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 Translational Sciences (OTS)
Office of Study Integrity and Surveillance (OSIS)

Application Period: March 25, 2024 – April 5, 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: Interdisciplinary Scientist

Series: AD-0401/0405/1320

Location(s): Silver Spring, MD

Salary: $99,200 - $185,746

Work Schedule: Full Time

Cures Band(s): Band B and Band C

Full Performance Band Level: Band B and 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 streamlined 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 are 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 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 Study Integrity and Surveillance (OSIS) is to ensure data supporting regulatory decisions are reliable by conducting and directing inspections of bioavailability/bioequivalence (BA/BE) and nonclinical (GLP) studies submitted to FDA.

Duties/Responsibilities

As an **Interdisciplinary Scientist**, the incumbent serves as a technical reviewer evaluating and conducting inspections of nonclinical laboratory studies (GLP studies) and the clinical and bioanalytical portions of bioavailability and bioequivalence studies supporting new and generic drug submissions to the FDA to help ensure the health and welfare of research participants, the reliability of study data, and compliance with United States laws and regulations, in support of protecting the public health. Responsibilities specific to the Office of Study Integrity and Surveillance include the following:

- Drafts assignments and supports foreign and domestic inspections conducted by FDA Investigators in the Office of Regulatory Affairs (ORA) of sites that perform the clinical portion of bioavailability and bioequivalence studies with safety, efficacy, immunogenicity, or pharmacokinetic endpoints.
- Reviews reports of inspections and evaluates inspectional findings for inspections conducted by FDA Investigators in ORA to ensure foreign and domestic clinical sites follow United States laws and regulations.
- Prepares and conducts foreign and domestic inspections of sites that perform the bioanalytical portion of studies with pharmacokinetic, pharmacodynamic, or immunogenicity endpoints.
- Reviews reports of inspections and evaluates inspectional findings for inspections conducted by scientists in OSIS in collaboration with ORA to ensure the analytical sites follow United States laws and regulations.
- Evaluates study sites' conduct and ability to protect research participants and generate accurate and reliable data.
- Prepares for and conducts inspections of unusual difficulty and complexity, with supervisory guidance.

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.

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.*

Basic Education Requirement:

Pharmacologist Series 0405 Basic Requirements
Biologist Series 0401 Basic Requirements
Chemistry Series 1320 Basic Requirements

Desired Education:
Our ideal candidate will possess:
Masters or Doctoral-level degree in scientific field.

Professional Experience:

Our ideal candidate will possess:

- Experience in applying knowledge of a major therapeutic area and/or related areas to assess, analyze or evaluate bioavailability and bioequivalence study designs, data, and conclusions of reports submitted by sponsors associated with IND, NDAs, BLAs, and ANDAs to support marketing of a drug.
- Experience with one or more bioanalytical methods used to quantitate concentrations of small and large molecules in human studies.
- Experience serving in a specific therapeutic area to resolve moderately complex problems.
- 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 that are used to support IND, NDAs, BLAs, and ANDAs.
- Experience with validating analytical 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 **April 5, 2024**, 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 'OSIS Interdisciplinary Scientist' in the subject line of the email.

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, experience described in resume, 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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