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 Research and Standards (ORS)
Division of Therapeutic Performance I (DTPI)

Application Period: May 16, 2024 - May 30, 2024

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: Deputy Division Director

Series: AD-0401

Location(s): Silver Spring, MD

Salary: Starting at $163,964

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

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 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 Generic Drugs (OGD) oversees the development and implementation of standards for the safety and effectiveness of generic drugs. OGD reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability. OGD establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocol and studies. OGD oversees all aspects of labeling submissions for ANDAs. OGD supports the continued efficacy and safety of all generic drugs approved under an abbreviated new drug application (ANDA).

The Office of Research and Standards (ORS) is committed to making safe and effective generic drugs available to the American public by ensuring that the Office of Generic Drugs (OGD) standards (as reflected in reviews, guidance, and communications to applicants and the public) continue to be based on the best currently available science and the results of the regulatory science research.

The Division of Therapeutic Performance I (DTPI) conduct regulatory science research to support development of generic drug products for the American public. DTPI ensures the therapeutic equivalence of approved generic drugs through post-approval and investigation of potential safety, product use issues or bioequivalence problems.

Duties/Responsibilities

As the **Deputy Division Director**, the incumbent serves as the primary advisor to the Division Director providing expert-level administrative, regulatory science and technical support activities on all matters related to chemistry, pharmacology, pharmacokinetic, and analytical tools used in the assessment of drug products, which supports the development of new quality and bioequivalence standards or guidance, and improve the existing quality and bioequivalence standards or guidance related to generic drug approvals.

- Directs staff who develop in vitro in vivo correlations for the use in generic drug review and policy development. Ensure that in vitro in vivo correlations used in the generic drug review are scientifically sound and supported by evidence consistent with FDA guidance.
- Oversees and supervises the development and implementation of new or adapted analytical tools for analysis of in-vitro, pharmacokinetic, pharmacodynamic bioequivalence studies. Identifies challenging regulatory questions in post-market surveillance, Abbreviated New Drug Applications (ANDAs) reviews and controlled correspondence that require the development of new chemical analytical methods or scientifically justified regulatory approaches.

- Prioritizes the development of new physical, biochemical, spectroscopic analysis methods to meet the needs of the Office of Generic Drugs and assigns staff to this work and oversees the execution of the work. Works with other stakeholders in the Office of Generic Drugs (OGD) to implement new analytical methods that provided better scientific decisions or make ANDA review processes more efficient. Bridges the non-clinical methods to clinical therapeutic understanding for relevance in bioequivalence decision-making in collaboration with the Division Director and other stakeholders.
- Prioritizes pharmacologic, pharmacokinetic, and physiochemistry regulatory science activities that expand the availability of generic drugs and ensure therapeutic equivalence of generic drugs.
- Works with the Division Director to initiate decision-making processes and documents, and participates with discussions and decisions concerning Office plans, programs, and activities, both in strategic planning and in the actual determination, allocation, and administration of Division program segment(s), functions, and activities.

Supervisory Responsibilities:

- Manages a regulatory program, providing leadership and management oversight to subordinate staff. Supervise and evaluates staff who serve as experts.
- Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time. Plans and sets long-range plans and schedules for the overall work of DTP, assures implementation by subordinate supervisors (or team leaders) and organizations of the goals and objectives, determines goals and objectives that need additional emphasis, determines the best approach and solution for resolving budget problems, and plans for long range staffing needs.
- 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 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:

Pharmacokineticist, AD-0401 Series:

Education: A bachelor's degree or higher in statistics, engineering, mathematics, physics, chemistry, data science, computer science, clinical pharmacology, pharmaceutical sciences, pharmacometrics, pharmacy, toxicology, biotechnology, or biopharmaceutics. The degree must be from an accredited program or institution.

OR

Experience: Relevant work in the design and interpretation of pharmacokinetic studies.

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of federal regulatory programs is required, and knowledge of drug law is desired.
- Significant experience in leading employees and functioning at the managerial level is desired.
- Expert skill in working independently and as a contributing, collaborative team member.
- Expert skill in organizing time effectively, determining division-level priorities, and moving work forward effectively and efficiently.
- Expert communicator who can drive collaboration, empower staff, and is committed to

the Public Health mission; and expert skill in written and verbal communications to prepare written documents and findings and to present findings and conduct briefings.
- Expert skill in identifying and analyzing problems, weighing relevance and accuracy of information; generate and evaluate alternative solutions, and make recommendations.
- Expert skill in pharmacology and pharmacokinetics related to the action of human drugs on the body and the integration of this knowledge with experience in building quantitative and qualitative multidisciplinary models of these pharmacological actions.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

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

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 the 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

Submit resume or curriculum vitae with cover letter by **May 30,2024** to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Cures position, please contact Lauren.Sams@fda.hhs.gov.

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