



Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Blood Research and Review (OBRR)
Division of Emerging and Transfusion Transmitted Diseases (DETTD)
Product Review Branch (PRB)

Application Period: December 9 – December 23, 2022

Area of Consideration: HHS-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: 0401

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

Salary: Starting at \$126,233 and is set to commensurate with education and experience.

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. 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 mission of the Center for Biologics Evaluation and Research (CBER) 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.

Duties/Responsibilities:

The Branch Chief for the Product Review Branch (PRB) reports to the Director, Division of Emerging and Transfusion Transmitted Diseases (DETTD) and is responsible for supervision, technical leadership, and guidance for activities pertinent to regulatory applications in the area of detection of infectious agents in blood and blood products and the diagnosis of retroviral infections. The incumbent is an internationally recognized authority in vitro diagnostic device development, manufacture, and compliance for infectious agents and, therefore, assumes responsibility to resolve exceptionally complex, controversial, or far-reaching scientific issues, problems, and policies in the areas of in vitro diagnostics that arise during review of submissions.

The PRB reviews, evaluates, and recommends appropriate action on BLAs, PMAs, 510(K) submissions and, as needed, IDEs, and INDs pertinent to the products within the Division's purview; initiates the development of regulatory policies applicable to blood establishments and manufacturers of donor screening products; evaluates adverse experience reports and observations regarding manufacturers' lack of compliance with regulations and determines or advises on appropriate action; and acts as product specialists, as part of Team Biologics of the inspection team for pre-license, pre-approval, and annual review of establishments manufacturing biological products or other products regulated by the Division.

Specifically, the Branch Chief will:

- Identify and assess emerging and long-standing issues that impact on the policies and review activities.
- Ensure authoritative regulatory review is conducted by employees, including pre-market performance, product-specific inspections, product release, and regulatory policies.
- Serve as a technical advisor to the Division Director in the handling of regulatory issues related to infectious agents transmissible through blood and blood products. Issues may be extraordinarily complex, sensitive, and often precedent setting matters of regulatory review, policy, and/or compliance.
- Provide consultation and serve as a source of information within the division on regulatory policies applicable to blood establishments and manufacturers of donor screening tests for blood and blood products and practices associated with manufacturing of these products as they relate to transfusion transmitted diseases.

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.
- 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:

<https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series>

Desired Education: (Candidates would ideally have a master's degree, doctoral degree, or both in a relevant field such as Biology or Microbiology.)

Desired Professional Experience: demonstrated experience in the premarket review and regulation of in vitro diagnostic devices.

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.

Vaccination Requirements:

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 your unofficial transcripts (if applicable), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with **“CBER/OBRR/DETTD/PRB Branch Chief”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **December 23, 2022**.

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.

