CURES VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Generic Drugs

Position: Deputy Director of Operations, Office of Generic Drugs

Series: AD-0601

Location(s): Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: 2/12/2020 – 3/12/2020

Salary: Starting at $162,339

Area of Consideration: United States Citizens or Nationals

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

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The Office of Generic Drugs is responsible for the development and implementation of standards for the safety and effectiveness of generic drugs; reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability; establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews,

industry protocols, and studies; and oversees all aspects of labeling submissions for ANDAs.

Position Summary:

Serves as the Deputy Director for Operations, OGD and participates fully with the OGD Office Director in providing executive leadership and direction to OGD. Provides oversight for the support of all OGD operational elements including formulating and establishing Office goals, strategies, policies, budget, allocating resources, interfacing with information technology management issues, and integrating CDER super Office issues relative to the CDER Generic Drug Program.

Supervisory responsibilities:

Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director. Provides occupational-specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization.

The incumbent has responsibility for overseeing efforts for ensuring robust, efficient, and effective regulatory operations, providing leadership and expert advice on processes and procedures, organization structures, and change management within OGD. Receives general supervision from the OGD Director. Is provided broad guidance and direction regarding management policies, procedures, and problems affecting the accomplishment of mission functions. Accomplishes operations within overall regulatory operations. Manages staff operations consulting with the OGD Director on policy-setting or extremely controversial situations. Exercises sound judgement and provides expert technical advice and assistance.

Duties/Responsibilities:

- Assists with implementing the Executive Performance Reporting and implementation. In addition, the incumbent has oversight as a major orchestrator of the development and implementation of programs, processes, and strategic initiatives to support important Office, Center, and Agency priorities.

- Oversees efforts for ensuring robust, efficient, and effective operations of all OGD elements.

- Provides leadership and expert advice on processes and procedures, organization structures, and change management within OGD.

- Evaluates the effectiveness of complex regulatory programs in meeting established goals and objectives across CDER and FDA Offices and with a broad range of organizational sub-units developing and executing a plan for improvement based on evaluation results.

- Advises and supports various leadership positions within OGD in development and implementation of business processes, quality management systems, administrative activities, and training and development activities within OGD.

- Independently evaluates and monitors program initiatives and their effectiveness. Develops solutions and implements new operational programs, processes, and systems where needed.

- Operates effectively and collaboratively across CDER organizational boundaries to identify and address issues of variability in all OGD operational elements, making recommendations for consideration by the OGD Director and/or the OGD Senior Leadership Team to ensure alignment and coordination of key OGD activities with Center and Agency priorities.

- Provides technical direction, oversight, and leadership to OGD's Associate Director for Knowledge Management (ADKM) and Generic Regulatory Affairs Team (GReAT) to execute program operations and processes that integrate and enhance the efficiency and consistency of OGD.

- Oversees the development of knowledge management tools, smart forms, and procedures with other Offices, including but not limited to the Office of Strategic Programs, Office of New Drugs, Office of Pharmaceutical Quality, and the Office of Computational Sciences.

- Provides direction and leadership on projects/studies which advance the state-of-the-art oversight of scientific and regulatory informatics, ensuring best practices and approaches are utilized in the development, delivery, enterprise resource planning, and business intelligence of all data management initiatives within OGD.

- Provides technical direction, oversight, and leadership to OGD's Senior Management Officer (SMO) who oversees the Program Management and Analysis Staff (PMAS) in the development and implementation of all administrative functions within OGD. PMAS oversees human resource management and budgetary management, with emphasis on developing and implementing robust administrative procedures and plans to recruit, hire, and retain a world-class regulatory workforce in the Office.

- Represents and acts as the advocate for the Office on various Agency and Center-level management committees that influence day-to-day operations of the Center and Office.

- Participates in working groups at all levels in the Agency. Represents the Office in crosscutting regulations on policy development for administrative operations. Maintains cooperative relationship with key individuals in other Centers to obtain their input on administrative operations and program initiatives.

- Works with stakeholders to appropriately inform and advise FDA as needed. Also coordinates and collaborates with officials related to fiscal year spending.

- Monitors, coordinates, and provides authoritative advice on revised or new legislations impacting fiscal year spending, budget allowance and execution. Identifies and handles sensitive, controversial, and critical problems that are complex and precedent setting in nature. Advises OGD senior management on potential impacts.

- Maintains current knowledge about new and/or revised legislation, guidance, policies and procedures that affect administrative operations. Uses subject matter expertise to set appropriate policy and regulations impacting program operations.

EEO Responsibility:

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.

The incumbent, in conjunction with his/her supervisor, develops an affirmative employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities.
Incumbent will be appraised on the effectiveness of his/her performance.

Professional Experience/Desirable Qualifications:

- Executive leadership experience with an established track record in leading organizations of significant size and complexity.

- Knowledge of Generic Drug development and knowledge of regulatory standards for safety and effectiveness of human drugs.

- Effective communicator who can drive collaboration, empower staff, and is committed to the Public Health mission.

Key requirements will include:

- Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for General Medical and Healthcare Series, 0601. This series requires at the minimum a Bachelor's level degree that focuses on the medical filed, health sciences or allied sciences. Please review the entire IOR to confirm the minimum education requirements in the following link General Medical and Healthcare Series, 0601

Conditions of Employment:

Security Clearance: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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 Financial 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.

How to Apply: All qualified candidates must submit their curriculum vitae and cover letter in which you describe why you feel you are uniquely qualified for this position electronically to Whitney Flickinger, Whitney.Flickinger@fda.hhs.gov.

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