Title 21 Vacancy Announcement
Lead Physician (Team Lead)
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products (OTP)
Division of Clinical Evaluation Hematology (DCEH)
Benign Hematology Branch (BHB)

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.

Overview:

Area of Consideration: The Public
Open & Close Dates: 11/04/2024 – 12/16/2024
Salary: Starting at $180,000 and is set to commensurate with education and experience
Band: D
Occupational Series: 0602
Duty Location: Silver Spring, MD
Remote Job: No
Telework-Eligible: Yes
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full-Time
Competitive Service: Yes
Promotion Potential: Band D
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: Yes
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.

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 Lead Physician (Team Lead) for the Benign Hematology Branch (BHB) within the Division of Clinical Evaluation Hematology (DCEH) under the Office of Clinical Evaluation (OCE), Office of Therapeutic Products (OTP). This position reports to the Branch Chief. The Lead Physician (Team Lead) has a specialty in Hematology, who serves as a secondary reviewer and is one of the principal advisors to the Division Director and other Center senior staff for the evaluation of the safety and effectiveness of novel biologic cell and gene therapies, plasma derived protein therapeutics, certain medical devices, and other OTP regulated medical products. The Lead Physician evaluates clinical trial designs for a variety of hematologic indications. This position can operate in either the Malignant Hematology Branch or the Benign Hematology Branch, as appropriate.

Specifically, the Lead Physician (Team Lead) will:

- Serve as a source of continuity following marketing approval and regularly review the adequacy of labeling.
- Provide secondary reviews (and infrequently primary reviews) of the results of studies or other information to determine the adequacy of clinical post- marketing requirements and commitments.
- Serve as a general resource to more junior staff to evaluate clinical trial designs and interpret regulations and guidance regarding the standards of safety and effectiveness for products regulated by OTP.
- Lead reviews to include assigning and evaluating work of team members on a regular and recurring basis.
- Perform regulatory review responsibilities that may include, but are not limited to, coordinating the review of INDs, IDEs, BLAs and their amendments and supplements, PMAs, 510(k)s), and product labeling.
- Assure that scientific reviews of regulatory submissions such as INDs, IDEs, BLAs, etc. are incorporated into a final assessment addressing all key aspects of the product(s) and proposed clinical trials.
- Provide authoritative advice to sponsors on such matters as, the design of clinical studies for products regulated by OTP.
- Make recommendations, both verbally and written, on initiative product development programs for OTP regulated medical products.
- Serve as a DCEH Branch spokesperson and recognized authoritative source of information on matters related to the development of new regulations and guidance documents pertinent to cell and gene therapy, plasma protein therapeutics and other OTP regulated medical products.
- Serve as an authoritative scientific expert that is sought by peers with respect to issues related to these products manufacturing, characterization, specification, and safety testing, and as to the adequacy of design, implementation, and analysis of clinical trials.

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.

- 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.
- 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 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.*

Qualifications:

Professional Experience/Desirable Qualifications:

- 5 years of graduate training in the specialty of the position to be filled or equivalent desired experience and Board Eligible/Board Certified in pediatric or adult hematology with experience/expertise in malignant and/or nonmalignant hematologic conditions.

Basic Qualification Requirements: There are no Individual Occupational Requirements for this series.
https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

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.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional 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 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 (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 ***"Title 21 CBER/OCE/DCEH/BHB Lead Physician (Team Lead)"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through December 16,2024.**

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.