Title 21 Detail Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of New Drugs (OND)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
(Multiple Vacancies)

Application Period: May 21, 2024 – June 4, 2024

Area of Consideration: Open to current employees. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service. **Please see below criteria**

Position: Lead Pharmacologist/Toxicologist

Job Family Series: AD-0405/0415

Not to Exceed Date: 180 Days

Salary: $139,395 - $191,900

Location(s): Silver Spring, MD

Work Schedule: Full-Time

Cures Band: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Will NOT be paid.

This detail (A Temporary Promotion Opportunity May be Considered) is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act.

a. Details from a Cures position to another Cures position are permitted.
b. Details from a non-Cures position to a Cures position are permitted except for: Title 42 (g) employees that are Visiting Associates, Visiting Scientists, and Staff Fellows 42 U.S.C. § 217 (a) Advisory Committee Members (and Consultants).
c. Employees being compensated under Cures will retain their current rate of pay under this authority.
d. Non-Cures employees will retain their current rate of pay under the authority to which their pay is currently set in their permanent position of record. Please contact your HR POC for additional information on 21st Century Cures Act.

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 Center for Drug Evaluation and Research (CDER) performs 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.

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 Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications (NDAs), interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM) is responsible for making safe and effective drugs for cancer available to the U.S. public. ORDPURM oversees development, approval, and regulations of drug treatments for cancer, therapeutic biologic treatments for cancer, therapies for prevention of cancer, and products for treatment of malignant hematologic conditions.

Duties/Responsibilities

As a **Lead Pharmacologist/Toxicologist** within the Office of New Drugs, Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine the incumbent will provide leadership and direction to a team of Nonclinical Scientist Reviewers (Reviewers) in the review and evaluation of Investigational New Drug applications (INDs), NDAs, BLAs, amendments and supplements to determine if drugs are safe and effective. The incumbent will also have a background in a relevant field that includes biology, immunology, pharmacology, physiology, chemistry/ biochemistry, toxicology, or pathology and serves as the technical authority on scientific, regulatory decisions as related to the nonclinical evaluation of the medicinal products under review in accordance with OND regulatory guidance.

- Assigns INDs, NDAs, BLAs assignments to scientific team members and make changes in work assignments to balance workload and increase effectiveness of operations. Provides authoritative technical guidance to the team on complex nonclinical data within the drug development review process.
- Conducts the first level review of INDs, NDAs, BLAs and ensures timely completion and archival of work products, by defining milestones, managing the progress of nonclinical assessments, and providing scientific and regulatory expertise and other resources as

necessary. Performs the secondary review of the submitted nonclinical application for technical validity of Pharmacology and Toxicology studies and regulatory recommendations to ensure that the analysis is scientifically sound, and the recommendations are consistent with Office, Center, and Agency regulations.

- Interacts with other team leaders and team members within the Division and provides technical expertise for difficult or high priority recommendations. Consults challenging nonclinical issues with the Supervisor, Division Director, Deputy Director, and other colleagues within the Division to gain feedback and to bring cross-team consistency in nonclinical approaches, for consistent interpretation of policy and practices within the Division and Office.
- Works closely with clinical review team leaders of the corresponding Clinical Divisions and provides scientific and regulatory feedback, and recommendations for clinical hold issues, product approval, or other critical decision making.
- Attends meetings, conferences, and symposia of scientific organizations to keep abreast of new developments in the field and to exchange ideas with the stakeholders as pertinent to nonclinical aspects of product development for a specific therapeutic field and as related to Divisional practices and policies. May attend meetings on behalf of the supervisor, as needed.
- Participates in guidance development and in Division-or Office-level initiatives, as needed, to improve nonclinical product development as well as operational procedures. Participates in workshops and symposia to review the state of the science and discuss opportunities to develop better nonclinical approaches for activity or safety assessment of products regulated within the Division.

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.
- 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 Requirements:

Education: A bachelor's degree or higher in toxicology, pharmacology, pharmaceutics, environmental sciences, medicinal chemistry, pharmaceutical sciences, or related sciences. The degree must be from an accredited program or institution.

OR

American Board of Toxicology certification

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

- Experienced and effective communicator who can drive collaboration, empower team members, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Demonstrated experience in leadership principles and concepts.
- Mastery knowledge of scientific methods and techniques related to the nonclinical data, pertinent laws, regulations, and Agency.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

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.

How to Apply

Submit resume with cover letter by **June 4, 2024**, to: Katrina.Benjamin@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact Katrina.Benjamin@fda.hhs.gov.

Please reference Job Reference ID: **OND-DPT-1001** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Katrina.Benjamin@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.