Title 21 Temporary Promotion/Detail Announcement NTE 120 days (Reimbursable)
Physician and DBCD Deputy Division Director
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)

Summary

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: FDA-wide
Open & Closing Date: December 20, 2024 – January 3, 2025
Salary Range: $195,000 – $309,337 and is set commensurate with education and experience.
Band: E
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: Temporary
Work Schedule: Full Time
Competitive Service: Yes

Promotion Potential: Band E
Supervisory Status: Supervisory
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

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.

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

Duties

The incumbent serves as the Deputy Division Director of the Division of Blood Components and Devices (DBCD) within the Office of Blood Review and Research (OBRR) and assists with managing daily operations of the Division. This position reports to the Division Director of DBCD. The incumbent serves as Deputy to the Director, DBCD, participating fully with the Director in ensuring the safety and effectiveness of biological therapies or devices regulated by OBRR. In conjunction with the Division Director, the incumbent provides specific technical and administrative direction to Division employees performing the work and functions of the organization.

Specifically, the Deputy Division Director will:

- Ensure adequate review of all regulatory submissions related to manufacture of biologic products, blood and blood components, and related medical devices, and provide definitive review guidance and direction regarding these applications.
- Determine whether to approve regulatory submissions for biological products, blood and blood components and devices regulated by DBCD.
- Oversee the pre-clinical and clinical review of Investigational New Drug Applications (INDs), or Investigational Device Exemptions (IDEs) submitted for biological products or devices regulated by DBCD and assess the adequacy of preclinical and/or clinical data to support the safety of proposed or ongoing clinical investigations and on the adequacy of design of these investigations.
- Participate in policy development regarding blood and blood components and other products applicable to the activities in DBCD
- Design, plan, implement, and evaluate the Division quality improvement projects involving collection, analysis, and use of data.
- Work with other Agency components and outside organizations on a variety of issues related to DBCD products.
- Engage with external and internal stakeholders during national and international meetings to provide the OBRR perspectives on regulation of blood and blood components and provides presentations on various regulatory topics.
- Assume full responsibility for directing the division in the absence of the Division Director
- Perform other duties as assigned.

Supervisory Responsibilities:
The Deputy Division Director provides executive leadership and management of a diverse, interdisciplinary staff of 55 FDA staff and contractual staff. The incumbent provides occupational specific technical and administrative direction to subordinate employees performing the work and functions of the Division, providing employees resources and information that insures a safe and healthy work environment. The Deputy Director obtains resources and identifies strategic objectives for the Division. Managerial tasks include defining jobs, selecting employees, and assigning work; defining technical work requirements and milestones; evaluating the Division and employees' accomplishments by accepting or rejecting work products; and presenting and defending the Division and employees' work to senior management and other offices. The incumbent also recommends employee promotions and recognition, approves leave, implements performance modifications, and takes corrective actions as appropriate.

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.
- 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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- One-year supervisory 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.*
- Applicants must submit a letter or email providing current supervisor approval.

Desired Professional Experience, Skills, and Education:

- Professional knowledge of medicine as from a licensed medical degree and which may include specialized and or/subspecialized medical training.
- Mastery of the clinical trial enterprise to define complex problems, analyze alternatives, and make decisions or recommendations that impact product development programs.
- Expert knowledge of other related research activities funded by the agency, and other agencies, and those carried out under nongovernmental auspices that impacts regulatory oversight of products under OBRR's jurisdiction.
- Knowledge of other related scientific disciplines having pertinence to OBRR's regulatory review program.
- Knowledge of Federal and agency regulations to ethics, policies, and procedures.
- Skill in building effective interpersonal relations and dealing with difficult and sensitive situations.
- Possess valid State or District of Columbia Physicians license.

- Mastery of Federal regulations and agency policies and procedures related to product development programs to include regulatory requirements for pre-market, marketing, and post-marketing regulatory submissions.

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.

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** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable)**, **latest PMAP (if applicable)**, **unofficial transcripts**, **Foreign Credit Evaluation (if applicable), copy of your active medical license/s (if applicable**), **copy of your board certification/s (if applicable)**, and **letter of interest (Word or PDF)** with with ***"Title 21 Cures TP/Detail CBER/OBRR/DBCD Deputy Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **January 3, 2025.**

Announcement Contact

For questions regarding this Title 21 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.