Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Generic Drugs (OGD)

Application Period: August 22, 2022 - September 2, 2022

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: Lead Physician

Series: AD-0602

Location(s): Silver Spring, MD

Salary: Starting at $180,000

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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) 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 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 mission of the Office of Generic Drugs (OGD) and its sub offices is to ensure high-quality, affordable generic drugs are available to the American public. OGD is the world leader in the science and regulation of generic drugs serving an essential role in advancing FDA's public health mission.

The Office of Safety and Clinical Evaluation (OSCE) supports the timely assessment of ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs with attention to coordinating complex scientific considerations. OSCE also supports the development and implementation of safety programs specific to a risk evaluation and mitigation strategy, required under the 2007 FDA Amendments Act, during the generic drug application review.

The Division of Clinical Review (DCR) assesses the 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 (FD&C) Act particularly involving complex generic products.

Duties/Responsibilities

As **Lead Physician,** the incumbent serves as principal advisor to the Division of Clinical Review (DCR) leadership for all classes of drugs, responsible for leading, planning, carrying out drug programs and research project reviews and studies, risk management, and evaluation of complex issues that may impact the safety, efficacy, and/or bioequivalence of a wide variety of generic products.

- Leads and mentors a team of interdisciplinary professionals performing scientific review work to support generic drug development, including management of workload in accordance with established divisional priorities and ensures timely completion of the assigned team tasks while ensuring that each employee has integral role in developing the final team product.
- Ensures the mission, vision, strategic goals, and values are communicated to the team and are appropriately implemented and integrated to the work program; maintains current knowledge to answer questions from team members on procedures, policies, directives, etc.
- Prepares reports and maintains records of work accomplishments and administrative information, as required, and coordinates the preparation, presentation, and communication of work-related information to the DCR Leadership.
- Represents the team's views and conveys the team's findings and recommendations in meetings and in working with other OGD/CDER/FDA staff as appropriate, the public and other customers on issues related to or that have impact on the teams' objectives, work products and tasks.
- Informs the supervisor of team and individual performance, recommends performance

ratings and individual development plans, communicates management issues and problems, and recommends corrective action.
- Concentrates on complex, long-range, and emerging problems and issues in the clinical evaluation of generic drug products in the review of abbreviated new drug applications (ANDAs) and pre-ANDA review activities, i.e., clinical study protocols, controlled correspondences, pre-ANDA submissions, and guidance development.
- Serves as a member of DCR, OSCE, OGD, CDER and Agency committees and working groups to consider problems or the direction of medical, scientific, and regulatory issues associated with or impacting the review of generic drug products.

Supervisory Responsibilities: N/A

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 at a later time.

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.

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, AD- 0602 Series

Degree: 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.

For more information please see: OPM Occupational Series Qualification Requirements.

Desired Professional Experience:

Our ideal candidate will possess:

- Experience and effective communicator who can drive collaboration, empower team members, provide expert consultation, coordinate program activities, and lead important programs.
- Demonstrated experience in leadership principles and concepts.
- Ability to communicate orally and in writing to gather and convey information, make oral presentations, and prepare reports, correspondence, and other written materials.
- Ability to collaborate with internal and external stakeholders.
- Ability to function within a regulatory environment and problem solve to meet challenging demands.

- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solution; makes recommendations.

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-Moderate Risk

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

How to Apply: Submit resume or curriculum vitae with cover letter by **September 2, 2022,** to: Megan.Conrad@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 Megan.Conrad@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact Megan.Conrad@fda.hhs.gov.

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