



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: February 16, 2024 – March 17, 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: Physician (Transfusion Medicine)

Series: 0602 (Physician)

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

Salary: Starting at \$165,000 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 C

Full Performance Band Level: Band C

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 (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 Research and Review (OBRR) evaluates and takes appropriate action on product applications submitted by manufacturers of biological products, blood and blood components, blood related devices, and tests for screening blood donors for markers of infectious diseases. OBRR plans and conducts research on the preparation and preservation of biologic products, blood, and blood components; methods of evaluating safety, purity, potency, and efficacy of such products; and development of reagents employed in screening blood donors for markers of infectious diseases. OBRR research programs aim to develop and maintain a scientific basis for establishing standards designed to ensure the continued safety, purity, potency and effectiveness of biological and 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 Physician (Transfusion Medicine) serves as an expert Physician and a key member of an inter-disciplinary team of scientists, physicians, and support personnel in the Office of Blood Research and Review (OBRR). The incumbent evaluates applications related to blood products for transfusion, devices for collection and processing of blood components, pathogen reduction methodologies for blood components intended for transfusion, plasma volume expanders (e.g., albumin, dextrans, and hetastarches), hemoglobins including synthetic versions and derivatives, and clinical development programs for investigational biologic products for safety and efficacy. This position reports directly to the Deputy Director of Division of Blood Components and Devices (DBCD).

Specifically, the Physician (Transfusion Medicine) will:

- Perform the regulatory review of a variety of regulatory submissions across the product development cycle to include but not limited to Pre-INDs, INDs, IDEs, NDAs, BLAs and their amendments and supplements, and PMAs, and 510(k)s.
- Review the available literature and through their experience and knowledge, evaluate the proposed trial(s) to determine the risks and its potential benefits, and review the design of the protocol(s) for its ability to test the clinical hypothesis established for the study and to generate data that will be useful in the determination of its safety and effectiveness.
- Analyze and determine the adequacy of clinical trial data submitted by the sponsor/applicants to support the safety and efficacy of novel blood and blood components, and other DBCD/OBRR regulated products.
- Communicate to sponsors any significant concerns regarding the safety of clinical trials contained in IND/IDE amendments arising from the review of adverse event reports and safety summaries.
- Provide advice and recommendations to sponsors regarding the clinical development of their product such as the design of their clinical studies, both verbally and in writing.
- Assess study findings and prepare written evaluations which become a part of the Agency's administrative record to properly administer the Federal Food, Drug, and Cosmetic Act.
- Evaluate issues of clinical benefits and risks with biostatisticians, other medical reviewers in CBER, CDER, and CDRH with expertise as appropriate, and with supervisory input consistent with statutes, regulations, and CBER policy.
- Participate in the development of policy as expressed in regulations and guidance documents.
- Represent the Agency at meetings with academic and industry sponsors of clinical research, and in interactions with other regulatory and scientific agencies and organizations.

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 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:

- Possess an active medical license in at least one state or U.S. federal jurisdiction.
- Expertise in Blood Banking and Transfusion Medicine.
- Experience in clinical trial design, analysis, and/or regulation.

- Mastery of skills in identifying problems, gathering information, drawing conclusions, recommending solutions, preparing reports, negotiating acceptance and implementation of recommendations on the products being reviewed.
- Ability to collaborate with others and establish and maintain effective working relationships with professionals at all levels.
- Experience in presenting findings and recommendations both verbally and in writing.

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](#).

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), latest PMAP (if applicable), unofficial transcripts, and letter of interest with **“CURES CBER/OBRR/DBCD Physician (Transfusion Medicine)”** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through March 17, 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.

