Physician and Physician (Transfusion Medicine)
Department of Health and Human Services (DHHS)
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)

Summary

The position is located in the Department of Health and Human Services (DHHS), 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) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.
At the Department of Health and Human Services (HHS) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) 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.

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.

Overview

Area of Consideration: The Public
Open & Closing Date: October 10, 2024 – December 2, 2024
Salary Range: $165,000 - $262,150 and is set commensurate with education and experience.
Band: C
Occupational Series: 0602
Duty Location: White Oak Campus, Silver Spring, MD
Remote Job: No
Telework Eligible: Yes – as determined by agency policy.
Travel Required: 25% or less
Relocation Expenses Reimbursed: No
Appointment Type: Permenant
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band C
Supervisory Status: Non-supervisory
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

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.
- Perform other duties as assigned.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive 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.
- Males born after December 31, 1959, must be registered with the Selective Service. Please go to http://www.sss.gov for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving, or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*

Desired Professional Experience, Skills, and Education:

- 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.

Qualifications

Basic Qualification Requirements:

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: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.
  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 US or Canada.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Education must be accredited by an accrediting institution recognized by the U.S. Department of Education in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

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 further information, visit the U.S. Department of Education website for Foreign Education Evaluation.***

How you will be Evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement: Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

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 unofficial transcripts, latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OBRR/DBCD Physician (Transfusion Medicine) – Nov 2024"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **December 2, 2024.**

Announcement Contact

For questions regarding this Title 21 Cures position, please contact CBERHumanCapital@fda.hhs.gov.

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FDA is an equal opportunity employer.