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: General Health Scientist

Pay Plan-Series: AD-0601

Location(s): Silver Spring, MD

Travel Requirements: 25% or less

Application Period: November 24, 2020 - December 14, 2020

Salary: Starting at $ 121,316 (Band D)

Area of Consideration: United States Citizens or Nationals

Relocation Expenses Reimbursement: Relocation reimbursement not 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 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) 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) mission is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This position is located in the Center for Drug Evaluation and Research (CDER), Office of Translational Sciences (OTS). OTS is composed of five sub-offices. The OTS Immediate Office supports translational medicine efforts for CDER and leads

the areas of technology transfer, data mining, health information technology, science and research oversight, and knowledge management. OTS also administers CDER's Oak Ridge Institute for Science and Education (ORISE) Program through its Office of Administrative Operations. The successful candidate for this position will be working within a diverse scientific group with complementary expertise to build a research operations group that will focus on the development of a robust research grant management program and a drug development science portfolio.

Position Summary:

The incumbent serves as General Health Scientist clinical matters pertaining to the Center's guidance, scientific policy, and activities relating to regulatory science initiatives.

Supervisory responsibilities: N/A

Duties/Responsibilities:

Provides initiatives on implementation of new policies and procedures, supporting the development of research projects tracking, the modernization of the research proposal review process, and the development of guidance around drug development science.

Performs comparative analyses of current and future policies to formulate appropriate strategies to address challenges related to execution of timetables for prompt action, and implementation of efficient and effective follow-up mechanisms.

Prepares reports on policy issues for both internal and external use, as appropriate, and establishes effective and expanding communication channels to provide targeted policy information to all involved parties.

Prepares a wide range of documents to communicate new policies to internal and external groups and participates with the senior staff in the development of policy initiatives and establishing and maintaining liaisons with experts within and outside the FDA, other Agencies, Congress and other external groups.

Tackles problems of all complexities for a project and seeks solutions. Aggregates useful information about challenges and shares with a broader community. Problem-solving may influence regulatory guidance documents and/or regulatory decisions.

Accountable for organizational assets used during the normal course of scientific, technical, and professional work. Documents and reports work-related expenses when using organizational supplies.

Provides technical leadership of a temporary grouping of employees, as in a matrix-type relationship or for special collaborations between employees or organizations.

Mentors others by identifying and communicating opportunities that match competencies with organizational capabilities. Individually recognized outside of own immediate organization as a master in their field of specialty.

Advises management on project activities to achieve organizational goals. Works on project activities for multiple projects.

EEO Responsibility:

Equal Employment Opportunity Policy Equal Employment Opportunity (EEO) for federal employees and job applicants (https://www.eeoc.gov/federal-sector/federal-employees-job-applicants)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.

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 (https://www.opm.gov/policydataoversight/disabilityemployment/reasonable-accommodations/) or how to contact an Agency (https://www.opm.gov/policydataoversight/disabilityemployment/reasonableaccommodations/).

Professional Experience/Desirable Qualifications:

- Master of an occupational specialty. Skilled in applying knowledge to all occupation-related duties and responsibilities
- 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 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 to have a bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position.

Desirable Education:

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences.

Conditions of Employment:

1. **Security Clearance:**

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

2. **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.

3. **How to Apply:**

Submit resume or curriculum vitae with cover letter by **December 14, 2020** to: **CDEROTSHIRES@fda.hhs.gov.** Please reference: **Office of Translational Sciences-General Health Scientist.**

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

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