U.S. FOOD & DRUG ADMINISTRATION

TITLE 21 CURES ANNOUNCEMENT

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)
OFFICE OF THERAPUETIC PRODUCTS (OTP)
OFFICE OF CLINICAL EVALUATION (OCE)
DIVISION OF CLINICAL EVALUATION HEMATOLOGY (DCEH)

Position: Physician (Hematology)*

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

Series: This position may be filled with the following series: Physician (602)

Location(s): White Oak Campus, Silver Spring, Maryland (location may be negotiable after selection)

Area of Consideration: Open to the Public

Travel Requirements: 25% or less

Application Period: June 1, 2023 – July 3, 2023

Cures Band: C

Full Performance Band Level: C

Cures Position Type: Non-Supervisory Physician

Salary Range: $165,000 - $262,150

Conditions of Employment: United States Citizenship or U.S. National.

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate/s selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:
The Food and Drug Administration (FDA) 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 Therapeutic Products (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 Office of Clinical Evaluation (OCE) 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 Division of Clinical Evaluation Hematology (DCEH) ensures the safety and effectiveness of biological therapies or devices regulated by OTP used in the prevention, treatment, and mitigation of disease.

Position Summary:
The Physician will serve as a clinical reviewer, with a specialty in Hematology, who is a reviewer and advisor 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 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/organizational unit, as appropriate.

Duties/Responsibilities:
Specifically, the Physician will:

- Perform the regulatory review of a variety of regulatory submissions for a hematology indication, in either the malignant or nonmalignant specialized areas, to include but not limited to Pre-INDs, INDs, IDEs, BLAs and their amendments and supplements, and PMAs, and 510(k)s.
- Review the technology on the available literature and through their experience and knowledge, evaluates the proposed trial(s) to determine the risks and its potential benefits, and reviews the design of the protocol(s) for its ability to test the clinical hypothesis established for the study and to generate data that will be useful in the determination of its safety and effectiveness.
- Provide advice and make recommendations to sponsors on such matters as, the design of clinical studies for OTP regulated products such as cellular and gene therapy products and plasma protein derived products, both verbally and in writing.
- Analyze and determine the adequacy of clinical trial data submitted by the sponsor/applicants to support the safety and efficacy of cellular and gene therapy products, plasma protein derived products, and other OTP regulated products.
- Recommend guidance to sponsors regarding all phases of clinical development and develops draft clinical guidelines and procedures, Federal register statements, and special projects.
- Determine the appropriateness of the design with respect to the objectives of the study and the development of the drugs or devices; assures that reviews are completed on time, that potential benefits are weighed against reasonable foreseeable risks to human subjects, and that proposals are developed; and provides guidance to sponsors in answering questions central to drug development in a timely and safe manner.
- Evaluate the safety and adequacy of routine clinical development of cellular and gene therapy products from the first administration in humans through large, definitive trials intended to establish safety and effectiveness.
- Work with reviewers from Center for Drug Evaluation and Research (CDER), Oncology Center for Excellence (OCE) and Center for Devices and Radiological Health (CDRH) to arrive at consensus and recommend decisions to sponsors verbally and/or in writing as warranted.

Professional Experience/Desirable Qualifications:
Three to four 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 Qualifications:
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

Conditions of Employment:

- One-year probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.
- 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.
- This position may be subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity Policy

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

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.

Reasonable Accommodation Policy

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.

Application Procedures:

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/OTP/OCE/DCEH Physician (Hematology)"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **July 3, 2023.**

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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