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 Manufacturing and Product Quality (DMPQ)
Manufacturing Review Branch 1 (MRB1)

Application Period: April 1, 2024 – April 21, 2024

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: Branch Chief

Series: 0696

Location: Remote Eligible position

Salary: Starting at $139,282

Telework Eligible: Yes – as determined by agency policy

Bargaining Unit: 8888

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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. 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.

Duties/Responsibilities

The Branch Chief for Manufacturing Review Branch 1 (MRB1) within the Division of Manufacturing and Product Quality (DMPQ) under the Office of Compliance and Biologics Quality (OCBQ) reports to the DMPQ Division Director. The MRB1 Branch Chief is responsible for the planning, organization, and supervision of the overall regulatory, administrative and control activities for the Branch. The Branch Chief is responsible for hiring decisions, work assignments, and the day-to-day operation of the Branch. The Branch Chief provides direction, clarification and interpretation of policy and technical issues for the Branch which consists of a professional staff. The Branch is responsible for the review of submissions, conducting inspections, and takes appropriate actions on investigational new drug (INDs) applications, marketing applications, supplements and amendments submitted to CBER. The review work is primarily the Chemistry, Manufacturing and Controls and facility-related sections for CBER-regulated products.

Specifically, the Branch Chief will:

- Provide guidance and support for all program activities, perform regulatory reviews of all submissions, coordinate the scientific reviews of the applications done by other Office divisions, conduct scientific reviews for assigned submissions, and develop policy with regard to the products under the jurisdiction of the Office, assuring consistency as appropriate with policies and actions of other Offices within the Center.
- Review, evaluate, and take appropriate action on INDs, marketing applications, supplements, and amendments submitted to the CBER, as part of the managed review process; and performs CMC and CGMP reviews.
- Support enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by CBER or field components.
- Evaluate and coordinate regulatory policy and actions proposed by the scientific division for approval/ disapproval of investigational and marketing applications.
- Meet with manufacturers to review facility design/CGMP/new products and technologies.
- Lead and provide oversight and direction for pre-license and preapproval inspections supporting Biologics License Application submissions and supplements and other marketing applications, as part of the CBER managed review process.
- Serve as the focal point of expertise and guidance to manufacturers, consumers, academia, Agency committees, other government agencies, DMPQ and Office staff on the implementation of new laws, regulations, and policies impacting on products; evaluates proposed regulations, Agency guidelines, and Center/Office policies for consistency of interpretation and meaning, accuracy, and practical application.
- Work with the Division Director and Deputy Director to develop the Agency position in response to request for advisory opinions from the regulated industry, non-government health related organizations, Department officials, etc., to cover the full range of subject matter areas within the Center.
- Provide expert technical and regulatory guidance and training to CBER and other Food and Drug Administration (FDA) components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality, in coordination with the Office of Communication, Outreach and Development.

Supervisory Responsibilities:
Organizational Management: Manages a Branch.
Program Management: Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.
Resource Management: Monitors and reports on resources needed to run a Branch in the Center.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies employee competency gaps.

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.

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 Professional Experience: Seeking candidates with experience/knowledge in manufacturing of biologics or drugs, experience with FDA review and regulations of biologics or drugs and supervising staff.

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.
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), SF50 (if applicable), latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OCBQ/DMPQ/MRB1 Branch Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **April 21, 2024.**

Announcement Contact

For questions regarding this Cures position, please contact CBERHumanCapital@fda.hhs.gov.

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FDA is an equal opportunity employer.