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)
Division of Blood Components and Devices (DBCD)

Application Period: May 22, 2024 – June 22, 2024

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: Division Director

Series: 0602 (Physician)

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

Salary: Starting at $210,000 and is set to commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Travel Requirements: 25% or less

Cures Band(s): Band F

Full Performance Band Level: Band F

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.

The Division of Blood Components and Devices (DBCD) reviews, evaluates, and takes appropriate action on applications related to the manufacturing of blood and blood components, plasma expanders, blood collection and processing devices, blood storage solutions, and medical device applications related to immunohematology testing of blood and blood components intended for transfusion. DBCD maintains mission-related, scientific programs to evaluate factors affecting the safety and effectiveness of whole blood and blood components and develops related policies.

Duties/Responsibilities

The incumbent serves as the Division Director of the Division of Blood Components and Devices (DBCD) within the Office of Blood Review and Research (OBRR) and manages daily operations of the Division. This position reports to the Director of OBRR. The Division Director evaluates and recommends appropriate action on blood and plasma Biologics License Applications (BLAs), and related supplements, as well as BLA applications related to, plasma expanders, such as albumin, high molecular weight dextran's, and hydroxyethyl starches.

Specifically, the Division Director will:

- Develops and maintains mission-related, scientific programs to evaluate factors affecting the safety and effectiveness of whole blood and blood components, apheresis-derived blood components, and plasma expanders, such as albumin, high molecular weight dextran's, and hydroxyethyl starches.
- Evaluate and recommend appropriate action on medical device applications related to immunohematology testing of blood and blood components intended for transfusion or companion diagnostic indications.
- Evaluate and recommend appropriate action on new drug application and abbreviated new drug application and related to blood storage containers, anticoagulant and blood storage solutions.
- Evaluate and recommend appropriate action on 510(k) automated blood collection devices, and 510(k) Blood Establishment Computer Systems (BECS) used in the manufacture of blood and blood components.
- Cooperate with the Office of Therapeutic Products (OTP) in the regulatory review and management of matters related to Banked Human Tissues.
- Provide clinical, pre-clinical, and clinical pharmacology review and recommends appropriate action on BLAs, investigational new drug applications (INDs), new drug applications (NDAs), PMAs and 510(k) submissions pertinent to manufacturing of blood products within the Office's purview.
- Review clinical trial design for IND and IDE studies proposed by industry for Division regulated products and reviews subsequent data received through BLA, Biologics License Supplements (BLS), or device marketing submissions.
- Work with other Agency components and outside organizations on a variety of issues related to these products.

Supervisory Responsibilities:

The Division Director manages a multi-disciplinary program, providing leadership and management oversight to 55 subordinate staff, including a Deputy Director, Branch and Lab. The incumbent provides technical, clinical, and administrative leadership and direction to the subordinate staff of the Division through subordinate supervisors and exercises the full range of first and second-level supervisory responsibilities.

Plans, assigns, oversees, and directs the work to be accomplished, ensuring timely performance of a satisfactory amount and quality of work; sets and adjusts priorities and timeframes for completion of the work; provides advice

and guidance to staff members; reviews work products and accepts, amends or rejects work; develops performance standards and serves as rating official on employee evaluations; serves as a hiring manager or approves selection for all positions; hears and resolves group and individual grievances and serious complaints; effects various disciplinary actions; approves leave and compensatory time, awards, reassignments, and other personnel actions; promotes team building; identifies and implements ways to streamline operations and increase workload productivity.

Determines the staffing levels needed, requests the resources required and allocates personnel to adequately and effectively perform the mission of the Division. Analyzes changes and trends in workload distribution and shifts human resources commensurate with such analysis. Identifies the impact of changing mission requirements and prepares documents necessary to justify and change position authorizations. Interacts with other managers and supervisors throughout the organization to identify, coordinate and resolve issues crossing organizational lines.

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.
- 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:

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:

- Strategically manages human, financial, laboratory, and/or information resources for a program and organization.
- Provides scientific and technical leadership, direction, and supervision to a multidisciplinary scientific, engineering and/or medical science staff.
- Provides expert technical and scientific guidance/assessment to senior leadership on complex, precedent setting, and/or controversial issues involving policies related to blood and blood products.
- Knowledge and understanding of the provisions, limitations, and practical applications of FDA issues, policies, laws, and regulations related to blood and blood products.
- Ability to communicate complex scientific concepts to a diverse audience (examples include, policy makers, manufacturers, scientists, universities, and the public).

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

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

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), unofficial transcripts, and letter of interest with ***"CURES CBER/OBRR/DBCD Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **June 22, 2024.**

Announcement Contact

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

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FDA is an equal opportunity employer.