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 Compliance and Biologics Quality (OCBQ)
Division of Biologics Standards and Quality Control (DBSQC)
Laboratory of Microbiology, In-vivo Testing and Standards (LMVTS)

Application Period: 4/17/2023 – 4/21/2023

Area of Consideration: 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: Laboratory Chief

Series: 0401

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

Salary: Starting at $132,368

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Band D

Full Performance Band Level: Band D

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 is the federal agency responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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 public health through the regulation of biological and related products including blood, vaccines, allergenics, human tissues, and cellular and gene therapies. CBER protects and advances the public health by helping to ensure that biological products are safe, pure, and potent. CBER also provides the public with information to promote the safe and appropriate use of biological products.

OCBQ's mission is to ensure the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance.

Duties/Responsibilities - The incumbent serves as the Laboratory Chief, providing administrative direction, regulatory review oversight, and scientific guidance to staff under his/her program regarding the review of test methods and implementation of testing. He/she will be responsible for evaluating the performance of staff under his/her supervision. The incumbent will provide regulatory recommendations and guidance as appropriate to his/her staff and serve as the liaison between staff and the product offices. The Laboratory Chief represents the Division, Office, Center, and Agency at local, state, national and international meetings, and establishes appropriate collaborations at all levels to train or maintain proficiency of the members of the Laboratory.

Specifically, the Laboratory Chief will:

- Provide oversight to staff under his/her direction, including implementation of microbiologic- or biologic-based tests conducted by manufacturers to ensure Drug Substance and Drug Product safety, purity, and potency; and oversight of the production, inventory, and distribution of CBER standards and reagents.
- Provide leadership in the implementation of new methods by creating or supporting training opportunities for his/her staff, purchasing equipment or tools that may be needed, ensuring new standard operating procedures are complete and approved in a timely fashion, and authorizing staff to perform tests.
- Ensure routine lot release testing is performed in a timely fashion and is conducted in compliance with ISO 17025 requirements.
- Ensure production of reference material is completed in compliance with ISO 17034 requirements.
- Identify risks and non-conformances that could impact work efficiency or quality, and ensure the implementation of improvements and corrective actions.
- Contribute to working groups which develop new methods, discuss harmonization of methods or validation/qualification of methods, and participate in meetings as an expert in analytical methods and/or validations.
- Serve as the expert in regulatory review and will review information requests and memoranda prepared by staff in his/her Laboratory prior to submitting them to the product office or Electronic Data Room.
- Prepare official correspondence and reports that are submitted to the Division and/or Office.
- Support the co- ordination, leveraging and harmonization of the regulatory business processes and procedures across the Center in support of CBER's mission-critical work as applicable, working as a team player with internal and intra-agency working groups to contribute to new guidelines and policies as needed to communicate with the regulated industry and other federal agencies, and international public health organizations in the context of FDA goals and objectives.

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.
- 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.
- One year supervisory probationary period may be required.

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: OPM Occupational Series Qualification Requirements

Desired Education:
Our ideal candidate would have a Ph.D. in Biology, have experience in working under a Quality System and using a Laboratory Management Information System. Experience in small scale production of biologics, for example preparation of reference material, is also desirable.

Desired Professional Experience:
Prior regulatory experience, particularly in the area of Biologics, is desirable. Experience with lyophilization, LIMS, QMIS, as well as having knowledge of USP Chapters and ICH Guidances related to microbiological assays and assay validations are also 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), a copy of your unofficial transcripts, SF50 (if applicable), latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OCBQ/DBSQC/LMVTS Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **4/21/2023.**

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.