



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 Generic Drugs (OGD)

Application Period: August 15, 2022- September 16, 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: Lead Pharmacologist

Series: AD-0405

Location(s): Silver Spring, MD

Salary: Starting at 126,233

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) 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 Generic Drugs (OGD) is to provide oversight, leadership, strategic direction, and ensure high-quality, affordable generic drugs are available to the American public. Oversees the development and implementation of standards for the safety and effectiveness of generic drugs, the review and assessment activities of Abbreviated New Drug Applications (ANDAs), their amendments and supplements to determine their approvability according to standards consistent with the Food, Drug and Cosmetic (FD&C) Act and relevant sections of the regulations.

The Office of Research and Standards (ORS) is responsible for implementing OGD's Generic Drug User Fee Amendments (GDUFA) regulatory science research program, providing pre-submission scientific advice on equivalence standards to ANDA sponsors through meetings, guidance, and correspondence, and providing consults and reviews of complex scientific issues identified in ANDAs or citizen petitions.

The Division of Therapeutic Performance (DTP II) conducts regulatory science research under the direction of senior scientist to ensure generic versions of the complex products available to the American public and to establish equivalence standards for generic drugs that will ensure therapeutic equivalence.

Duties/Responsibilities

As **Lead Pharmacologist** in the Division of Therapeutic Performance II (DTP II), Office of Research and Standards (ORS) within OGD, the incumbent leads a team of professionals who, focusing on immediate release oral drug products, lead the product-specific guidance development process providing timely product specific guidance and pre-application scientific advice to generic drug developers.

- Supports the ANDA assessment process through consults on novel approaches to bioequivalence, and plans, coordinates and evaluates programs and activities associated with regulatory science research.
- Ensures that the organization's strategic plan, mission, vision, and values are communicated and integrated into the team's strategies, goals, objectives, and work.
- Identifies, distributes, and balances workload and tasks among employees in accordance with workflow, skill level, and/or occupational specialization.
- Provides adjustments to accomplish the workload in accordance with established priorities as dictated by generic drug user fee agreements and those related to prioritization for public health, drug access (shortages) or other priorities as established by the Division to ensure timely accomplishment of assigned team tasks.
- Serves as coach, facilitator and/or negotiator in coordinating team initiatives and in consensus building activities among team members, coordinates administrative functions related to team management, and monitors and reports progress of work to encompass supervisors' priorities and instructions on work priorities, methods, deadlines, and quality have been met.
- Attends meetings of professional scientific societies to present investigative results,

remain cognizant of developments in the field, and exchange ideas with other scientists.

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.*

Education Requirement:

Pharmacology, AD-0405 Series

Degree: A doctoral degree with 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.

Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for Pharmacology Series, 0405. For more information, please see: [OPM Occupational Series Qualification Requirements](#).

Desired Education:

Our ideal candidate will possess:

Highly qualified scientific expert in drug bioavailability, metabolism, and pharmacokinetics. Responsible for planning, coordinating, and managing the drug bioequivalence program exercising direct oversight of highly trained scientific personnel engaged in review activities.

Professional Experience:

Our ideal candidate will possess:

- Expert experience and knowledge of drug bioavailability, drug metabolism, and pharmacokinetics.
- Ability to identify and/or develop internal and external policies that impact the work of the organization.
- Demonstrated ability to identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations and/or implement program changes.
- Demonstrated ability to prepare communications, and ability to communicate orally to present findings, conduct briefings.
- Ability to lead a team of individuals with varied interdisciplinary skills.
- Skill in organizing time effectively, determining team priorities, and moving work forward effectively and efficiently.
- Skill in developing networks and building alliances, collaborating across boundaries to building strategic relationships and achieve common goals.

Desired Professional Experience: N/A

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/High 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.

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. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 **September 16, 2022**, to: Lauren.Sams@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”.

Announcement Contact

For questions regarding this Cures position, please contact Lauren.Sams@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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