Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Vaccines Research and Review (OVRR)
Division of Clinical and Toxicology Review (DCTR)
Toxicology Staff (TS)

Application Period: April 8, 2024 – April 19, 2024

Area of Consideration: Government-wide
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: Pharmacologist

Series: 0405

Location: White Oak Campus, Silver Spring, MD

Salary: Starting at $117,962 and set commensurate with education and experience.

Travel Requirements: 25% or less

Telework Eligible: Yes – as determined by agency policy.

Title 21 Band: C

Full Performance Band Level: C

Work Schedule: Full Time

Bargaining Unit: 3591

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by assuring those available vaccines, allergenic extracts, and related product are safe and effective.

The Division of Clinical and Toxicology Review (DCTR) directs and performs the review process for investigational new drug (IND) applications, biological license applications (BLAs), and amendments with regard to biological drug products regulated by the Office. DCTR coordinates the processing of INDs and BLAs through the other Divisions within the Office and coordinates licensing activities among the Divisions. DCTR develops policies and procedures applicable to the review of preclinical information, clinical trial design, and data submitted in support of BLAs and INDs.

The Toxicology Staff (TS) performs toxicology reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the Staff's purview. The TS provides recommendations on toxicology programs intended to support IND and BLA submissions. The staff contributes to interpretation of toxicology data submitted in support of INDs and amendments, and BLAs and supplements. The TS develops regulatory policies and documents concerning toxicology information for products regulated by the Office. The staff cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, and others regarding toxicology issues related to products regulated by the Office. The TS provides toxicology consultative reviews in response to requests from other Agency components and serves as a source of toxicology information within the Center on products regulated in the Office.

Duties/Responsibilities

The incumbent serves as the Pharmacologist for Toxicology Staff (TS) of the Division of Clinical and Toxicology Review (DCTR) within the Office of Vaccines Research and Review (OVRR) under the Center for Biologics Evaluation and Research (CBER). As an expert in regulatory related toxicology and veterinary medicine, the incumbent provides professional review, or reviews staff evaluations of applications for vaccines and related products. These products are being considered for use in proposed clinical investigations for effectiveness, safety, and labeling. This includes the review of information submitted by pharmaceutical firms for proposed use of investigational new human drug products.

Specifically, the Pharmacologist will:

- Review toxicological study reports submitted by industry in order to determine if questions of drug safety and/or effectiveness need to be addressed, includes information conveyed in labeling of human vaccine and related products and/or withdrawal from the market.
- Serve as expert federal consultant to industry on vaccine and related products for approval policy, medical, scientific and ethical issues relating to new drug development and approval.
- Recommends policy and participates in decisions relating to the drug approval process.
- When appropriate, initiates, directs and validates toxicological research to develop data in support of standards for the review of new drug as well as recommends and reviews intramural and extramural research, as well as research grants, leading to the subsequent development of policies on data requirements.
- Performs administrative and managerial duties as assigned which are associated with program management and operation.

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 supervisory 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 below Education/Graduate Training Requirements 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/Graduate Training Requirements:

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 Education: Candidates would ideally possess a Doctor of Veterinary Medicine (DVM) degree.

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: 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.

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

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

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

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), copy of your unofficial transcripts, SF-50 (if applicable), and letter of interest with ***"CBER/OVRR/DCTR/TS Pharmacologist"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through April 19, 2024.

Announcement Contact

For questions regarding this Cures position, please contact CBERHumanCapital@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.