



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: 10/14/24 – 11/01/24

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: Consumer Safety Officer*

*Multiple selections can be made from this announcement

Series: 0696

Location: White Oak Campus, Silver Spring, MD

Salary:

Band A: Starting at \$82,764

Band B: Starting at \$99,200

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Bands A/B

Full Performance Band Level:

Band A FPBL: Band B

Band B FPBL: Band B

Travel Requirements: Less than 25%

Bargaining Unit: 3591

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.

Duties/Responsibilities

The incumbent serves as the Consumer Safety Officer in the Bioresearch Monitoring (BIMO) Branch (BMB) within the Division of Inspections and Surveillance (DIS) under the Office of Biologics Quality (OCBQ) within CBER. BMB is responsible for coordinating and providing support to the review teams for Investigational New Drug Applications (IND), Investigational Device Exemptions (IDE), Biologics License Applications (BLA), Pre-Market Applications (PMA), and supplements. BMB manages a full range of work within the BIMO program areas for Sponsors/Monitors/Contract Research Organizations (CRO), Sponsor-Investigators, Clinical Investigators, Institutional Review Boards (IRB), and Pre-Clinical Laboratories. BMB coordinates and provides direction to the Office of Inspections and Investigations (OII) field offices for application-driven, directed/for-cause, and surveillance inspections. BMB recommends (based on applicable evidence) and coordinates with the Division and Office management, Office of Chief Counsel (OCC) or Centers as appropriate, the development and administration of potential administrative and legal actions based on complete gathering and analysis of facts, logical, and informed conclusions and practical considerations. BMB works with OII to prepare BIMO inspection work plans and allocate resources for the CBER BIMO inspection programs. BMB manages and tracks data entered into various CBER Data Repository Systems and ensure quality and efficient reporting to these systems.

Specifically, the Consumer Safety Officer will:

- Apply scientific, regulatory, and policy knowledge to analyze facts and develop logical conclusions and recommendations.
- Prepare complex technical inspection assignments of preclinical laboratories, IRBs, clinical investigators, sponsors/monitors/CROs.
- Review and evaluate inspection reports, analyze the evidence collected to determine if policies were violated and information from related BLAs, INDs, IDEs, PMAs or other documents and sources.
- Assess whether the rights, safety, and welfare of human subjects are protected, and whether the data evaluated during the inspection may be considered reliable.
- Determine which sections of the law and regulations appear to have been violated based on analysis of the evidence, assess the level of risk and regulatory significance of the violations.
- Provide technical input to evaluate the chronology of evidence contained in inspectional reports, analytical reports, and summary of case history as reflected in the pertinent files.
- Reconcile and coordinate the facts and opinions on the case available within and outside the Agency.
- Summarize findings and submit substantive recommendations that are usually accepted based on incumbent technical knowledge.
- Independently develop strategies for achieving compliance and initiate appropriate compliance actions.
- Research precedent BIMO cases to ensure that the proposed approach is consistent with past actions.
- Complete inspections by preparing letters or memorandums that require review and concurrence by the Division Director, Office Director, and possibly the Office of the Chief Counsel (OCC).
- Determine appropriateness to pursue enforcement actions, such as issuance Untitled Letters, Warning Letters, letters initiating disqualification proceedings, and coordinates the enforcement action through to final agency approval.
- Manage disqualification actions until completion, requiring interaction with staff in other offices in the Agency.
- Provide guidance, assistance, interpretations, recommendations, and evaluations to CBER employees, OII field offices and investigators, other Centers, Agencies, and Government Units, Industry and Consumers specific to problematic areas of concern within CBER and throughout FDA.
- Provide scientific, legal and policy input to the training program and preparation of compliance programs and guidance for use by center staff and field investigators, in performing BIMO inspections.
- Train and act as a mentor for less experienced Branch staff, both formally and informally.
- Participate in meetings with industry that are directly related to a BIMO enforcement action, as well as, in meetings with OII, other Centers, or other FDA components to discuss cross-cutting issues relevant to the BIMO program.

- Represent BMB, the Division, and the Office in the development of training events for CBER, OII, and other Agency staff.
- May speak at conferences and professional meetings before the regulated industry, clinical investigators, and the medical/scientific community on applicable regulations, guidance, and policies.
- Support the Center's and Agency's mission as a partner in special work projects, task groups, or individual assignments, potentially serving as a Project Manager.
- Perform other duties as assigned.

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 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: [OPM Occupational Series Qualification Requirements](#)

Desired Professional Experience:

- Candidates would ideally have a master's degree in a medical or scientific field.
- Highly skilled in written and verbal communication.
- Experience working with clinical trials.

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.

Additional Information

If you are serving, or have served in the last 5 years (from 12/01/2023) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment. You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50,

Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

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/DIS/BMB/Consumer Safety Officer**” in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **11/01/24**.

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.

