



Title 21 Vacancy Announcement
Biologist
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 Biological Standards and Quality Control (DBSQC)
Lab of Biochemistry, Virology, and Immunochemistry Branch (LBVI)

Summary:

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 U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

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.

Overview:

Area of Consideration: FDA-Wide
Open & Close Dates: 01/02/2025 – 01/15/2025
Salary: Starting at \$82,764 and is set to commensurate with education and experience
Band: A/B
Occupational Series: 0401
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band B
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

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](#)

Duties:

The incumbent serves as the Biologist for the Lab of Biochemistry, Virology, and Immunochemistry Branch (LBVI) within the Division of Biological Standards and Quality Control (DBSQC) under the Office of Compliance and Biologics Quality (OCBQ). This position reports to the Lab of Biochemistry, Virology, and Immunochemistry Branch (LBVI) Lab Chief. The incumbent serves as a Biological Reviewer for testing licensed and non-licensed biological products for market release and regulatory review of Biologics License Applications (BLAs) and supplements.

Specifically, the Biologist will:

- Utilize an understanding of the agency policies and priorities, and the provisions and intent of new programs and regulations, to make decisions regarding testing needs and regulatory reviews.
- Perform routine lot release testing according to requirements of International Organization for Standardization (ISO) 17025 to facilitate the lot release process and approval of regulatory submissions.
- Contribute to the preparation of reference material or standards, including the calibration and stability testing of these standards, or preparation and characterization of candidate vaccine viruses, according to requirements of ISO 17034.
- Participate in writing procedures and work instructions for the methods and equipment used in testing of products under supervisory guidance.
- Draft refinements to existing Standard Operation Procedures (SOPs) when their present form becomes obsolete or warrants updating.
- Participate in transfer of methods from manufacturers and other Offices within the Agency to DBSQC and in method validation/verification studies.
- Confirm equipment used in testing is qualified and calibrated.
- Communicate with supervisor or Equipment Manager when equipment fails, requires qualification, preventative maintenance, or calibration.
- Report and conduct investigations for deviations and non-conformances under supervisory guidance.
- Perform qualification of reagents used in testing.
- Collaborate with other CBER representatives to secure or produce Reference Standards that are appropriate for current technology and testing.
- Review scientific literature and attend seminars to keep informed regarding test methods and techniques used by DBSQC and manufacturers of biological products.
- Review Lot Release Protocols from manufacturers to confirm specifications are met and tests are conducted following licensed procedures.
- Perform administrative and scientific regulatory review for Biologics License Applications (BLA) and supplements.
- Prepare review memos, participate in conference calls, evaluate manufacturer's responses.
- Participate in meetings with representatives of the regulated industry and other sponsors of biological products about potential product quality issues or to discuss scientific or regulatory issues involved in product applications.
- Within scientific and assigned product area, contribute to discussions regarding methods, method validation, standards or reference reagents.

Requirements:

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving or have served in the last 5 years 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.

Qualifications:

Basic Qualification Requirements:

*In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following **requirements**:*

- Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.
OR
- Combination of education and experience: Courses equivalent to a major, as shown above, plus appropriate experience or additional education.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

- Our ideal candidate will possess Laboratory work experience with handling and preparation of influenza viruses.

If you are using education completed in foreign colleges or universities, see the [Foreign Education](#) section below for additional 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 further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

How you will be evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement: Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

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](#).

How to Apply:

Please submit **electronic resume or curriculum vitae** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable), latest PMAP (if applicable), unofficial transcripts, Foreign Credit Evaluation (if applicable), and letter of interest (Word or PDF)** with **"Title 21 CBER/OCBQ/DBSQC/LBVI Biologist"** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through 01/15/2025.**

Announcement Contact:

For questions regarding this Title 21 (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.

