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 Translational Sciences (OTS)

Position: Physician

Pay Plan-Series: AD-00

Location(s): Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: 04/01/2020- 04/15/2020

Salary: Starting at Band F

Area of Consideration: United States Citizens or Nationals

Relocation Expenses Reimbursement: N/A

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.

This position is located in the Center for Drug Evaluation and Research (CDER), Office of Translational Sciences (OTS). We:

- Promote scientific collaboration and innovation in drug regulatory review across CDER.
- Assure the validity of clinical trial design and analysis in regulatory decision-making.
- Develop and apply quantitative and statistical approaches to decision making in the

regulatory review process.
- Ensure alignment of CDER research with CDER goals.
- Serve the CDER scientific community in establishing technology transfer agreements that are vital to collaboration with the broader scientific community.
- Maintain knowledge management databases that can be the basis of improvements in the regulatory review process.
- Oversee bioavailability/bioequivalence and non-clinical inspections to help ensure the availability of safe and effective new and generic drugs.

Position Summary:

The incumbent serves as a professional Physician expert on clinical matters pertaining to the Center's guidance, scientific policy, and activities relating to regulatory science initiatives. The incumbent serves as a regulatory expert advisor to the OTS Director.

Supervisory responsibilities: N/A

Duties/Responsibilities:

Serves as an OTS super office-level expert and provides technical oversight and coordination of regulatory science activities with counterparts in Office of New Drugs. Serves as the Office focal point and primary contact for OTS's regulatory and policy issues.

Provides expert and authoritative advice, guidance, assistance, interpretations, consultations and recommendations to top level and senior Agency and Departmental officials program directors, scientific and professional personnel, industry representatives, intra/inter - governmental counterparts and others concerning medical device policies, programs and activities. Represents the Office, Center Director and FDA as necessary.

Serves as a regulatory scientist using a high level of medical expertise to plan, coordinate and evaluate OTS's programs and activities.

Leads, plans, schedules, and executes policies and procedures as assigned by OTS management. Works in a collaborative manner to establish consistent approaches related to regulatory science activities.

Provides oversight, technical expertise, leadership, and consultative service to OTS on critical aspects of regulatory science, particularly those that involve the broadest, most complex topics.

Serves as the subject matter expert in regulatory science and, as assigned, on cross Office and CDER working group's related to regulatory science. Maintains an up-to-date understanding of

the regulatory science in order to inform and improve the scientific and business practices for drug approval and drug safety within CDER Office programs.

Facilitates collaborations between OTS, CDER, and FDA collaborators, other government agencies and nonfederal stakeholders.

Researches, analyzes, consults, and participates in making final decisions that become accepted Office-level procedures and processes in areas related to regulatory science.

Collaborates with the Office of New Drugs and other CDER offices to write and issue concept papers/ guidance to address approaches to foster innovative drug development strategies.

Develops curricula for CDER staff which incorporates new scientific and research information on novel clinical trial designs. Develops and coordinates regulatory science activities and policies related to drug or drug development tool activities.

Contributes towards the formulation of options and alternatives related to regulatory science policy development. Keeps up with literature and scientific developments in the field.

Develops research projects to fill gaps in knowledge related to regulatory decisions. Provides scientific support in developing and/or updating guidance and policy; reviews documents submitted for regulatory action.

Advises the OTS management on issues related to scientific subject matter; and provides verbal and written responses reflecting relevant information, study findings and recommendations.

Develops new concepts, methods, and strategies for utilization of regulatory science data. Compiles data to prepare presentations to support Agencies recommendations on scientific issues.

Addresses complex, long-range, and emerging problems and conflicts related to drug safety as applied to the products for which CDER is responsible. Keeps fully abreast of crucial and precedent setting issues under review within the various CDER offices and in the regulated industry.

Serves as a recognized scientific authority and receives and addresses unique, far-reaching, and previously unresolved problems for analysis and resolution.

Studies regulatory problems in depth and consults with other scientists within and outside the FDA office and centers, and others in the Federal government as necessary. Works toward the development of standards of medical science for drug safety and efficacy.

Reviews, analyzes and resolves a variety of complex industry applications to apply new scientific and technological developments to novel and critical problems which cannot be resolved by the use of conventional method.

Recognizes the need for and develops new procedures to solve critical or novel problems or to perform more refined analyses. Advises others in the application of Agency rules, regulations and procedures.

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:

Mastery knowledge of an up to date understanding of regulatory science in order to inform and improve the scientific and business practices for drug approval and drug safety within CDER Office program.

Mastery professional knowledge of theories, principles and methods of research in medicine and associated scientific disciplines sufficient to allow employee to review a variety of complex industry applications, to apply new scientific and technological developments to novel and critical problems which cannot be solved by the use of conventional method.

Mastery professional knowledge of recent developments in medical science and associated scientific disciplines; applicable Agency laws, regulations, policies, procedures and guidelines; scientific information on unexpected side effects, injury, toxicity or scientific reactions associated with the regulated and related products.

Mastery knowledge of state-of-the-art areas of clinical medicine and research (such as the use of surrogate markers of exposure and disease) to recognize the need for and then develop new procedures to solve critical or novel problems or to perform more refined analyses.

Mastery professional knowledge of drug safety and all classes of drugs to serve as a regulatory scientist using a high level of medical expertise and to advise others in the application of Agency rules, regulations and procedures.

Effective oral and written communications skills to prepare reports of findings, draft papers or guidance documents for publication and to provide advice to other scientists using knowledge of the Food and Drug Cosmetic Act; and to facilitate collaboration between CDER and FDA collaborators, other government agencies and non-federal stakeholders.

Mastery professional skills to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication to provide advice to senior officials and provide recommendations.

Mastery professional expert knowledge of clinical matters pertaining to the Center's guidance, scientific policy, and activities relating to regulatory science initiatives to serve as a regulatory expert advisor to the OTS Director and other professionals.

Key requirements will include:
This position requires the incumbent have a Doctor of Medicine, Doctor of Osteopathic Medicine or Equivalent. Must possess a full and unrestricted license or registration as a Physician.

Desirable Education:

Doctor of Medicine, Doctor of Osteopathic Medicine or Equivalent

Conditions of Employment:

Security Clearance:

This position requires a background check and the incumbent has access to documents and facilities.

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: Submit resume or curriculum vitae with cover letter by **4/15/2020** to: **CDEROTSHIRES@fda.hhs.gov.** Please reference: **Office of Translational Sciences-Physician.** MD, MD/JD, MD/MPH, MD/PhD candidates are encouraged to apply.

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

FDA is an equal opportunity employer.