



Title 21 Vacancy Announcement
Division Director
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)

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:

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| Area of Consideration: The Public |
| Open & Close Dates: 11/12/2024 - 12/20/2024 |
| Salary: Starting at \$210,000 and is set to commensurate with education and experience. |
| Band: F |
| Occupational Series: 0602 (Physician) |
| 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 F |
| Supervisory Status: Yes |
| 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 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.

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 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.

Qualifications:

Basic Qualification Requirements:

In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following requirements:

- **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.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

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

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** (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 **"Title 21 CBER/OCE/DCEH Division Director"** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through December 20, 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.

