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 Vaccines Research and Review (OVRR)
Division of Review Management and Regulatory Review (DRMRR)

Application Period: September 3, 2024 – September 16, 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: Biologist*
**Multiple selections can be made*

Series: 401

Location: White Oak Campus, Silver Spring, Maryland

Salary Range: $117,962 – $164,260 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by the agency

Type of Appointment: Permanent

Remote Job: No

Title 21 Band: C

Full Performance Band Level: C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Competitive Service: Yes

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.

These positions are being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidates selected for these positions 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.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by regulating and assuring that

available vaccines, allergenic extracts, and related products are safe and effective.

The Division of Review Management and Regulatory Review (DRMRR) directs and performs the review process for Investigational New Drug (IND) Applications, Biologics License Applications (BLAs), and amendments regarding biological drug products regulated by the Office. DRMRR coordinates the processing of INDs and BLAs through the other Divisions within the Office and coordinates licensing activities among the Divisions. DRMRR develops policies and procedures applicable to the review of preclinical information and clinical trial design and data submitted in support of BLAs and INDs.

The Regulatory Review Branches (RRBs) are responsible for handling issues and regulatory submissions related to preventive and therapeutic bacterial, viral, and parasitic vaccines for infectious disease indications, allergenic products, live biotherapeutic products and microbiome-related products.

Duties/Responsibilities

The incumbent serves as a Biologist for one of the Regulatory Review Branches (RRBs) within the Division of Review Management and Regulatory Review (DRMRR) under the Office of Vaccines Research and Review (OVRR). This position reports to the Regulatory Review Branch Chief. The Biologist coordinates and performs the review process of Investigational New Drug applications (INDs) for biologics and Biologics License Applications (BLAs), including supplements to BLAs and related regulatory submissions. The incumbent plays a central role in assisting Agency decision-making and recommending advice with regards to these applications. The incumbent serves as the project manager for information requests from upper management, other organizational divisions, and the regulated industry.

Specifically, the Biologist will:

- Serve as point of contact for OVRR in communicating the decisions and advice to the Sponsors of these Applications and manufacturers of these vaccines.
- Coordinate, attend, and manage meetings (e.g., Pre-IND, IND, pre-BLA, BLA, etc.) with representatives of pharmaceutical companies, IND Sponsors and licensed manufacturers of vaccines.
- Review data submitted by manufacturers and Sponsors of new biologics to be used for clinical investigations and compose subsequent official responses.
- Evaluate the adequacy of the IND submission to ensure compliance with the New Drug regulations prior to interstate shipment of products.
- Review sections of these submissions that pertain to their area of expertise.
- Evaluate manufacturing and animal immunogenicity data with particular emphasis on identification of hazards, including presence of potential and known harmful agents, relevance to clinical development and conformity to quality control criteria.
- Evaluate all aspects of the clinical study protocol including safety and effectiveness of a drug when used in the particular study population.
- Evaluate clinical study protocols for design elements and regulatory compliance.
- 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.
- 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.
- 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.
- **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.*

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 below Education/Graduate Training requirements 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.

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 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.

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 unofficial transcripts, SF50 (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"Title 21 CBER/OVRR/DRMRR Biologist, Band C"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **September 16, 2024.**

Announcement Contact

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

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