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 22, 2021 – December 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: Supervisory Associate Director

Series: AD-0405 & AD-0602

Location(s): Silver Spring, Maryland

Salary:
Series 0405, Starting at $144,128
Series 0602, Starting at $195,000

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 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 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 Act particularly involving complex generic products.

Duties/Responsibilities

The Supervisory Associate Director assists DCR's management team to oversee the scientific review activities of each review team and serves as an authoritative source and leading expert in guiding DCR's multidisciplinary scientific/clinical teams.

The incumbent consistently processes, uses, and communicates an expert understanding of highly complex FDA policies and regulations during the review process and when interacting with Agency staff and representatives of regulated industry. Duties and responsibilities include the following:

- In coordination with DCR Director and Deputy Director, the incumbent ensures effective productivity for the Division's review staff and the quality of those review activities. Provides guidance on policy and administrative matters. Oversees the development of procedures and practices to assure a consistent, efficient process. Collaborates with team leaders to assign tasks among review staff and sure balanced workload across DCR teams. Serves as an immediate supervisor to two scientific and professional multidisciplinary teams.
- Serves as a primary DCR representative coordinating DCR international activities and liaising with OGD international harmonization efforts. The incumbent is a subject matter expert on DCR clinical review policies and strategies and serves as the DCR senior staff coordinating and overseeing divisional involvement of FDA in international settings, such as International Council on Harmonization, and participates in multilateral collaborations with foreign regulatory agencies to align U.S. clinical and point bioequivalence standards with those of other countries.
- Coordinates with other OGD sub-offices and Division Staff to review regulatory assessments and review practices of safety considerations ensuring consistency of GDUFA meeting responses and correspondences, information requests, deficiency letters and FDA actions on clinical safety determinations within the ANDA applications across the Office of Safety and Clinical Evaluation.
- May serve as OSCE/DCR subject matter expert in meetings, conferences, and symposia of scientific organizations to represent the Agency and serve as its spokesperson with respect to developments in the field, to exchange ideas with other scientific peers

engaged in related areas, and to acquire and impart background information pertinent to the conduct of organizational responsibilities.
- Shares responsibility with DCR leadership in representing DCR on working groups and committees and addresses regulatory issues related to generic drugs. Contributes to developing OGD policies on assessments of bioequivalence studies with clinical endpoints as well as generic drug safety consult reviews and coordinates implementation of the policies and related procedures within OGD. Serves as a key member of the DCR leadership team and communicates teams' performance on implementation of the policies and procedures to DCR leadership.

Supervisory Responsibilities: Supervises professional and scientific multidisciplinary clinical team(s) providing leadership and management oversight to subordinate staff. Provides occupational and specific technical and administrative direction 25% or more of the time to supporting staff and team leads performing the work of the organizational unit. Obtains resources and identifies strategic objectives to the organization. Additionally, this position collaborates and coordinates with the DCR Director and Deputy Director to assist supporting and managing a clinical evaluation program.

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:

Pharmacology Series, 0405

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

Evaluation of Education: The positions in this series are multidisciplinary positions, since the work involves the application of a scientific knowledge of biochemistry, physiology, pharmacology, and such related sciences as microbiology, biophysics, genetics, mathematics, and statistics.

Courses in chemistry, organic chemistry, biochemistry, general physiology, and animal, human, microbial, or cellular physiology may be used to meet the 30-semester-hour requirement in chemistry and physiology. Under some circumstances, i.e., where the course work provided additional insight into the biophysical, biochemical, and physiological relationships involved, courses in such subjects as cytology, embryology, cellular or microbial genetics, and biophysics may be used to meet this requirement.

Courses in pharmacology, pharmacodynamics, pharmacotherapeutic, molecular pharmacology, and other similar subjects may be used to meet the 12-semester-hour requirement in pharmacology. Courses dealing intensively with pharmacologically oriented subjects may also be used to meet this 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:
In addition to meeting the basic educational requirements listed above, competitive candidates would have also earned a doctoral degree in the scientific discipline of pharmacology.
The desired knowledge, skills, abilities include 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 12/10/2021 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 at Megan.Conrad@fda.hhs.gov.

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