



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 Medical Products, Tobacco & Specialty Laboratory Operations

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

Location: Rockville, MD, ; Jamaica, NY, Irvine, CA, Detroit, MI, San Juan, PR, Atlanta, GA, Winchester, MA, Cincinnati, OH or Philadelphia, PA

Opening Date: 2/15/2017

Closing Date: Applications are being accepted on a rolling/continuous basis.

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:

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 Office of Regulatory Science (ORS) provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and leads the planning, development, and implementation of the Office of Regulatory Affairs (ORA) 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' 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 enhance preventative capabilities beyond the scope of current programs while expanding the use of new and emerging analytical technologies.

The Office of Medical Products, Tobacco & Specialty Laboratory Operations is comprised of multiple laboratories located throughout the nation as well as three Staff Offices responsible for various functions associated with Shelf Life extension, Tobacco, Generic Drug User Free Amendments (GDUFA) and Nanotechnology.

Position Summary:

The Associate Director, Medical Products, Tobacco & Specialty (MPTS) Laboratory Operations is a highly strategic and visible role that oversees a number of the aforementioned laboratories located throughout the U.S. and Puerto Rico. This individual will have delegated authority and responsibility for executive leadership, oversight, and managerial direction of scientific support for Medical Products, Tobacco and the Specialty Labs staff programs associated with various product and/or service teams engaged in research and engineering.

The Associate Director, MPTS Laboratory Operations will exercise full management authority for laboratory operations by providing overall direction and program management. Laboratory operations are nationwide, which lends itself to the complexity of operations for programmatic and policy responsibilities. In addition, the organization is comprised of MPTS staff offices involved in functional specializations. The organizational structure, with the laboratories situated in eight different locales, as well as the specialization requirements and specialized functions will place extraordinary demands from a managerial perspective, requiring a sophisticated and capable leader. The Associate Director has multiple direct reports which manage approximately 275 scientific professional and administrative personnel, the MPTS Program Staff Director and a management analyst.

The Associate Director, MPTS Laboratory Operations will make a direct impact and effect on nationwide operations and activities within the FDA lab network, including the development of scientific laboratory programs and policies; the formulation of program goals, objectives and broad operating policies for MPTS; the evaluation of administrative policy direction for ORS regulatory science involving MPTS

programs; and the development and implementation of strategic technical plans for the evolution and enhancement of ORS laboratories.

Duties/Responsibilities:

- Keep 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 medical products and tobacco products and their components.
- Assist the Director, Office of Regulatory Science as well as ORA senior leadership with elevating awareness of issues associated with MPTS laboratories.
- Exercise independent judgment, initiative, creativity 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.
- Improving services, practices, and systems through effective and efficient strategic thinking, critical analysis, resource allocation leadership, policy development, and communications.
- Collaborate with other ORS senior officials in providing guidance and executive leadership for MPTS laboratory responsibilities.
- Maintain a knowledge and awareness of the Director, Office of Regulatory Science and ACRA's interests and objectives as they relate to and support the Agency's agenda. Exercise analytical judgment in order to anticipate potential issues or concerns that may arise.
- Collaborate with Management in formulating and developing ORS plans, strategies, objectives, goals, and priorities, and make recommendations that have direct impact and effect on laboratory operations and activities.
- Develop overarching policy and procedure activities for MPTS laboratory operations and specialty labs; serve as a conduit to the Centers serviced by the MPTS laboratory operations and specialty labs associated with Shelf life extension, Tobacco, Nanotechnology and GDUFA related activities.
- Manage and control overall laboratory operations to include specialized laboratory functions as well as the implementation of policies and procedures which have been formulated in consult with the Director, Office of Regulatory Science 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.
- Provide advice and guidance to the Director, Office of Regulatory Science 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 affect regulatory activities of the Agency.
- Participate with the Director, Office of Regulatory Science and other ORS Management to establish

an orderly, logical, and efficient approach to diagnosing issues/ problems, and to assess impact on the organization's strategic initiatives.

- Identify and gather relevant information, ensuring a holistic approach to data gathering and analysis; assesses short- and long-term impact of decisions.
- Plan, manage, and conduct the application and/ or implementation of special management or program initiatives regarding MPTS assignments and projects for the Director, Office of Regulatory Science, and or ACRA. This includes the establishment and maintenance of contacts and relationships with high-level officials of the Department, other executive Departments, and Agencies and Congress.
- Participate fully with the Director, Office of Regulatory Science 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.
- Work with all levels of management to promote better utilization of management practices and provision of regulatory and compliance services.
- Initiate and lead the management and operations change process; create commitment and drive among key stakeholders; discuss problem areas; identify need for and initiate studies to develop the most practical and economic approach. Take steps to remove barriers or accelerate the change; demonstrate a commitment to innovation and continuous improvement of laboratory operations.
- Develop plans and make recommendations to resolve problem areas involving scientific, regulatory and compliance procedures and methods.
- Ensure that appropriate work measurement and evaluation procedures are in place in the conduct of work.
- Serve as a recognized scientific authority in specialized programs associated with medical and tobacco 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.
- Establish organizational management policies and contribute to ORA/ ORS program policy development.
- Identify and resolve potential policy conflicts; ensure that management decisions support scientific laboratory policy goals; consider policy implications of management decisions; and coordinate management decisions with appropriate Centers.
- Demonstrate a dedication for improving management and operations, with a commitment to finding more effective and efficient operations. Motivate others to translate ideas and decisions into results; understand and leverage the formal and informal organizational structures to get work done.

- Review and appraise laboratory activities in terms of achieving program goals and objectives, and accomplishing stated responsibilities. Participate in the formulation of policies and objectives, in regard to resource allocation decisions, which affect the total organization.
- Establish procedures for tracking progress. Coordinate and integrate the efforts of personnel across the laboratories to provide optimum use of overall resources. Ensure operational practices, approaches, methods and techniques are the latest and most effective.
- Initiate, coordinate, and/ or respond to requests for intra/ interagency participation, cooperation and interaction with other Centers/ Offices, Departmental Agencies and with outside constituencies on matters of mutual interest. Within the context of ORS scientific laboratory policy, make recommendations that commit the Office to a course of action. Apply thorough and comprehensive program knowledge and keep abreast of developments that are related to, or have bearing on, operational activities.
- Participate in, and contribute to, meetings and conferences with top level agency/ departmental officials, senior program managers and subject matter specialists.
- Determine the need for, and selection of, subordinate supervisory staff; as well as key professional and administrative staff necessary to carry out the laboratory missions.

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:

- Recognized scientific authority in specialized programs associated with Medical Products, Tobacco and/or Specialty Laboratory projects and their components.
- Able to travel up to 25% to various FDA sites across the US. Initial travel may be greater, as onboarding requires familiarization with headquarters and laboratory facilities.
- 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.
- 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.

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.

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 the ORA Executive Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov.

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