Title 21 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)
Clinical Review Branch 1 (CRB1)

Application Period: June 24, 2024 – June 28, 2024

Area of Consideration: FDA-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: Branch Chief

Series: 602

Location: White Oak Campus, Silver Spring, Maryland

Salary Range: $180,000 – $288,365 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes

Title 21 Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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.

These positions are being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidates selected for these positions 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 safe, and effective.

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 regulating and assuring that available vaccines, allergenic extracts, and related products 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 Clinical Review Branch 1 (CRB1) performs clinical 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 branch's purview. The Branch provides recommendations on clinical programs intended to support IND and BLA submissions. CRB1 contributes to interpretation of clinical data submitted in support of INDs and amendments, and BLAs and supplements, including data submitted for postmarketing surveillance. Additionally, the Branch cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others regarding clinical issues related to products regulated by the Office. CRB1 performs clinical consultative reviews in response to requests from other Agency components and serves as a source of clinical information within the Center on products regulated by the Office.

Duties/Responsibilities

The incumbent serves as the Branch Chief for the Clinical Review Branch 1 (CRB1) within the Division of Clinical and Toxicology Review (DCTR) under the Office of Vaccines Research and Review (OVRR) and oversees physicians and other staff working within the Branch. This position reports to the Division Director of DCTR. The Branch Chief sets overall policy and conducts scientific and regulatory review of the work of the Branch and is assigned a full range of supervisory responsibilities. The overall supervisory responsibilities include ensuring timely performance of satisfactory amount and quality of work from subordinates and reviewing such work in order to accept, amend, or reject it.

Specifically, the Branch Chief will:

- Evaluate plans and protocols to conduct tests and clinical trials of investigational new vaccines and related products in humans.
- Review the base of knowledge available regarding the pharmacology and toxicology of identical, similar, and related biologics by evaluating the findings of the applications; consider the scientific rationale of the proposed test or trial to determine the likelihood of the investigational drug being able to produce the intended clinical effect; and review the design of the protocol(s) for its potential to test the clinical hypothesis established for the study and procedural data which can be useful in determination of the drug's safety and effectiveness.
- Determine if Phase 2/3 protocols for study of such products relate to the establishment of safety.
- Conduct an evaluation of available data in the IND and prepare a written review.
- Direct Divisional response to treatment IND or treatment protocol applications, coordinates response from other components of the Center/Agency and make recommendations to the Division Director.

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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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:

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the United States or Canada.

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 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.

Desired Professional Skills and Experience:

An ideal candidate would possess an active medical license in at least one state or U.S. federal jurisdiction.

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.

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 unofficial transcripts, SF50 (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"Title 21 CBER/OVRR/DCTR/CRB1 Branch Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through June 28, 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.