



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 Therapeutic Products (OTP)
Office of Clinical Evaluation (OCE)
Division of Clinical Evaluation Hematology (DCEH)

Application Period: 9/6/2024 – 10/19/2024

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: Division Director

Series: 0602 (Physician) – Table 3: Starting at \$210,000 and is set to commensurate with education and experience.

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

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Title 21 Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 the Director for the Division of Clinical Evaluation Hematology (DCEH) within the Office of Clinical Evaluation (OCE) under the Office of Therapeutic Products (OTP) and manages daily operations of the Division. This position reports to the Director of OCE. 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, plasma protein therapeutics, and other products regulated by OTP. The incumbent serves as Division Director, DCEH, and ensures the safety and effectiveness of biological therapies or devices regulated by OTP used in the prevention, treatment, and mitigation of disease.

The Director manages daily operations of the Division and regularly serves as a close advisor to the OCE Director and Deputy Office Director. The incumbent is responsible for fully implementing the requirements of specific Equal Employment Opportunity, Food and Drug Administration (FDA), and Department of Health and Human Services (HHS) programs. The incumbent additionally carries out and supports other special HR programs of the Federal Government, HHS, and FDA as needed.

Specifically, the Division Director will:

- Serve as the Director and supervise staff and oversee work focused on malignant and nonmalignant hematologic disorders.
- Oversee policy and/or research regarding hematology related clinical issues, such as trial design issues and safety; and oversee the development of written policies, identify critical problems in clinical trial methodology.
- Oversee the clinical review program in evaluating clinical data and protocols that involve biological products, especially cell and gene therapies, plasma derived products and devices, for the treatment of hematologic disorders.
- Provide guidance to sponsors regarding all phases of clinical development. Oversee in developing hematology related clinical guidelines and procedures.
- Direct BLA review committee or the review committee for the medical device marketing application for marketing of biological therapies or devices regulated by OTP based on application of policy and standards to the safety and effectiveness of the therapies.

Supervisory Responsibilities:

Organizational Management: Manages a Division which includes both a Malignant Hematology and a Benign Hematology Branch.

Program Management: Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.

Resource Management: Monitors and reports on resources needed to run a Division in the Center.

Personnel Performance Management: Counsels and rates immediate subordinates.

Human Capital Management: Identifies employee competency gaps.

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 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.

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. The 0602 (Physician) series require a degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. In addition to a degree, candidates 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 Education:

- Our ideal candidate will possess an M.D. or D.O degree and be board-certified or board-eligible in adult or pediatric hematology.

Desired Professional Experience:

- An experienced Physician with a strong scientific background in the area of hematology.
- Strong leadership and skill in strategic planning, problem solving, and making policy and programmatic decisions.
- Knowledge and experience regarding FDA scientific and review policies in the hematology area is desirable.
- Supervisory experience is desirable.
- Skilled at building partnerships and collaborations with internal or external stakeholders.

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 and letter of interest with **“CURES CBER/OTP/OCE/DCEH Division Director”** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through October 19, 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.

