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)
Office of Quality Surveillance (OQS)
Division of Quality Intelligence I & II (DQI)

Position: Supervisory Operations Research Analyst

Series: AD - 1515

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

Travel Requirements: 25% or less

Application Period: November 11, 2020 – November 17, 2020

Salary: Starting at $142,701 (Band E)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

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 compensated under the provisions of the authority.

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

Introduction:

The Food and Drug Administration (FDA) 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) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC). 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 Quality Surveillance (OQS) is responsible for quantitative and qualitative data analysis to assess, understand, and communicate the state of quality for all regulated sites and products using all relevant data and advanced techniques. OQS identifies, documents, analyzes, and manages the most accurate information about the entire inventory of CDER-regulated sites and products (i.e., the supply chain), and develops a comprehensive risk-ranking of all sites to drive CDER surveillance monitoring and guide CDER-Office of Regulatory Affairs (ORA) inspection planning. OQS also establishes new inspection protocols, assesses site data, designs training, and manages drug surveillance inspection program oversight.

Position Summary:

As **Supervisory Operations Research Analyst**, the incumbent plans and directs staff activities and oversees the scientific review and quality evaluation of matters relating to post-market quality issues, risk-based assessment, and strategic policy analysis. Interacts with subordinates, consisting of 8-12 multi-disciplinary and technical employees. The highly technical team work on the use of merging and cleaning data regulatory intelligence, analytics, statistics, and modeling tools.

Supervisory responsibilities: Provides leadership and management oversight to subordinate staff. Supervises and evaluates staff of who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Obtains and identifies strategic objectives for the organization.

Duties/Responsibilities:

- Collaboratively participates in decision making processes, meetings, and discussions and fully engages in actual determination, allocation, and administration of the program segment, functions, and activities of the Division.
- Provides supervision and participation in over-arching site and product surveillance activities, including resource allocations (work-planning), ad hoc/triggered inspection or short-term assignments, and drug quality sampling programs. Leverages data and expertise to identify and monitor leading indicators of potential quality problems and/or product availability issues.
- Provides leadership and participation with New Inspection Protocol Project –

Surveillance Inspection and Pre-Approval Subgroups, including development of intelligent questionnaires for use on pharmaceutical manufacturing Current Good Manufacturing Practices (CGMP) inspections.
- Executes strategies involving the collection, analysis, and application of site and product data for better surveillance decisions.
- Provides expert scientific and regulatory advice and guidance concerning approaches and options that are sound and feasible to Division goals and conforms to Medical Product User Fee programs and regulations governing quality intelligence.

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.

Click here for more information on Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when:
- An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job.
- An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace.
- An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events.

You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis.

Learn more about disability employment and reasonable accommodations or how to contact an agency.

Professional Experience/Desirable Qualifications AD-1515:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the level of the position. Qualifying experience involves a working knowledge of current FDA, CDER and OPQ regulations, policies, and procedures pertaining to safe, effective, high quality drugs including new drugs, generic drugs, biological products and biosimilars, as well as OTC drugs.

- Experience in analyzing, planning, and adjusting work operations of subordinate organizational segments to meet program requirements and objectives within available resources.
- Demonstrated experience in applying leadership principles and concepts; managing and leading a diverse staff.
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative decisions; makes recommendations
- Successful experience in organizational change management.
- Expert ability to communicate, verbally and in writing, and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Ability to work independently and as a contributing and collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.

Key requirements will include:

Desirable Education:

Degree: in operations research; or at least 24 semester hours in a combination of operations research, mathematics, probability, statistics, mathematical logic, science, or subject-matter courses requiring substantial competence in college-level mathematics or statistics. At least 3 of the 24 semester hours must have been in calculus.Please review the entire IOR to confirm the minimum education requirements in the following link. Operations Research Analyst, 1515

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 the 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.

How to Apply: All qualified candidates should submit a curriculum vitae,cover letter describing why you are uniquely qualified for this position and unofficial transcripts (if you have foreign transcripts please submit s foreign transcript evaluation from an accredited company), including how you possess the desired experience and qualifications identified above, electronically by **November 17, 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 Job Code: **Supervisory Operations Research Analyst, OQS.**

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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