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: October 28, 2022 - November 25, 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: Deputy Division Director (Pharmacokineticist)

Series: AD-0401/0405/0660/1320

Location(s): Silver Spring, Maryland

Salary: Starting at: $148,484 up to $230,284

Work Schedule: Full Time

Full Performance Band Level: Band E

Cures Band(s): Band E

Travel Requirements: Up to 25%

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) 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.

The Office of Research and Standards (ORS) is responsible for implementing OGD's Generic Drug User Fee Amendments (GDUFA) regulatory science research program, providing pre-submission scientific advice on equivalence standards to ANDA sponsors through meetings, guidance, and correspondence, and providing consults and reviews of complex scientific issues identified in ANDAs or citizen petitions.

The Division of Therapeutic Performance II (DTPII) conducts regulatory science research to support development of generic drug products for the American public and to establish equivalence standards for generic drugs, ensuring therapeutic equivalence. DTPII manages the product-specific guidance process to provide scientific advice for generic drug development.

The Deputy Division Director position is in OGD's Office of Research and Standards, Division of Therapeutic Performance II.

Duties/Responsibilities

As the **Deputy Division Director**, the incumbent serves as the alter ego to the Division Director in the oversight, leadership, and management of the division. This includes aiding in the management and direction of the regulatory science and technical support activities on all matters related to chemistry, pharmacology, pharmacokinetic, modeling, simulation, and analytical tools used in the assessment of generic drug products.

- Oversees and supervises the development and implementation of new or adapted scientific tools for analysis of in-vitro, pharmacokinetic, pharmacodynamic bioequivalence and clinical bioequivalence studies. Identifies challenging regulatory questions in post-market surveillance, ANDA reviews and controlled correspondence that require the development of new chemical analytical methods or scientifically justified regulatory approaches.
- Supports the Division Director to prioritize the development of new scientific methods to meet the needs of the OGD and assigns staff to this work and execute the work. Works with other stakeholders in the OGD to implement new scientific methods that provided better scientific decisions or make ANDAs 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.

- Manages staff that compiles and prepares data, periodic and special reports; and prepares manuscripts for publication in professional scientific journals. These communications describe the scientific foundation of the generic drug review program to internal and external stakeholders including the generic drug industry and academic experts. Attends meetings of professional scientific societies to present papers on investigative results, remain cognizant of developments in the field, exchange ideas with other scientists and develop background pertinent to the program.
- Serves on CDER committees related to generic drugs review and provides expert inputs on the use of advanced science in generic drug review to these groups. Supports the Division Director in initiating the decision-making processes and documents with discussions and decisions concerning Division and 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.
- Prioritizes pharmacologic, pharmacokinetic, and physiochemistry regulatory science activities that expand the availability of generic drugs and ensure therapeutic equivalence of generic drugs.

Supervisory Responsibilities: Manages a regulatory program, providing leadership and management oversight to subordinate staff at least 25% of the time.

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.

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:

Biological Science Series, 0401:

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. For more information, please see: OPM Occupational Series Qualification Requirements, 0401

Pharmacology Series, 0405:

Degree: major in 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. For more information, please see: OPM Occupational Series Qualification Requirements, 0405

Pharmacy Series, 0660:

Degree: Doctoral degree in Pharmacy. For more information, please see: OPM Occupational Series Qualification Requirements, 0660

Chemistry Series, 1320:

Degree: physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics. For more information, please see: OPM Occupational Series Qualification Requirements, 1320

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply knowledge of federal regulatory programs is required, and knowledge of drug law is desired.

- Demonstrated experience in leading employees and functioning at the managerial level is desired.
- Experience utilizing advanced collaboration skills to drive collaboration, empower staff, and is committed to the Public Health mission.
- Experience identifying and analyzing problems, weighing relevance and accuracy of information; generating and evaluating alternative solutions, and making recommendations.
- Demonstrated 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 multidisciplinary models of these pharmacological actions.

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

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.

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 **November 25, 2022,** to: ORSPMASTeam@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 the ORS PMAS Team at ORSPMASTeam@fda.hhs.gov.

Announcement Contact

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

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