Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Translational Sciences (OTS)
Office of Clinical Pharmacology (OCP)

Application Period: March 4, 2024 – March 15, 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: Lead Pharmacokineticist

Series: AD-0401

Location(s): Silver Spring, MD

Salary: Starting at $139,395

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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Translational Sciences (OTS) is to empower a diverse, collaborative, and high performing workforce to champion innovation and advance global human drug development.

The Office of Clinical Pharmacology (OCP) is a dynamic, purpose-driven organization dedicated to promoting and protecting global public health through the application of clinical pharmacology and translational medicine principles. OCP plays a pivotal role in advancing the development of innovative new medicines by applying state-of-the-art scientific principles. OCP promotes therapeutic optimization and individualization through best practices in research, policy development, and drug evaluation throughout the product lifecycle.

This position is in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

Duties/Responsibilities

As a **Pharmacokineticist**, the incumbent serves in the Division of Cancer Pharmacology II in the Office of Clinical Pharmacology Serves as a principal advisor to the Division Director, Deputy Division Director, and Associate Directors in a specified therapeutic area, and leads a team of clinical pharmacology reviewers in this therapeutic area responsible for issues pertaining to clinical pharmacology and biopharmaceutics reviews. Represents the Division/Office at crucial meetings with industry and expected to have prepared in advance for the agenda and express the position of the Division/Office on scientific issues in clinical pharmacology.

- Responsible for planning, coordinating, and evaluating the programs and activities of the Division for the therapeutic area for which he/she is responsible. This responsibility requires close personal contact with the “state of the science and therapeutics” to include the most advanced theories and practices in the specific therapeutic area into the Division and Office programs.
- Stays up to date on complex, long range, and emerging problems of drug safety, efficacy, and dosing, as well as conflicts in the therapeutic area as applied to the products being regulated. Keeps fully abreast of crucial and/or precedent setting cases, scientific and clinical interpretations, or analyses under review with the Division and in the regulated industry as well as cases in the Office.
- Demonstrates awareness and knowledge of the design and analysis of human pharmacokinetic and pharmacodynamic studies, including single or multiple dose studies, mass balance studies, food effect, bioequivalence, drug-drug interactions, hepatic or renal impairment studies, QT prolongation studies, pediatric studies and in vitro and in vivo human metabolism and transporter studies including a working knowledge of PK/PD (Pharmacokinetic Pharmacodynamic relationships), modeling and simulation and pharmacogenomics.
- Applies current knowledge of research in a particular scientific discipline and

therapeutic areas and research conducted by the regulated industry in therapeutic responsibility to advise organizational leadership of interrelated programs, current developments, and problems related to products under review and ensure that rapid advances in translational science such as quantitative clinical pharmacology and pharmacogenomics are incorporated into regulatory reviews. Ensures that model informed drug development (MIDD) principles are being applied in drug development and review. Applies knowledge of therapeutic area understanding to provide a medical practice context for clinical pharmacology.

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- Demonstrates clear and concise communication skills, supplemented with training in oral and written communication skills and a commitment to work within the Division and across the other Divisions in the Office (e.g., pharmacometrics, genomics) to optimize the quality of the drug review(s) applicable to the specialized therapeutic area(s).
- Recognizes authority and lead in the specific therapeutic area, is expected to resolve unique, far-reaching, and previously unresolved problems, design/recommend studies relating to specific drug issues, and consults with other professionals both within and outside the Federal government as necessary.
- Ensures timely and effective communication with the sponsors. The incumbent ensures timely completion of reviews by his/her team members according to GRMP (Good Review Management Principles) timelines.
- Coordinates and manages the work assigned to the team in a specific therapeutic area with the objective of assuring timely, high quality and efficient review. Sets priorities and coordinates work in the specific therapeutic area. The incumbent assures uniformity and consistency in the development of policies and procedures governing clinical pharmacology and biopharmaceutics review. Develops active cooperation and productivity of the therapeutic area for which he/she is responsible. Counsels, mentors, and supports the professional development of their respective team of reviewers in this therapeutic area and personally explains critical and significant scientific concepts.
- Leads or serves as a member of Division/Office task forces and study groups called together to consider general problems and/or specific solutions for issues surrounding various 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 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: 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.

Desired Professional Experience:
Our ideal candidate will possess:

- Relevant work in the design and interpretation of pharmacokinetic studies.
- Knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties. Qualifying professional pharmacy experience may involve, but is not limited to:
    - Dispensing medications prescribed by physicians and other health practitioners and providing information to health practitioners and patients about proper usage of medications and side effects.
    - Evaluating medication use patterns and outcomes for patients in hospitals or managed care organizations.
    - Performing administrative, consultative, or staff advisory work for a medical facility's pharmacy program.
    - Planning, monitoring, and evaluating medication programs or regimens.
    - Establishing medication handling procedures for the storage and preservation of medications.
    - Researching medical literature and/or clinical medication information to provide accurate responses to inquiries; and/or
    - Maintaining all medication records required by law.

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

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 qualifications 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

Applicants should submit a letter of interest (cover letter) and current resume by **March 15, 2024**, to CDEROTSHires@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume or email with "do not share".

Please adhere to the following submission protocol:

Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name.

- **Please reference Job Reference ID: 'OCP/DCPII Pharmacokineticist in the subject line of the email.**

Announcement Contact

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

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FDA is an equal opportunity employer.