Title 21 Detail/Temporary Promotion NTE 120 days Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products (OTP)
Office of Clinical Evaluation (OCE)
Division of Clinical Evaluation General Medicine (DCEGM)
General Medicine Branch 2 (GMB2)

Application Period: August 31, 2024 – October 31, 2024

Area of Consideration: FDA-wide
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: Lead Physician

Series: 0602

Location(s): White Oak Campus, Silver Spring, MD. 24145-0031.

Salary: Starting at $180,000 and is set to commensurate with education and experience

Work Schedule: Full-Time

Telework Eligible: Yes – as determined by agency policy

Title 21 Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25%

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.

Duties/Responsibilities

The incumbent serves as a Lead Physician for a General Medicine Branch 2 (GMB2) within the Division of Clinical Evaluation and General Medicine (DCEGM) under the Office of Clinical Evaluation (OCE) and Office of Therapeutic Products (OTP). This position reports to the applicable GMB2 Branch Chief. DCEGM evaluates the adequacy of the study design of clinical trials at all stages of product development and reviews the results of clinical trials of OTP regulated investigational products for the treatment, diagnosis, and prevention of a variety of neurological and ophthalmological indications. DCEGM provides guidance to sponsors during drug development and assuring consistency in the evaluation process. The incumbent in this position serves as a Lead Physician, expert reviewer, and one of the principal advisors to the Branch Chief, Division Director, and other Center senior staff. OTP is a newly established Super Office within CBER which is responsible for the continued safety, purity, potency, and effectiveness of cellular, tissue, and gene therapies and other products regulated by OTP.

Specifically, the Lead Physician will:

- Serve as a Team Leader and Principal Advisor for the Branch Chief responsible for planning, coordinating, and implementing the Branch programs and activities.
- Provide expertise and evaluate the safety and effectiveness of novel biologic cell and gene therapies, plasma protein therapeutics, and OTP regulated medical devices and other regulated products for numerous disease conditions.
- Serve as a general resource and ensure consistency in the evaluation of clinical trial designs and interpret regulations and guidance regarding the standards of safety and effectiveness for products regulated by OTP.
- Lead, review, and evaluate work of team members on a regular and recurring basis.
- Review the technology in evaluations based on the available literature and their expertise.
- 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 produce data that is useful to determine its safety and effectiveness.
- Provide authoritative advice to sponsors on product development programs including the design of clinical studies for products regulated by OTP.
- Serve as a GMB2 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.
- Represent and speak on behalf of the Agency regarding OTP regulated products including for national and/or international meetings; technical societies or trade associations; national or international health agencies; department level activities; and national or international collaborative regulatory activities.
- Perform regulatory review responsibilities that may include, but are not limited to, coordinating the review of INDs, IDEs, BLAs and their amendments and supplements, pre-market approval (PMAs), pre-market Notifications (510(k)s), and product labeling.
- Identify and analyze areas in need of new policy formation, such as but not limited to, best practices for review.
- Work in outreach efforts to industry, academia, and patient advocacy groups in the support of Branch activities.
- Lead task forces and working groups intended to study complex, long-range, and emerging issues or directions in the scientific/engineering fields related to the clinical evaluation of cell therapy, gene therapy, tissue-engineered products, and plasma therapeutic products, as needed.

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.
- 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 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.
- If you are serving or have served in the last 5 years (from 12/01/2023) 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.

Qualifications

To be placed into a Title 21 (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 Title 21 appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards 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 Requirement:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Desired Education:

- An ideal candidate would possess an active medical license in at least one state or U.S. federal jurisdiction.

Desired Professional Experience:

- Mastery of advanced medical theories, practices, and techniques as applied to drug evaluation. typified by the completion of an approved medical residency program supplemented by clinical or research experience.
- Mastery knowledge of the Federal Food, Drug, and Cosmetic Act; experimental design; theories and practices to use in new drug evaluation; and current clinical and research data and activities related to drug product development especially for rare diseases.
- Mastery expert knowledge of the FDA/OTP regulatory science and associated disciplines to allow the review a variety of complex INDs, IDEs, BLAs, PMAs, 510(k)s, master files, supplements and amendments from manufacturers of products intended for use nationally in the diagnosis, treatment, and the prevention of specific diseases in humans.
- Effective written communication skills to develop policy, guidance(s) to industry, internal procedures, and responses to Congressional inquiries, and to provide advice to CBER senior officials.
- Effective oral communication skills to exercise tact, diplomacy, and technical expertise to communicate with Center/Agency policies as related to the development of rare disease drugs.
- Mastery professional skills collaborating and facilitating with a variety of officials at various levels of authority from both public and private organizations including senior management officials, Center level officials, Office of the Commissioner, other FDA Centers, other federal agencies, Congress, the scientific/medical community, academia, and the regulated industry.

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

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, letter/email indicating supervisory concurrence, and letter of interest with ***"Title 21 Detail/Temporary Promotion CBER/OTP/OCE/DCEGM/GMB2 Lead Physician"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through October 31, 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.