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)

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

Position: Bioresearch Monitoring Program Director

Series: 601 – General Health Science or 400 – Biological Sciences

Location: Rockville, Maryland

Opening Date: Thursday, January 21, 2016

Closing Date: Friday, March 18, 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.

FDA's Office of Regulatory Affairs (ORA), Office of Operations (OO) is searching for a Bioresearch Monitoring Program Director (BIMOPD). The incumbent in this position will serve as the Bioresearch Monitoring Program Director and is responsible for overseeing and ultimately managing all of the field biologic product professional program activities and is the key point of interface with the Center scientific, compliance and program offices in both the planning for the use of these resources as well as accountable for the field implementation of operational plans. As the BPD, the incumbent will advise Assistant Commissioner for Operations (ACO), the Associate Commissioner for Regulatory Affairs

(ACRA), and other senior FDA officials and others on all operational, scientific, regulatory and policy-making activities that affect ORA-wide programs, projects and initiatives or have an impact on development and achievement of long-range program goals.

Duties/Responsibilities:

Major duties and responsibilities include but are not limited to:

- Negotiates the multi-year field work plan covering both planned and unplanned work between ORA and the Centers which is binding on both parties to carry out unless and until it is modified with agreement of both parties.
- Works with Centers to identify the nature, quantity and geographic location of the work that needs to be done and can be planned. These would include such diverse and critical activities as surveillance inspections, for cause inspections, import review and sample collections, and laboratory testing and applied research needs.
- Designs, develops and implements plans that provide estimates for important activities such as: for unplanned work, pre-approval inspections, investigating complaints, and required investigations of incidents that suggest Food, Drug, and Cosmetic (FD&C) Act violations and/or public health concerns.
- Recommends to the ACO and the ACRA the annual level of BIMO field resources to be reserved in the field allocation for public health emergencies. Assures that as the year progresses any reserves are reprogrammed to non-emergency work when available.

Additional duties and responsibilities:

- Creates and maintains strong working relationships with high level Federal Officials, Members of Congress, Scientists, University Administrators, and industry to assess the political and institutional environment in which decisions are made and implemented.
- Serves as the senior advisor to the ORA leadership and Centers on all matters pertaining to the ORA BIMO field program relating to investigational matters.
- Manages the implementation of change in the field and headquarters ORA programs in response to changes in legislation, major court decisions, budget changes and alike.
- Monitors and tracks regulatory actions and works with Centers to assure adequate coordination between the ORA, FDA Offices and Centers, the Department of Health and Human Services, and other Federal Agencies.
- Collaborates on the development of BIMO training programs to assure that specialists in the FDA Centers and the field are trained in the same operational procedures so that regulated industry experiences uniform, consistent application of FDA regulatory standards.
- In consultation with the ACRA, ACO, and other ORA leadership develops long range strategic, scientific and tactical plans for the specialization of ORA resources including BIMO investigational staff to meet the ORA's current and future needs.
- Serves as the field BIMO focal point for the long-term change process of moving ORA to a program alignment of resources to assure that FDA speaks with one voice on BIMO field regulatory programs, all the while assuring that year-by-year existing structures implement the public health risk-based priorities of the Bioresearch Monitoring program.
- Works with the ORA Office of Resource Management and other ORA leadership to monitor the budget execution of the Bioresearch Monitoring program resources in the field to assure conformance with Congressional and Office of Management and Budget allocations.

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:

- Extensive knowledge in drug product development, manufacturing, studies, and surveillance;
- 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 BIMO 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 PhD transcript (with foreign credentials evaluation if applicable) to BIMOPD Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov.

Back to: Executive Positions at ORA

FDA is an equal opportunity employer.