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 Viral Products (DVP)
Laboratory of Vector Borne Diseases (LVBD)

Application Period: March 27, 2023 – April 10, 2023

Area of Consideration: The Public
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: Lab Chief

Series: 401, 403

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

Salary: Starting at $132,368 and is set to commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25%

Bargaining Unit: 8888

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 product are safe and effective.

The Division of Viral Products (DVP) plans and conducts research related to the development, manufacture, and testing of vaccines as well as performs research and provides expertise on viruses known or suspected to constitute contaminants of cell substrates used for manufacture of biologics.

Duties/Responsibilities

The incumbent serves as the Lab Chief for the Laboratory of Vector Borne Diseases (LVBD) within the DVP and the OVRR and manages daily operations of the Lab. The incumbent is responsible for supervision, technical leadership, and guidance regulating products used for the diagnosis, prevention and treatment of emerging viral diseases. This position reports to the DVP Director. LVBD carries out research related to the development, manufacture, and testing of vaccines. The Lab is also responsible for the review of chemistry, manufacturing, and control data submitted in various Investigational New Drugs (INDs) and Biological License Applications (BLAs). Additionally, the Lab is involved in lot release sign-off and participation in pre-and post- licensing inspection of vaccine manufacturing facilities.

Specifically, the Lab Chief will:

- Direct and supervise a team of scientists in their research and regulatory work.
- Oversee research efforts at the leading edge of vaccine development which may require the development or modification of techniques to accomplish these goals. The projects are complex and require an integrated team approach.
- Direct the more critical and immediate problems and provide oversight for the LVBD staff efforts.
- Perform supportive administrative tasks to include preparing requisitions, justifications, and market research for new equipment purchases, and maintaining and updating inventories of accountable property.
- Provide expertise regarding regulating products utilized for the diagnosis, prevention, and treatment of emerging viral diseases.
- Provide oversight and guidance for the regulatory review conducted by staff under the incumbent's supervision.
- Ensure that regulatory reviews of the supervised staff are in-depth and authoritative in scope and contribute directly to the Agency decision-making related to regulating biological products in the area of emerging viral diseases.
- Integrate experience, skills, and knowledge in the virology, molecular biology, and immunology during the review and regulation of approved products, including the complex vaccines that will be the subject of future IND and BLA submissions.
- Serve as a critical resource for solution of problems related to vector-borne viral infection in the research and regulatory arenas.
- Maintain a high level of scientific expertise and skill in the areas of viral pathogenesis and genetics.
- Prepare manuscripts based on the results obtained from experiments and prepare abstracts of the data to be presented within the Center and during national or international conferences.
- Interact with other FDA personnel and industry representatives regarding regulatory issues.
- Be recognized as an expert in various areas that includes many RNA viruses and serve as a resource for other researchers in the DVP for assessing viral entry and pathogenesis.
- Conduct independent review of INDs and BLAs, create regulatory memoranda, and interact with the Center and industry personnel regarding regulatory concerns.

Supervisory Responsibilities:

Organizational Management: Manages a Laboratory.
Program Management: Runs multiple projects. Identifies best uses of available resources to achieve tasks. Identifies projects needed to achieve activities.
Resource Management: Determines best use of resources to achieve tasks. Identifies resource needs for multiple projects.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Conducts or arranges actions to meet employee competency goals; identifies personnel in need of competencies.

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. *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. 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

Desired Education:

An ideal candidate would possess a Ph.D. or M.D. degree and postdoctoral experience in areas relevant to the mission of the Lab.

Desired Professional Experience:

- An experienced scientist with a strong scientific background in virology
- Strong leadership and skill in strategic planning, problem solving, and making policy and programmatic decisions
- Knowledge and experience regarding FDA scientific and review policies 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), copy of unofficial transcripts, SF50 (if applicable), latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OVRR/DVP/LVBD Lab Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **April 10, 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.

FDA is an equal opportunity employer.