Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of Generic Drugs (OGD)
Office of Safety and Clinical Evaluation (OSCE)

Application Period: September 1, 2021 - September 30, 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: OSCE Director (Supervisory Physician)

Series: **AD-**0602

Location(s): Silver Spring, MD

Salary: Starting at $235,000

Work Schedule: Full-time

Full Performance Band Level: Band G

Cures Band(s): Band G
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 compensated 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 Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) located at the Food and Drug Administration (FDA) is recruiting to fill the position of Director, Office of Safety and Clinical Evaluation (OSCE). The Office of Generic Drugs (OGD) is responsible for the development and implementation of standards for the safety and effectiveness of generic drugs; reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability; establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocols, and studies; and oversees all aspects of labeling submissions for ANDAs.

Duties/Responsibilities

- As the Office Director, oversees the Immediate Office and three Divisions in the OSCE, which includes; the Division of Clinical Review that assesses bioequivalence studies with comparative clinical endpoints and protocols supporting ANDAs and amendments and supplements; the Division of Pharmacology/Toxicology Review, which assesses the safety of generic drug formulations; and the Division of Clinical Safety and Surveillance which facilitates broad postmarket safety surveillance review and collaborative projects; coordinates the review of risk evaluation and mitigation strategies for ANDAs as well as conducts Bio-Investigational New Drug (IND) evaluations.
- Serves as principal advisor to the OGD Director and other CDER leaders on safety and clinical evaluation activities that affect Office/Center generic drug programs, projects, and initiatives. Works collaboratively with the OGD Director and other leaders in OGD to formulate and set the Office's strategic direction for clinical assessment and differences between the generic drug and its reference listed drug (RLD).
- Oversees and directs the implementation of timely assessment of ANDAs submitted under section 505(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act on bioequivalence standards for generic drugs with attention to coordinating complex scientific considerations.
- Directs the development of novel bioequivalence study recommendations.
- Formulates plan to evaluate the effectiveness of program operations related to the ANDA programs (including pre-ANDA program involvement) to meet established goals and objectives within the program Office, CDER and FDA. Ensures routine analysis of workload and program performance are conducted across the Office for ANDA programs.
- Provides executive level leadership and directions related to organizational plans, methodology and resources for evaluating assessments in meeting established goals and objectives. Sets and establishes an executable change management and implementation plan for improvements based on evaluation results

- Provides oversight of the coordination with Office of New Drugs in the development and implementation of safety programs specific to risk evaluation and mitigation strategies (REMS), during the generic drug application review. Provides executive and administrative direction and leadership through subordinate Division Directors within the organization involved in the complex task of identifying, and evaluating clinical bioequivalence problems including potential clinical safety or product use issues for generic drugs. Exercises full authority in carrying out the variety of day-to- day operations of the OSCE programs including understanding all projects underway and an intimate understanding of major policy issues.
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- Assures OSCE is consistent with statutory and regulatory requirements and established policy and procedures. Assures OSCE management decisions are made in timely manner and are consistent with the highest clinical/scientific rigor.
- Oversees the resolution of Identified clinical bioequivalence problems for generic drugs as well as of both pre- and post-marketing safety concerns, particularly those that involve the broadest and most controversial, sensitive, and complex subjects. In addition, depending on the scale of the issue, OSCE may require cross-center involvement with the Office of Pharmaceutical Quality (OPQ), Office of Surveillance and Epidemiology (OSE), and Office of New Drugs (OND).
- Ensures the comparative safety of generic drug formulations, including excipients and impurities in the drug substance or drug product, from pharmacology or toxicology perspectives to determine if the proposed formulation has a similar risk profile as its RLD.

- Oversees the recommendations from a Pharmacology/Toxicology perspective on the comparative safety of a proposed generic drug and related product specification limits in ANDAs, amendments, and supplements. Directs the assessment of the safety of impurities and excipients in Drug Master Files (DMFs) that are referenced by ANDAs.
- Represents the Office of Generic Drugs in both external and internal settings such as conferences, professional meetings, committees and working groups and interacts with the regulated industry, the clinical/scientific community, and government agencies to communicate CDER policy developments regarding clinical bioequivalence and to exchange information with various stakeholders such as development of guidances and insights gained from ANDA reviews.
- Represents the Office and OGD in interfacing and negotiating within CDER and with individuals representing organizations such as the Congress; other Federal agencies; State, local, and foreign governments; the regulated industry;professional and industry organizations; and public interest groups.

Supervisory Responsibilities: Manages a multi-disciplinary program. Provides leadership and management oversight to approximately 80 subordinate support staff and division directors 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. Supervises a staff of scientists that provide clinical and scientific expertise in the evaluation of complex generic drug review issues. 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 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.

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:

- 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:

The applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the executive level. This includes the following:

- Experience in executive leadership with an established track record in leading drug development and knowledge of regulatory standards for safety and effectiveness of human drugs.
- Demonstrated managerial experience in diverse organizations of significant size and complexity. Experience in organizational change management.
- 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. Perceives organizational and political reality and acts accordingly.
- 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

Security Clearance: Non-Critical Sensitive – High Risk

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 these 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 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

All qualified candidates can submit curriculum vitae and cover letter in which you describe why you feel you are uniquely qualified for this position electronically to Whitney.Flickinger@fda.hhs.gov by COB September 30th. 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 Whitney.Flickiner@fda.hhs.gov. Please reference Job Reference ID: OSCE Director

Announcement Contact

For questions regarding this Cures position, please contact Whitney.Flickinger@fda.hhs.gov.

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

FDA is an equal opportunity employer.