VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Global Regulatory Operations and Policy (OGROP)
Office of Regulatory Affairs (ORA)
Office of Regulatory Science (ORS)

Title 42 U.S.C. 209(f) Special Consultants

Position: Supervisory Interdisciplinary Scientist (Laboratory Director)

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

Location(s): Alameda, CA; Bothell, WA

Application Period: Applications will be accepted on a rolling basis until positions are filled.

Salary Range: Salary is commensurate with education and experience.

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

Relocation Expenses Reimbursement: You may quality for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position will be filled as a Title 42 209 (f) appointment. This is an Excepted Service position under Title 42. This appointment does not confer any entitlement to a position in the competitive service and no entitlement to Merit Systems Protection Board (MSPB) appeal rights.

Introduction:

The 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.

Position Summary:

The Laboratory Director manages all phases of the multi-disciplinary food and feed laboratory programs and analyses aimed at effective accomplishment of the Agency's consumer protection mission. The Director is responsible for planning, organizing, staffing, directing, controlling, and budgeting of resources and operations to attain maximum accomplishment of the ORS, ORA, and FDA food and feed programmatic objectives. Programmatic responsibilities include analysis of regulatory samples, development of analytical methods, providing scientists for consumer protection mission, including determining compliance of regulated products and enterprises with the Federal Food, Drug, and cosmetic Act, related regulations and legislation, and advancing FDA science.

Duties/Responsibilities:

- Direct through subordinate managers and supervisors, a workforce of professionals engaged in key Agency multi-disciplinary scientific analyses, investigations, laboratory operations, research, and methods development.

- Participate fully in formal and informal policy and planning activities to formulate overall program operating goals, objectives and milestones in support of Office of Regulatory Science (ORS), Office of Regulatory Affairs (ORA) and the FDA.

- Direct through subordinate managers and supervisors, a workforce of professionals engaged in key Agency multi-disciplinary scientific analyses, investigations, laboratory operations, research, and methods development.

- Participate fully in formal and informal policy and planning activities to formulate overall program operating goals, objectives and milestones in support of Office of Regulatory Science (ORS), Office of Regulatory Affairs (ORA) and the FDA.

- Responsible for ensuring the laboratory maintains a third party laboratory accreditation

status and complies with the ISO 17025, AOAC laboratory testing guidelines and other applicable requirements.

- Ensure 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.

- Provide the climate and the impetus, at the executive level, for full utilization and effective management of the work force.

- Responsible for furthering the goals of equal employment opportunity by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to race, color, religion, sex, national origin, age or handicap.

- Develop an affirmative action plan for the area supervised, including appropriate objectives and goals; and monitors and periodically assesses progress.

Professional Experience/Desirable Qualifications:

The U.S. Food and Drug Administration is a highly visible, collaborative and impactful organization. As such, this individual must be flexible to operate in a driven culture and capable of exercising good judgment, leadership and decision making capabilities in times of ambiguity.

Key requirements will include:

- 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.

- Recognized scientific authority in specialized programs associated with food and feed laboratory projects and their components.

- Knowledge of pertinent laws, regulations, policies and precedents.

- Regulatory laboratory experience subject to ISO 17025 standards.

- Exceptional analytical skills, able to interpret and apply scientific instructions, policies, procedures and guidelines.

- Proven professional experience and stature in their area of expertise, commensurate with the duties of the position being filled.

- Skill in adapting analytical techniques and evaluation criteria to measure program efficiency.

- Demonstrated ability to approach assigned duties in a highly organized, detailed and accurate manner.

- Ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.

- Excellent written and oral communication and influence skills, with the ability to inspire confidence and work successfully with diverse audiences.

- Demonstrated strength with organizational management, leadership and team-building.

- Creativity in problem identification and resolution and a relentless drive to accomplish company goals and objectives. A can-do attitude is a must.

- Polished and professional presence with capacity to act as a highly visible representative of the organization.

- Able to travel up to 25%

Qualifications:

Applicants must possess an M.D., D.V.M, Ph.D. or equivalent doctorate in one of the following: biological sciences, microbiology, chemistry, agriculture, natural resource management, basic medical science, physical sciences, life sciences, engineering, 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.

Conditions of Employment:

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) 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 http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

To apply: Send letter of interest addressing your experience in the major duties and responsibilities of the position, CV and bibliography, SF-50 for current federal employees only, and doctoral degree transcripts (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov.

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