TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
U. S. Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Regulatory Science (ORS)
Office of Medical Products and Specialty Laboratory Operations (OMPTSLO)
Irvine Medical Products Laboratory (IRVL-MP)

Position: Director, Irvine Medical Products Laboratory

Series: 401- Biologist, 403- Microbiologist, 1320- Chemist

Location(s): Irvine, CA

Travel Requirements: Occasional Travel up to 25%

Application Period: February 19, 2021 to March 5, 2021

Salary: Starting at $144,128 (Cures Band E)

Area of Consideration: Applications will be accepted from all qualified internal and external applicants.

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 U.S. Food and Drug Administration (FDA) is the scientific, regulatory and consumer protection agency responsible for protecting the public health by helping to assure the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our

nation's food supply, cosmetics, products that emit radiation, and by regulating the manufacture, marketing and distribution of tobacco products. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods, as applicable, more effective, safer, and of higher quality; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health. In addition to protecting the health of millions of American consumers, FDA's activities have a direct impact on multi-billion dollar industries throughout the global economy.

The FDA's Office of Regulatory Affairs (ORA) is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA supports FDA Product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. In collaboration with FDA Centers, ORA also develops FDA-wide policy on compliance and enforcement.

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 16 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.

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

Position Summary:

The Irvine Medical Products Laboratory (IRVL-MP) is one of eight laboratories in the Office of Medical Products, Tobacco, and Specialty Laboratory Operations (OMPTSLO). This Office provides oversight on scientific issues and laboratory analysis related to pharmaceuticals, medical devices, radiochemistry, and forensic chemistry. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources.

The Director, IRVL-MP's core functions involve essential laboratory analysis and research services to protect the public health and safety in regulatory program areas that can include human and veterinary drugs, devices, cosmetics and biological products, based on ORA's scientific program needs and laboratory capabilities. The Laboratory Director is responsible for overall operation and administration of all laboratory activities, to include scientific, executive, strategic, and program leadership.

Duties/Responsibilities:

The Director, IRVL-MP provides strategic leadership, coordination, and expertise to the Associate Director and Deputy Associate Director of the OMPTSLO, the ORS Director and Deputy Director, and other ORA senior leaders on scientific issues related to policy and regulations. Provides advice concerning the management of the IRVL-MP 's field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.

Provides scientific support in the review of regulatory documents, the development of regulatory decisions and the analysis of post market surveillance issues. Leads the planning, development, and implementation of ORA's scientific programs including the development, modification, and validation of test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance public health protection and respond to emergencies.

Fosters development and use of innovative technologies to meet public health needs. 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.

Obtains resources and identifies strategic objectives for the organization. Exercises supervisory and/or managerial authorities. The Laboratory Director is a second line supervisor over 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.

Performs laboratory analysis of samples to: Assess their compliance with laws and regulations enforced by the agency; and obtain information through national surveillance programs for the purpose of identifying potential problems or trends. Providing evidence regarding analytical findings as requested. Conducts research to develop and refine methodologies used in the analysis of samples and to explore new systems of analysis. Serving as a resource in scientific knowledge and providing expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.

Provides technical oversight for both domestic and international inspections that require in-depth knowledge of laboratory techniques and practices and potential causes of adulteration. Maintaining liaison with scientists and scientific bodies with interests pertinent to laboratory activities. Providing analytical support to Headquarters components as needed. Maintains viable Quality Management System and compliance with ISO 17025 accreditation requirements. Assures that subordinates are trained and fully comply with the provisions of the

ORA Laboratory Manual and associated requirements and ORA Quality Management Systems Program.
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, predominantly Chemists and Microbiologists, but also Biologists, Physical Scientists, and Research Chemists and/or Research Microbiologists.

Responsible for carrying out assigned duties in a manner consistent with the safety policies defined by the supervisor.

Supervisory responsibilities: The Director, IRVL-MP serves as the supervisor, through subordinate managers, to the Chemistry Branch, Microbiology Branch, Quality Management staff, and Operational Support Staff.

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.

Desirable Education:

- An advanced degree in law, science, public health, management or other related field from an accredited college/university.

Information can be found for individual occupational requirements at the following links:

General Natural Resources Management and Biological Sciences Series, 0401

Microbiology Series, 0403

Chemistry Series, 1320

Professional Experience/Desirable Qualifications:

- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or import activities
- Executive level experience (i.e., GS-14 or above or equivalent, 2nd or 3rd line supervisory experience) in directing a large organization of 50 or more employees.
- Experience directing subordinate managers.
- Experience establishing organizational policy, including the implementation of new legislative authorities or other significant mandates.
- Demonstrated ability to communicate effectively both internally and externally to a large number of staff located in different geographic areas.
- 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.
- Training, professional development, and outside professional activities that provide evidence of initiative, resourcefulness and potential for effective job performance at a senior level, and honors, awards, or other recognition for performance or contributions related to the position.

Conditions of Employment:

United States Citizenship is required.

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: All qualified candidates should submit a curriculum vitae, cover letter describing qualifications and interest relevant to this position, and copies of official transcripts (if you have foreign transcripts please submit a foreign transcript evaluation from an accredited company), electronically by March 5, 2021 to ORAExecutiveRecruitment@fda.hhs.gov.

For questions please contact Kathleen Davis, kathleen.davis1@fda.hhs.gov, 240-704-0436.

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