TITLE 21 DETAIL 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)

Position: Laboratory Director, Forensic Chemistry Center (FCC)
This announcement is for a 60-day detail as the Laboratory Director, FCC

Series: AD-0401, 0403, 1320

Location(s): Cincinnati, OH

Travel Requirements: Up to 25% travel required

Application Period: 12/7/2022 – 12/14/2022

Salary: Starting at $168,914 (Cures Band F, Pay Table 1)

Who may apply: Open to current 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.

Special Notes: This detail is available immediately. Temporary promotion will be considered. You may qualify for reimbursement of relocation expenses in accordance with FDA policy.

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

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.

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

The Office of Medical Products and Specialty Laboratory Operations (OMPSLO) advises the Office of Regulatory Sciences (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 Forensic Chemistry Center (FCC), a laboratory located within the OMPSLO. 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. This highly technical laboratory has broad functional responsibilities and scope in program areas that include both criminal and regulatory testing and research involving human and veterinary drugs, food and feed, devices, cosmetics, and biological products. Laboratory findings may result in criminal prosecutions and/or regulatory decisions/actions that directly affect consumers, businesses and industries involved with FDA regulated products on a national scale. This laboratory has a unique national and international responsibility intended to support the Agency's public health mission and forensic chemistry requirements on a world-wide basis.

Duties/Responsibilities:

The Director is responsible for providing leadership, guidance, and technical direction necessary for full and effective program accomplishments and the effective utilization of available resources. The Director manages all phases of laboratory analyses assigned to the FCC for testing and research to develop and refine methodology used in the analysis of samples and to explore new systems of laboratory analysis. The Director 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. The Director plays a major role in national policy determination through the selection of test methods employed and development of scientific data to support risk assessment in public health crisis associated with regulated commodities. This position is responsible to the Associate Director, OMPSLO, 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

Supervisory responsibilities:

- Supervises a staff of professional, technical, and support staff performing up to the GS-15 level to accomplish the work of the Center.
- Exercises second-level supervisory authorities and responsibilities involving work assignment and review over two or more subordinate branches as well as administrative and personnel management functions relative to subordinates.
- 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.
- 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 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.

Applicants must possess an advanced degree at the master's level in one of the following: engineering, physical sciences, biological sciences, chemistry, microbiology, or related scientific fields that provide knowledge directly related to analytical laboratory and regulatory science work.

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. Up to 8 semester hours in statistics or course work that includes the principles, theory or practical application of computers or computer programming may be accepted

Professional Experience:

- Scientific knowledge in the fields of specialty and related technologies to make substantive decisions concerning the scientific process and work of the laboratory

staff.

- Possesses professional knowledge of scientific principles, theories, practices, and established methodology to analyze complex and unprecedented samples and, as needed, to develop and modify analytical methods to solve problems.
- Possesses knowledge of established laboratory procedures, the FDC Act and related regulations, other laws and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory action; knowledge of the practices and related problems associated with the raw materials, products or manufacturing for the industries or commodities in areas of assigned responsibility.
- Analyzing and evaluating complex scientific data to recommend improvements to the regulatory review process, using research findings to provide coordination and leadership on a range of regulatory science issues, developing and implementing strategic technical plans for development and enhancement of scientific programs.

Desired Professional Experience:

- Experience with technology transfer and public private partnerships is valued.
- Demonstrated scientific collaboration with academic and international public health laboratory partners is desired.
- Demonstrated leadership and organizational management skills.
- Experience with technology transfer and public private partnerships is valued.
- Experience with FDA law and associated criminal and civil enforcement is desired.
- Demonstrated networking skills including scientific collaboration with industry, academic, and law enforcement partners is valued.
- Demonstrated supervisory leadership and organizational management skills are valued.

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 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, ORAExecutiveandScientificDetails@fda.hhs.gov. Applications will be accepted through December 14, 2022. Please reference Job Reference ID: Laboratory Director, FCC 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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