



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 TISSUES AND ADVANCED THERAPIES (OTAT)
DIVISION OF CLINICAL EVALUATION AND PHARMACOLOGY/TOXICOLOGY (DCEPT)

Application Period: March 22 – May 20, 2022.

Area of Consideration: 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 (Hematology)*

Series: 0602

* Multiple selections will be made from this announcement
(Malignant Hematology Branch Chief and Nonmalignant Hematology Branch Chief)

Location(s): White Oak, MD

Salary: \$180,000

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: Non-Bargaining

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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) 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.

The Office of Tissues and Advanced Therapies (OTAT) plans and conducts research related to the development,

manufacture, and testing of cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products in order to develop and maintain a scientific base for establishing standards for safety, purity, potency, and effectiveness.

The Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) develops and maintains the Office's Clinical, Clinical Pharmacology, and Pharmacology/Toxicology Review Programs. Provides clinical, clinical pharmacology and non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview. Provides recommendations on clinical, clinical pharmacology, and non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

Duties/Responsibilities

The incumbent will serve as a Lead Physician, with 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 OTAT regulated medical products. The 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 will:

- Serve as a source of continuity following marketing approval and regularly review the adequacy of labeling. Provides 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 OTAT.
- 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 OTAT. Makes recommendations, both verbally and written, on initiative product development programs for OTAT regulated medical products.
- Serve as a DCEPT 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 OTAT 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.

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.

Qualifications

To be placed into a 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 Cures 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.

Education Requirement:

A. DEGREE: You must have a Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association (<https://www.ama-assn.org/councils/council-medical-education>); Association of American Medical Colleges (<https://www.aamc.org/>); Liaison Committee on Medical Education (<https://www.aamc.org/services/first-for-financial-aid-officers/lcme-accreditation>); Commission on Osteopathic College Accreditation of the American Osteopathic Association (<https://osteopathic.org/accreditation/>); or an accrediting body recognized by the U.S. Department of Education (<https://www.ed.gov/>).

OR

B. 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 (ECFMG) (<https://www.ecfm.org/>) a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination. For more information please see: [OPM Occupational Series Qualification Requirements](#).

AND

LICENSURE: Applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. You must provide a copy of your medical license with your application.

AND

GRADUATE TRAINING: Subsequent to obtaining a Doctor of Medicine or Doctor of Osteopathic Medicine degree, a candidate must have had at least 1 year of supervised experience providing direct service in a clinical setting, i.e., a 1-year internship or the first year of a residency program in a hospital or an institution accredited for such training. 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. Descriptions of such programs are described below.

NOTE: You must provide a copy of your Doctor of Medicine transcripts (unofficial copy), foreign equivalency, or ECFMG results with your application to document that you have met the education requirement. Failure to do so will result in you being rated ineligible for this position. Your transcripts must show completion/conferred date. Unofficial transcripts will be accepted in the application package. Official transcripts will be required prior to your starting work.

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.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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), copy of your active medical license, copy of your transcripts (unofficial), SF50 (if applicable), latest PMAP (if applicable), and letter of interest with **“CURES CBER/OTAT/DCEPT Lead Physician (Hematology)”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **May 20, 2022**.

Candidate resumes may be shared with hiring officials within CBER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this 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.

