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 Vaccines Research and Review (OVRR)
Division of Clinical and Toxicology Review (DCTR)

Application Period: December 11, 2023 – December 15, 2023

Area of Consideration: HHS-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: Deputy Division Director

Series: Physician (0602)

Location(s): White Oak Campus, Silver Spring, MD

Salary: Starting at $195,000 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Cures Band: Band E

Full Performance Band Level: Band E

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.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by assuring those available vaccines, allergenic extracts, and related products are safe and effective.

The Division of Clinical and Toxicology Review (DCTR) directs and performs the review process for investigational new drug (IND) applications, biological license applications (BLAs), and amendments with regard to biological drug products regulated by the Office. DCTR coordinates the processing of INDs and BLAs through the other Divisions within the Office and coordinates licensing activities among the Divisions. DCTR develops policies and procedures applicable to the review of preclinical information, clinical trial design, and data submitted in support of BLAs and INDs.

Duties/Responsibilities

The Deputy Division Director reports directly to the DCTR Division Director. The incumbent collaborates fully with the Division Director to direct a staff of physicians and scientists engaged in the review and evaluation of Investigational New Drug Applications (INDs), Biologics License Applications and Supplements (BLAs and sBLAs) concerned with biological products regulated by the OVRR.

Specifically, the Deputy Division Director will:

- Serve as a technical authority in making scientific decisions and judgments in connection with the review and evaluation of clinical and "preclinical" animal data.
- Provide oversight and direction of all DCTR's national and international programs related to clinical evaluation of vaccines and other products regulated by OVRR.
- Develop enhanced policies and processes, long range planning, and authority over funding intended to improve and assure the quality of work output and the efficient management of a diverse, multidisciplinary workforce.
- Determine whether preclinical pharmacological tests and other toxicological evaluations performed on new or marketed products are adequate to support clinical uses.
- Evaluate or direct the evaluation of statements of investigators and progress reports on the conduct and results of clinical investigations. Determines whether clinical investigations are progressing satisfactorily and determines whether a notification of termination or exemption should be issued.
- Attend formal meetings between sponsors, applicants, manufacturers, and Office personnel.
- Collaborate with the DRMRR Division Director and the Office Director to direct a variety of other administrative and regulatory actions such as, responses to requests for emergency use of investigational products, requests for export of investigational biological products, requests for cost recovery, and responses to applications for "Treatment INDs" and "Treatment Protocols" under 21 CFR 312.34, and for "Accelerated Approval" under 21 CFR 601.40.

Supervisory Duties:

Organizational Management: Assists in managing a Division.
Program Management: Runs a functional activity. Oversees multiple projects. Identifies inputs and outputs needed to perform functional activities.
Resource Management: Consolidates and balances resource needs of multiple projects in a functional activity or Division.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies ways to meet employee competency goals.

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.
- 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 below Education/Graduate Training Requirements 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/Graduate Training Requirements:

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

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 United States or Canada.

Desired Professional Experience:

- Managing or assisting in managing a clinical or translational research office.
- Developing short- and long-term programmatic goals.
- Communicating scientific concepts to a lay audience.
- Supervisory experience is highly desirable.

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), copy of your unofficial transcripts (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), SF-50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CBER/OVRR/DCTR Deputy Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **December 15, 2023.**

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.

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