



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 Inspections and Surveillance (DIS)
Bioresearch Monitoring Branch (BMB)

Application Period: March 11, 2024 – March 20, 2024

Area of Consideration: FDA-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: Branch Chief

Series: 0696

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

Salary: Starting at \$139,395

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Table 1, Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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.

Duties/Responsibilities

The incumbent serves as the Branch Chief for the Bioresearch Monitoring Branch (BMB) within the Division of Inspections and Surveillance (DIS) under the Office of Compliance and Biologics Quality (OCBQ). This position reports to the DIS Division Director. The 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.

Specifically, the Branch Chief will:

- Plan, manage, organize, and direct all the bioresearch monitoring operations, program segments, functions, and activities of the Branch as carried out by a highly trained and skilled staff of Consumer Safety Officers and other medical/scientific professionals who are responsible respectively for the program segment(s) of the Branch.
- Work with the Associate Director for Bioresearch Monitoring to develop policy and procedures governing the standards for BIMO activities related to CBER regulated products. This requires thorough knowledge of the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, Agency policies, and procedures and familiarity with the organization of CBER.
- Apply a knowledge of administrative and program management principles and skills to carrying out the mission of the Branch as well as to address and solve unusual and often precedent setting problems associated with bioresearch monitoring, compliance, or surveillance program segments.
- Contribute to and fully participate in the decision-making processes, meetings, and discussions concerning Branch program segments, functions, and activities, both in strategic planning and in the actual determination, allocation and administration of the program segments, functions, and activities.
- Provide authoritative advice and assessments of the impact of actual and proposed actions on the program segment(s), functions, and activities of the Branch.
- Develop and implement Branch policies and plan and make critical decisions and provide expert advice and counsel concerning approaches and options that are sound and feasible in relation to Branch goals and objectives and Federal budgetary and economic realities.
- Represent the Division/Branch in dealing and negotiating with individuals representing organizations such as other parts of FDA (e.g., ORA), other Federal agencies (e.g., NIH); the related industry; professional and industry organizations; State, local, and foreign governments; and public interest groups.
- Direct the preparation, clearance, and finalization of Branch responses to inquiries covering all aspects of the program segments, functions, and activities of the Branch.
- Prepare analyses on the impact of proposed changes to laws and Agency regulations, which affect the functions, program segments, and activities of the Branch.
- Performs other duties as assigned.

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:

- General health care/medical background and leadership/management is required.
- Knowledge of the FD&C and PHS Acts and related regulations, policies, and procedures.
- Knowledge of Bioresearch Monitoring.
- Ability to communicate orally in a variety of professional settings.
- Ability to communicate complex issues to a variety of audiences in writing.

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), SF50 (if applicable), latest PMAP (if applicable), copies of transcripts (if applicable), and letter of interest with **“CURES CBER/OCBQ/DIS/BMB Branch Chief”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through 3/20/2024.

Announcement Contact

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

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FDA is an equal opportunity employer.

