employee performance management system. Observes workers' performance; demonstrates and conducts work performance critiques. Provides informal feedback and periodically evaluates employee performance. Resolves informal complaints and grievances. Develops work improvement plans, recommending personnel actions as necessary.

Provides advice and counsel to workers related to work and administrative matters. Effects disciplinary measures as appropriate to the authority delegated in this area. Reviews and approves or disapproves leave requests. Assures that subordinates are trained and fully comply with the provisions of the safety regulations and the Laboratory Quality Assurance Program

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.
- This position requires up to 25% travel.

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. ***Qualified*** applies to all candidates for Title 21 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 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.

Candidates must qualify for one of the following series:

General Natural Resources Management and Biological Sciences Series, 0401

Microbiology Series, 0403

Chemistry Series, 1320

Desired Education: Advanced Degree at M.D., D.V.M, Ph.D. or equivalent doctorate level is valued in one of the following: physical sciences, biological sciences, chemistry, microbiology, or related scientific fields that provide knowledge directly related to consumer safety officer work.

Desired Professional Experience:

- Advanced knowledge and experience in the supervision of a laboratory providing analytical and forensic analyses and problem-solving capabilities.
- Demonstrated strength with organizational management, leadership and team building and the ability to manage multiple, competing priorities and work in a flexible, dynamic, and fast-paced environment.
- Experience in managing a highly technical, diverse group of analytical scientists.
- Experience in the application of analytical laboratory quality control and quality assurance practices and procedures.
- Experience collaborating with top level officials within the organization as well as officials from federal, state, or city governments, professional health organizations, the regulated industry, consumer organizations, etc. to accomplish goals.
- Experience in understanding and collating highly technical scientific data and effectively communicating the information to customers with technical and non-technical backgrounds including managers and law enforcement personnel.
- Skill and ability to calibrate and operate various instruments and computer systems in an analytical laboratory; knowledge of established laboratory procedures, the FD&C Act and related regulations, other laws and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory actions.
- Advanced knowledge of all the major FDA programs and the industries regulated by those programs and a comprehensive knowledge of the legislation, laws, and regulations.
- Superior knowledge of the various sciences and technologies which apply to the products regulated by the Agency.
- Ability to gauge the effort at hand, to select what needs to be done, recognizing the impact in terms of risks involved; ability to accomplish work through others at all

necessary levels within the agency and in other federal and international organizations to achieve appropriate and timely support.

- Ability to analyze complex and sensitive regulatory issues involving numerous variables; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory counterparts. Must possess a professional knowledge of scientific principles, theories, practices and established methodology sufficient to analyze complex and unprecedented samples and, as needed, to develop and modify analytical methods.

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 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, redacted 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 May 22, 2023. Please reference Job Reference ID: Laboratory Branch Director, FCC.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAExecutiveandScientificRecruitment@fda.hhs.gov .

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