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 Therapeutic Products (OTP)
Office of Clinical Evaluation (OCE)
Division of Clinical Evaluation General Medicine (DCEGM)
General Medicine Branch 4 (GMB4)

Application Period: 05/19/2023 – 06/16/2023

Area of Consideration: The Public.
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: 0602 (Physician)

Location(s): White Oak Campus, Silver Spring, MD. 24145-0031.

Salary: 0602 (Physician) = Table 3: Starting at $180,000 and is set to commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Cures Band(s): Band D

Full Performance Band Level: Band 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.

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 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.

Duties/Responsibilities

The incumbent serves as the Branch Chief for the General Medicine Branch 4 (GMB4) within the Division of Clinical Evaluation General Medicine (DCEGM) and the Office of Clinical Evaluation (OCE) under the Office of Therapeutic Products (OTP) and manages daily operations of the Branch. This position reports to the Director of DCEGM. OTP is a newly established Super Office within CBER which is responsible for the continued safety, purity, potency, and effectiveness of cellular, tissue, and gene therapies and other products regulated by OTP. This Branch evaluates the design and results of non-oncology, non-hematology clinical trials with investigational biologic agents and devices that have been submitted to the Office. In addition, the Branch is charged with providing guidance to sponsors during the process of drug development, assuring consistency in the evaluation process, and establishing guidelines in clinical methodology.

Specifically, the Branch Chief will:

- Direct the clinical review program and oversee the review and evaluation of clinical protocols and other clinical information related to regulatory submissions, such as investigational New Drug (INDs) applications and Investigational Device Exemptions (IDEs) particularly for cell and gene therapies, plasma-derived products, and devices with biologic output.
- Provide clear guidance to sponsors related to all phases of clinical development to facilitate subject safety and expeditious drug development.
- Supervise the review and evaluation of clinical data submitted in marketing application to evaluate evidence of safety and effectiveness.
- Serves as a Center and Agency authority providing advice on clinical issues regarding development of biological therapies or devices regulated by OTAT.
- Develop clinical guidelines and procedures, Federal register statements, and special projects.
- Manage and supervise the Branch staff and oversee work pertaining to prevention, treatment and cure of multiple medical conditions.
- Develop policy and/or research regarding clinical issues, such as trial design issues and safety.
- Oversee the development of written policies and identify critical problems in clinical trial methodology.
- Mentor and promote the professional development of members of the Branch.
- Represents the Center, FDA, and Department of Health and Human Services on committees and at scientific/professional meetings with both national and international groups and organizations.

Supervisory Responsibilities:

Organizational Management: Manages a Branch.
Program Management: Runs multiple projects. Identifies best uses of available resources to achieve tasks. Identifies projects needed to achieve activities.
Resource Management: Determines best use of resources to achieve tasks. Identifies resource needs for multiple projects.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Conducts or arranges actions to meet employee competency goals; identifies personnel in need of competencies.

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.
- Males born after December 31, 1959 must be registered with the Selective Service.
- 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 Requirement:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series.

Desired Professional Experience:

- Experience in clinical trial design, analysis, and/or regulation.
- Ability to prioritize and make critical decisions.
- Developing short- and long-term programmatic goals.
- Work collaboratively with a diverse cadre of customers and stakeholders.
- Knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Experience monitoring trials of investigational agents for safety.
- Medical board certification or eligibility is recommended but not required.

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.

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), SF50 (if applicable), latest PMAP (if applicable), copy of medical license, unofficial transcripts, and letter of interest with ***"CURES CBER/OTP/OCE/DCEGM/GMB4 Branch Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through June 16, 2023.**

Announcement Contact

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

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FDA is an equal opportunity employer.