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 Generic Drugs (OGD)
Office of Safety and Clinical Evaluation (OSCE)
Division of Clinical Review (DCR)

Application Period: November 1, 2021-November 10, 2021

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Division Director **(Physician)**

Series: AD-0602

Location(s): Silver Spring, Maryland

Salary: Starting at $210,000

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 10% or less

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

This position is being filled under a stream-lined 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 this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

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 are safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) 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.

The Office of Safety and Clinical Evaluation (OSCE), Division of Clinical Review (DCR) is responsible for assessing bioequivalence studies with comparative clinical endpoints and protocols supporting Abbreviated New Drug Applications (ANDAs) and amendments and supplements to ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) particularly involving complex generic products. Provides recommendations for approval, or identifies deficiencies or the need for additional data, in the demonstration of bioequivalence in ANDAs, amendments, and supplements.

Duties/Responsibilities

The incumbent serves as an advisor to the Director and Deputy Director of OSCE, and is responsible for planning, coordinating, and evaluating the programs and activities of the division. In this capacity, the incumbent oversees regulatory and technical directions related to generic drug bioequivalence studies with clinical endpoints and/or protocols; identifies potential clinical safety or product use issues or bioequivalence problems; provides guidance for resolving the matters; and evaluates drug disposition data and specialized drug delivery systems to assure bioequivalence of generic drug products. The incumbent serves as an authority on clinical issues related to the review and approval of generic drug products. Maintains professional contact with the medical communities (both within CDER as well as external professional organizations e.g., American Medical Association, American Academy of Pediatrics) to incorporate the most advanced clinical theories and practices affecting the Office's review activities.

The Division Director provides leadership and oversight, through the subordinate supervisors, of specific regulatory activities including:

- Ensures effective productivity for the Division's review staff and the quality of those review activities. Managers operates through subordinate supervisory staff over the daily activities. Provides guidance on policy and administrative matters. Oversees the development of procedures and practices to assure a consistent, efficient process.
- Over see's division's implementation of Office policies and plans that include making critical decisions and provide expert advice and counsel concerning approaches and options that are sound and feasible in relation to the OGD/OSCE goals and objectives and Federal budgetary and economic realities. Continually evaluates budget, fiscal, and administrative controls to manage Office program segment(s) and services. Develops and makes recommendations for the enhancement and improvement of the mission and functions of the Office.
- Serves as an authority on clinical issues related to the review and approval of generic drug products and advises the OSCE Office Director for matters that involve product safety, efficacy, and/or bioequivalence of a wide variety of drug products. Works in cooperation with the Division of Pharmacology and Toxicology Review as well as the Division of Clinical Safety and Surveillance, in the evaluation of pre- and post-

marketing safety information for generic products.

- Develops and implements policies requiring a clinical perspective pertaining to novel bioequivalence studies, including for novel or complex drug delivery systems to assure bioequivalence of generic drug products.
- Provides oversight of other activities of the Division, which may include consultative reviews, pre-consults, Risk Evaluation and Mitigation Strategies (REMS) protocols, citizen petitions, regulation revision, etc. Provides guidance and advice to regulated industry through review staff and direct participation in pre-ANDA meetings, controlled correspondence, product-specific guidance, and via conferences and meetings, to discuss problems and questions pertaining to matter under the responsibility of the Division.

Supervisory Responsibilities: Manages a clinical evaluation program providing leadership and management oversight to approximately 20+ subordinate support staff performing the work and functions of the organizational unit. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time. Obtains resources and identifies strategic objectives for the organization.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations later.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields

2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement:

Physician Series, 0602
Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

Licensure: For all grade levels and positions, applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Desired Professional Experience:
Our ideal candidate will possess knowledge, skills, abilities, and competencies necessary to perform at the supervisory level. This includes the following:

- Experience in drug development and knowledge of regulatory standards for clinical and safety assessment of human drugs.
- Demonstrated managerial experience.
- Effective communicator who can drive collaboration, empower staff, and is committed to the Public Health mission.

- Ability to identify the internal and external politics that impact the work of the organization.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solution; makes recommendations.
- Ability to communicate 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.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive- High Risk

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

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.
Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume or curriculum vitae with cover letter by November 10, 2021 to Courtney.Mason@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact Courtney.Mason@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact Courtney Mason.

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