



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), GS-14

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

Location: Philadelphia, PA

Opening Date: 12/22/2017

Closing Date: 1/24/2018

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 Philadelphia Laboratory Director reports to the ORS Associate Director of Laboratory Operations, Medical Products and Tobacco and Specialty Laboratories. The Laboratory Director serves as a second-level supervisor and is responsible for the effective utilization of available resources and for providing leadership, guidance and technical direction necessary for full and effective program accomplishments of the laboratory functions. The Laboratory Director is responsible for managing all phases of laboratory analyses in connection with samples of FDA-regulated commodities assigned to the laboratory for testing and analysis. ORS Laboratories also conduct research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.

Duties/Responsibilities:

- Planning, scheduling, and controlling laboratory operations, and formulating, implementing, and coordinating laboratory work plans.

- Performing laboratory analysis 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.
- Providing evidence regarding analytical findings as requested.
- Conducting 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.
- Provide assistance 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.

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.
- 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., Ph.D. or equivalent 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 [Ethics and Integrity Office Website](#).

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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