TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Pharmaceutical Quality (OPQ)

Deputy Super Office Director of Science (Supervisory Interdisciplinary Scientist)
AD-1320/401/403/405

Position: Deputy Super Office Director of Science (Supervisory Interdisciplinary Scientist)

Pay Plan-Series: AD-1320/401/403/405

Location(s): White Oak Campus, Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: February 24, 2020 – March 6, 2020

Salary: Starting at $197,241

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 Center for Drug Evaluation and Research (CDER or Center) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs. CDER's drug regulatory responsibilities include premarket

review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Pharmaceutical Quality (OPQ) oversees and coordinates the overall regulation of human pharmaceutical quality within CDER, including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

Position Summary:

The primary purpose of the position is to serve as an overall Deputy Director of Science who reports to the Director of the Office of Pharmaceutical Quality and is responsible for developing and leveraging common interests regulatory research and review programs to support the development of science-based regulatory policy, regulation, and guidance; and shares responsibility for the management and direction of a multi-disciplinary staff in the Office of New Drug Products (ONDP), Office of Pharmaceutical Manufacturing Assessment (OPMA), Office of Biotechnology Products (OBP), Office of Lifecycle Drug Products (OLDP), and the Science and Research Staff (SRS).

Program activities include providing leadership and technical direction in planning, managing, and directing broad national and international regulatory review and scientific related activities to the development and manufacturing of human drug products.

Supervisory responsibilities: Manages multiple interdisciplinary portfolios and provides leadership and direction for multiple program offices in coordination with the Deputy Director of Science and the Super Office Director. Shares responsibility with the Super Office Director to provide overall program direction to subordinate Sub-Offices through the responsible managers of these Offices. As the Deputy Director of Science, provides direction to a portion of the 1300 budgeted staff including supervisory scientific, legal, professional, technical, administrative, and clerical personnel ranging in pay scale from General Schedule, Title 21, Title 42, Title 38.

Duties/Responsibilities:

Provides program direction of drug and drug product quality regulatory review. Provides executive leadership and technical direction in planning, managing, and directing broad national and international regulatory review and scientific activities related to the development and manufacturing of human drug products.

Represents the Director/Office in meetings, discussions, and conferences with senior Agency and Departmental officials, regulated industry representatives, the medical, scientific, and academic communities, national and international scientific and health related professional organizations, Congress, and representatives from other Federal, state, local and international

governmental agencies to present and explain Office activities, actions, plans, and policies.

Serves as the lead on special projects and activities of interest and concern to the Office Director that involve sensitive and controversial problems, issues, or actions related to policy and/or program matters which may results from a public health emergency or may have congressional interest.

EEO Responsibility:

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:

- Significant experience in managing large organizations with a regulatory mission, including a demonstrated ability to:
  - Product results and lead change;
  - Lead people; and
  - Building coalitions and collaborate across boundaries to achieve common goals.

- Significant experience in the enforcement of federal laws and regulations, including the Food, Drug, and Cosmetic Act.

- Demonstrated ability to identify and analyze complex problems, generate and evaluate alternative solutions, and make evidence-based decisions.

Minimum Education Requirements:

This is an interdisciplinary position that may be filled in the following series: Chemist (1320), Biologist (0401), Microbiologist (0403), and Pharmacologist (0405)

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Conditions of Employment:

Security Clearance: Non-Sensitive – High Risk

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 thee 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 Disclosure Report (OGE 450 or 278) 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 https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity Policy:
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.

How to Apply: All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above, electronically to by March 6, 2020 to OPQ_Cures_Recruitment@fda.hhs.gov. For questions please contact Dominique Mitchell, Supervisory Administrative Officer, via email at dominique.mitchell@fda.hhs.gov. Please reference: Deputy Director of Science.

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