



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: Associate Director for Lab Operations, Food and Feed

Series: 1320- Chemist, 1310- Physicist, 701- Veterinary Medical Officer, 602- Medical Officer, 414- Entomologist, 403- Microbiologist, 401- Biologist

Location: ORS – Rockville, MD, PRL-NW – Bothell, WA, SAN – Alameda, CA, PRL-SW – Irvine, CA, DEN – Lakewood, CO, KAN – Lenexa, KS, ARL – Jefferson, AR, NRL – Jamaica, NY, SRL – Atlanta, GA

Opening Date: January 25, 2016

Closing Date: February 26, 2016

Salary Range: Salary is commensurate with education and experience.

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

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:

Become a part of the Department that touches the lives of every American! At the Department of Health and Human Services (DHHS) you can give back to your community, state, and country by making a difference in the lives of Americans everywhere. Join HHS and help to make our world healthier, safer and better for all Americans.

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, products

the 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 Office of Regulatory Science provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and leads the planning, development, and implementation of ORA's scientific programs including the development, modification, and validation of test methods and measurements techniques, risk assessments and hazard analyses.

The requirements of laboratory systems are continually evolving to address new products, emerging pathogens/adulterants, and cutting-edge scientific methods and the Office of Regulatory Affairs' (ORA) laboratories must maintain pace with these evolutions to ensure FDA's ability to protect public health. Existing and emerging science challenges require ORA to change the paradigm of traditional laboratory approaches. Current regulatory testing and method development is directed at known and emerging public health threats through execution of compliance programs and response to outbreaks and other emergency situations. To meet the future public health demands, ORA laboratories must move to enhances preventative capabilities beyond the scope of current programs while expanding the use of new and emerging analytical technologies.

The Office of Food and Feed Laboratory Operations will be comprised of eight laboratories located throughout the nation as well as two Staff Offices responsible for various functions associated with Food and Feed and emergency situations, i.e., Food Emergency Response Network (FERN).

Duties/Responsibilities:

Incumbent will serve as Associate Director of Lab Operations- Food and Feed (ADLOFF), Office of Regulatory Science (ORS) with delegated authority and responsibility for executive leadership, oversight, and managerial direction of scientific support of Food and Feed Staff Programs associated with various product and/or service teams engaged in research and/or engineering.

Major duties and responsibilities include but are not limited to:

- Collaborates with other ORS senior officials in providing guidance and executive leadership for Human and Animal laboratory responsibilities. The incumbent maintains a knowledge and awareness of the ORA senior leaders' interests and objectives as they relate to and support the Agency's agenda and exercises analytical judgment in order to anticipate potential issues or concerns that may arise. The incumbent collaborates with management in formulating and developing ORS plans, strategies, objectives, goals, and priorities. The incumbent makes recommendations that have direct impact and effect on laboratory operations and activities.
- Keeps abreast of leading edge scientific practices in all domain areas, e.g., microbiology, biology, chemistry, pharmacology, and other physical medical sciences oriented to laboratory analysis of regulated foods and feed and emergency situations, i.e., FERN and their components. The incumbent assists the ORS Director as well as ORA senior leadership with elevating awareness on laboratory issues associated with Food and Feed.
- Exercises independent judgment, initiative, creatively and executive leadership in a variety of

substantive activities related to the planning, development, execution and coordination of ORA's scientific laboratory research, investigations and regulatory and compliance activities.

- The incumbent is responsible for improving services, practices, and systems through effective and efficient strategic thinking, critical analysis, resource allocation leadership, policy development, and communications.
- Develops overarching policy and procedures activities for Food and Feed laboratory operations and specialty labs and serves as a conduit to the Centers serviced by the Food and Feed laboratory operations and as specialty labs associated with Food and Feed activities. Manages and controls overall laboratory operations to include specialized/emergency laboratory functions and as well as the implementation of policies and procedures which have been formulated in consult with the ORS Director and other ORA and Agency senior management. Work entails ensuring the development of work plans for the Centers as well as ensuring that accreditation processes are in place with respect to laboratory production activities.
- Provides advice and guidance to the ORS Director and other ORS/ORA Management on the appropriateness and direction of current program and management activities and policies and the need for policy or program changes. These activities, projects, and functions are of critical importance to ensure appropriate and timely action in effecting improvements in laboratory performance and outcomes that affects the regulatory activities of the Agency.
- Participates with the ORS Director and other ORS Management to establish an orderly, logical, and efficient approach to diagnosing issues/problems to assess impact on organization's strategic initiatives; identifies and gathers relevant information, ensuring a holistic approach to data gathering and analysis; assesses short- and long-term impact of decisions.
- Plans, manages, and conducts the application and/or implementation of special management or program initiatives regarding Food and Feed assignments and projects for the ORS Director, and or Associate Commissioner for Regulatory Affairs (ACRA) which involves the establishment and maintenance of contacts and relationships with high-level officials of the Department, other executive departments and Agencies and the Congress.
- Participates fully with the ORS Director and ORA senior Management in discussions and decisions concerning Agency plans, programs and activities, both in strategic planning and in actual determination, allocation and administration of human resources.
- Works with all levels of management to promote better utilization of management practices and provision of regulatory and compliance services.
- Initiates and/or leads the management and operations change process; creates commitment and drive among key stakeholders; discusses problem areas, identifies need for and initiates studies to develop the most practical and economic approach; and takes steps to remove barriers or accelerate the change; demonstrates a commitment to innovation and continuous improvement of laboratory operations.
- Develops plans and makes recommendations to resolve problem areas involving scientific, regulatory and compliance procedures and methods. Ensures that appropriate work measurement and evaluation procedures are in place in the conduct of work.
- Serves as a recognized scientific authority in specialized programs associated with Food and Feed projects and their components. Responsible for making broad operational policy and decisions affecting the size, scope, and direction of laboratory programs under his/her purview which may have nationwide impact and require new and innovative solutions.
- Monitors and tracks regulatory actions and works with CFSAN to assure adequate coordination between the ORA, Office of the Chief Counsel (OCC) and the CFSAN.

Mandatory Managerial/Executive Qualifications:

Candidates must have the ability to bring about strategic change, both within and outside the organization, to meet organizational goals; the ability to lead people toward meeting the organization's vision, mission, and goals:

- Ability to meet customer expectations.
- Ability to manage human, financial, and information resources strategically.
- Ability to build coalitions internally and with other Federal agencies, State and local governments, nonprofit and private sector organizations, foreign governments, or international organizations to achieve common goals.

Desirable Qualifications:

Candidates should have:

- Executive level administrative or managerial experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment.
- Demonstrate leadership competence and abilities to:
 - Develop complex and basic program goals, and assure that agency goals and priorities are considered in carrying out and completing responsibilities.
 - Direct and guide projects, including long-term and short-range planning.
 - Establish objectives and priorities.
 - Conduct periodic program assessments.
 - Plan and direct the work of a large scientific review staff.
- Experience indicating the ability to communicate and effectively interact with high level government officials, the scientific/academic communities, medical or health related organizations, members of congress and top level representatives of counterpart Federal agencies, foreign government, officials, CEO level and senior representatives from regulated industry, and other stakeholders.

It is desirable that candidates have:

- Practical knowledge of the application of FDA laws and regulations.
- Training, professional development, and outside activities that provide evidence of initiative, resourcefulness and potential for effective job performance such as invitations, presentations and international activities.
- Receipt of honors, awards or other recognition for performance or contributions based on managerial excellence.
- Professional leadership activities.

Qualifications:

Applicants must possess an M.D., Ph.D. or equivalent in one of the following: biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, 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.

ORA is seeking recognized scientific leaders with experience and knowledge of laboratory operations related to food and feed programs. Additionally, candidates should have knowledge of FDA programs and public health policies. Highly qualified candidates will have experience with management and leadership, outreach, and ability to communicate orally and in writing. They should have strong interpersonal skills in presenting recommendations and negotiating solutions to disputed recommendations, as well as the ability to think and plan strategically as they will set the course for short- and long-term food and feed policy at ORA. Multi-disciplinary experience is a plus. Candidates must be able to function well independently as well as in a team setting, able to manage and adapt to multiple complex priorities, handle long-term projects and adapt to ambiguity.

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 a M.D./Ph.D. transcript (with foreign credentials evaluation if applicable) to ADLOFF Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov.

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