Title 21 Vacancy Announcement
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 Clinical Pharmacology (OCP)
Division of Applied Regulatory Science (DARS)

Application Period: 1/19/2022 – 2/9/2022

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: Interdisciplinary Scientist

Series: 0401/0405/1320

Location(s): Silver Spring, MD US

Salary: $106,823 - $163,624
Commensurate with experience

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 10% or less

Bargaining Unit:

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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs. This Interdisciplinary Scientist position is located in the Division of Applied Regulatory Science (DARS), Office of Clinical Pharmacology (OCP), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

Duties/Responsibilities

DARS is engaged in mission-critical applied research to develop and evaluate novel tools, standards, and approaches to assess the safety, efficacy, quality, and performance of CDER regulated products. DARS research activities encompasses *in vitro* and *in vivo* laboratory studies, computational analyses, bioanalytical methods research, and integrated clinical research. DARS has continued to build upon its clinical research experience to address critical regulatory, drug development, and public health questions. Topic areas of focus include: **1)** assessing emergent regulatory/public health questions for widely used OTC/Rx/generic drugs, **2)** translational pharmacodynamic (PD) response or safety biomarkers for new drugs (opioids/opioid antagonists; cardiac safety), and **3)** PD biomarkers to speed the development of biosimilars.

The incumbent will work on a multi-disciplinary team performing reviews of the literature, assist in designing clinical studies, and interpreting and analyzing clinical study data. The incumbent will have responsibilities related to successful execution of DARS-led clinical trials from research concept through the clinical study report.

The incumbent will participate in developing best practices, methods, and operational standards related to clinical study conduct, sample analysis, data analysis, and data management for DARS-led clinical studies.

The incumbent will lead review and interpretation of clinical trial results to enable timely internal decision-making

The incumbent compiles data to prepare period and special reports relative to the work of the division and manuscripts for publication in professional scientific journals.

Responsibilities include designing (clinical) studies and analysis plans, performing quantitative analyses on clinical and/or laboratory data available to the FDA, writing and publishing scientific manuscripts, and presenting findings internally and externally.

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.

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.*

Basic 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: 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.

Professional Experience:

The ideal candidate will have a combination of the following:

- In-depth knowledge of clinical pharmacology, clinical study conduct, and data analysis
- Strong attention to detail with the ability to analyze, interpret and present study data coupled with an aptitude for learning.
- Excellent communication and interpersonal skills as this candidate will be expected to work productively in a collaborative, cross-functional team environment.
- Excellent written and verbal communication skills.
- Ability to work independently and as part of a team with a self-motivating and positive attitude.
- Ability to learn new techniques, perform multiple tasks simultaneously, keep accurate records, follow instructions, and comply with division/center policies.

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: 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 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. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.

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: Applicants should submit a letter of interest (cover letter) and current resume/curriculum vitae by February 9, 2022 to: CDEROTSHires@fda.hhs.gov. Please indicate in the subject line of the email that you are applying for the OCP Interdisciplinary Scientist position. 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 or

email with “do not share”.

Announcement Contact

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

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

FDA is an equal opportunity employer.