



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Clinical Pharmacology

Application Period: April 29, 2024 – May 10, 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: Supervisory Pharmacokineticist

Series: AD- 0401 **AD-0401**

Location(s): Silver Spring, Maryland

Salary: Starting at \$163,964

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 25%

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) 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 generic drugs.

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 mission of the Office of Clinical Pharmacology (OCP) promote therapeutic optimization and individualization through best practices in research, policy development, and drug evaluation throughout the product lifecycle.

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.

Duties/Responsibilities

As the **Deputy Division Director**, the incumbent serves as one of the Office of Clinical Pharmacology Divisions: Pharmacometrics (DPM) and provides scientific and regulatory leadership and direction to the Division for its review, regulatory outreach, and stakeholder engagement efforts and assigned therapeutic area.]

Provide scientific leadership and management to scientific and professional staff who perform review of pharmacometrics, pharmacokinetic, pharmacodynamic, bioavailability, bioequivalence, and drug metabolism data in INDs, NDAs, and their supplements and amendments for the purpose of determining acceptability of such submissions.

The incumbent works collectively with the Director to provide oversight to staff assigned to review and approve, disapprove, or recommend new bioavailability, bioequivalence, and drug metabolism studies and/or protocols, and identify potential clinical pharmacology and biopharmaceutical problems and prepare protocols and guidance for conducting relevant studies.

Supervisory Responsibilities:

The incumbent shares fully with the Director to manage the Divisions functional discipline, providing leadership and management oversight to subordinate staff. In collaboration with the Director, supervise and evaluate staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision to staff performing the work and functions of the organizational unit. 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:

General Natural Resources Management and Biological Sciences Series, 0401:

Degree: biological sciences, agriculture, natural resource management, chemistry, or related

disciplines appropriate to the position.

OR **Combination of education and experience:** Courses equivalent to a major, as shown above, plus appropriate experience or additional education.

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.

General Medical and Healthcare Series, 0601:

Degree: Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Pharmacy Series, 0660

Degree: Doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE), or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Licensure Requirements: Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Desired Education:

Our ideal candidate will possess a doctoral- level degree from an accredited institution of higher learning, including Pharm.D., Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or another research doctoral degree widely recognized in U.S. academe as equivalent to a Ph.D.

Professional Experience:

Our ideal candidate possess:

Senior leadership experience, including the ability to mentor scientific staff as well as facilitate others professional growth and development. Demonstrated ability to provide strong leadership and promote maximum potential of a large organization with a multicultural workforce.

Desired Professional Experience:

Our ideal candidate possess:

- Exceptional oral and written communication skills and experience in translational sciences and that exhibits an ability to apply a fundamental understanding of pharmacometrics, and clinical pharmacology, to the life cycle of drug development.
- Ability to function within a regulatory environment and problem solve to meet challenging demands. Ability to apply an understanding of Federal Regulations related to the work of the Center for Drug Evaluation and Research
- Senior leadership experience with track record of being a scientific thought leader,

including the ability to mentor scientific staff as well as facilitate others professional growth and development. Demonstrated ability to provide strong leadership and promote maximum potential of a large organization with a multicultural workforce. Ability to interface and collaborate with diverse audiences. Demonstrated commitment to outreach and collaboration with internal and external stakeholders.

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

This position requires a security clearance and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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 **May 10, 2024** to: CDEROTSHires@fda.hhs.gov

Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions please contact CDEROTSHires@fda.hhs.gov

Please reference Job Reference ID: OCP/DPM Supervisory Pharmacokineticist

Announcement Contact

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

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free environment.

FDA is an equal opportunity employer.

