**Title 21 Vacancy Announcement**
**U.S. Department of Health and Human Services (HHS)**
**Food and Drug Administration (FDA)**
**Office of Translational Sciences (OTS)**
**Office of Clinical Pharmacology (OCP)**
**Division of Translational and Precision Medicine (DTPM)**

**Application Period:** July 17, 2023 – July 28, 2023

**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:** Interdisciplinary Scientist (Pharmacokineticist)

**Series:** AD-0401/0405/1320

**Location(s):** Silver Spring, MD

**Salary:** $94,199 - $171,976

**Work Schedule:** **Full-Time**

**Cures Band(s):** Band B

**Full Performance Band Level:** Band C

**Travel Requirements:** 25% or less

**Bargaining Unit:** 3591

**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 (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 health through application of clinical pharmacology and experimental medicine principles.

The Division of Translational and Precision Medicine (DTPM) in OCP is a multidisciplinary team consisting of translational scientists with clinical pharmacology, human genomics, epidemiology, and molecular biology expertise. The Division works to ensure that clinical pharmacology principles and precision medicine strategies are applied appropriately in all phases of drug development to maximize benefit and reduce risk to patients. DTPM is seeking incumbents for an interdisciplinary position that provides special scientific expertise in the areas of pharmacogenomics, biomarkers, and targeted therapeutics.

## Duties/Responsibilities

As a **Pharmacokineticist,** the incumbent provides scientific expertise as a member of multi-disciplinary scientific and medical teams engaged in review, evaluation, and decision-making regarding approvability of submissions and applications requesting FDA regulatory consideration of clinical research. As the recognized authority in pharmacogenomics and precision medicine, resolves unique, far-reaching, and previously unsolved problems, designs and recommends studies concerning specific drug issues, and consults with other professionals both within and outside the Federal government as necessary.

- Ensures that rapid advances in translational science such as quantitative clinical pharmacology and pharmacogenomics are incorporated into regulatory reviews.
- Applies expert knowledge of the design and analysis of human pharmacokinetic and pharmacodynamic studies to reviews and evaluations of approvability of regulatory submissions.
- Meets with representatives of the regulated industry to discuss problems pertaining to the use of precision medicine approaches in drug development and maintains clear communication in these meetings. Attends professional meetings both within and outside the Federal government and makes presentations in abstract or podium format. Addresses professional groups on the area of personal expertise as that area affects the mission for which the organization is responsible.

Supervisory Responsibilities: None

## 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 Sciences Series, 0401

**A. Degree:** biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

**OR**

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

Pharmacology Series, 0405

**Degree:** A 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.

Chemistry Series, 1320

A. **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.

**OR**

B. **Combination of education and experience:** Course work equivalent to a major as shown in A above, including at least 30 semester hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience or additional education.

For more information, please see: OPM Occupational Series Qualification Requirements.

**Desired Education:**

Our ideal candidate will possess a master's or doctoral-level degree in scientific field.

**Professional Experience:**

Our ideal candidate will possess a combination of the following:

- Experience in applying knowledge if a major therapeutic area and/or related areas to assess, analyze or evaluate study designs, data, or conclusions, submitted by sponsors of pharmacology or biopharmaceutics submissions associated with IND, NDAs, BLAs, and ANDAs to support marketing of a drug.
- Experience serving in a specific therapeutic area to resolve moderately complex problems.
- Experience drafting and recommending studies for specific drug issues.
- Experience communicating findings, making recommendations, and drafting written summaries, to convey information on a wide range of pharmaceutical regulatory issues.
- Experience interacting with agency staff and stakeholders.

**Desired Professional Experience:**

Our ideal candidate will possess:

- Strong interpersonal communication skills.
- Experience with analytical and bioanalytical techniques covering small and large molecule analyses.
- Experience with validating analytic methods and conducting sample analysis using

validated methods.
- Familiarity with how clinical and nonclinical studies are conducted to ensure study subjects are protected and reliable data is generated.
- Thorough, detail-oriented, inquisitive, and driven to identifying problems and potential solutions.

## 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

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

Applicants should submit a letter of interest (cover letter) and current resume by **July 28, 2023**, to CDEROTSHires@fda.hhs.gov. 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**
- **Reference 'OCP Interdisciplinary Scientist--DTPM' in the email subject line.**

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”.

## How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

## Announcement Contact

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

The U.S. Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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