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 Blood Research and Review (OBRR)

Application Period: October 5 – 20, 2023

Area of Consideration: 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: Office Director

Series: 0602 (Physician)

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

Salary: Salary is commensurate with education and experience and starts at $235,000

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Cures Band(s): Band G

Full Performance Band Level: Band G

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.

The Office of Blood Review and Research (OBRR) plans and conducts research related to the development, manufacture, testing and activities of biological blood products, including those related to AIDS and those prepared by genetic engineering and synthetic procedures, in order to develop and maintain a scientific base for

establishing standards designed to ensure the continued safety, purity, potency and effectiveness of biological blood products.

Duties/Responsibilities

The Director for the Office of Blood Research and Review (OBRR) is responsible for organizing, staffing, managing, and directing the work of physicians, scientists and support personnel of several divisions and laboratories engaged in research in the fields of hematology and transfusion transmitted diseases, the evaluation and licensing of blood collection and processing facilities, and the review and action upon applications for blood establishments and blood products. As such, the Office Director plays a key role in guarding and protecting the integrity and safety of the nation's supplies and sources of blood and blood components. The Director reports directly to the Center Director.

The Office Director provides advice and counsel to the Center Director, Commissioner and officials of other agencies including those associated emergency preparedness and the national defense, on all matters within his/her sphere concerning blood and blood products.

Specifically, the Office Director will:

- Establish and coordinate policy and program objectives of the Office and its regulatory research and review function within overall program objectives of the Center, Agency, Department, and other government agencies.
- Participate with subordinate division directors in the planning and development of overall Office activities, policies, and procedures involving interpretation and adaptation of Center program and policy objectives and making a variety of policy decisions.
- Direct through subordinate division directors, activities including development and operation of policies pertinent to investigational new drug applications (IND's), product license applications, and medical device applications submitted by researchers and manufacturers. These programs have an impact on all the health professions and the health of the nation.
- Review and approve articles and papers prepared by the divisions intended for publication in scientific journals and notices and policy statements to be published in the Federal Register.
- Represent the Center, FDA, the Department, and the Federal Government on committees and at professional meetings, both national and international, making commitments, suggestions, and recommendations concerning programs, policies, and evaluation of activities within own areas of responsibility and expertise.
- Prepare and present testimony to Congress and other outside bodies. Attend and participate in Congressional hearings on issues relating to areas covered by the Office.

Supervisory Responsibilities:

Manages a multi-disciplinary program, providing leadership and management oversight to 130+ subordinate staff, including division directors. The Director provides technical, clinical, and administrative leadership and direction to the subordinate staff of the Office through subordinate supervisors and exercises the full range of first and second-level supervisory responsibilities.

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.
- 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.

- 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 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:

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

Desired Professional Experience:

- Prior managerial or supervisory experience.
- Ability to prioritize and make critical decisions.
- Developing short- and long-term programmatic goals.
- Work collaboratively with a diverse cadre of customers and stakeholders.
- Extensive professional knowledge and understanding of current FDA regulations, policies, and procedures.
- Experience overseeing the review of pharmacology/toxicology studies for products regulated by CBER/OTP.

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), SF50 (if applicable), copy of your transcript/s, latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OBRR Office Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov.

Applications will be accepted through October 20, 2023.

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.