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: May 22, 2024 – June 5, 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: Interdisciplinary Scientist (Team Lead)*
**Multiple selections can be made*

Series: 401, 403, 696, 1320

Location: White Oak Campus, Silver Spring, Maryland

Salary Range: $139,395 – $191,900 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes

Title 21 Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

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.

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 the Interdisciplinary Scientist (Team Lead) for one of the RRBs within DRMRR under OVRR. This position reports to the Regulatory Review Branch Chief. The Interdisciplinary Scientist (Team Lead) is a nationally authoritative regulatory review scientist and Branch Team Lead in coordinating the review of CMC, pre-clinical, analytical, statistical, and clinical data for these products. The incumbent and other members of the Branch serve as scientists that lead review teams that must integrate the review efforts on the various regulatory submissions in order to draw valid conclusions in support of the regulatory actions.

Specifically, the Interdisciplinary Scientist (Team Lead) will:

- Serve as the Interdisciplinary Scientist (Team Lead) of a review team that must integrate the review analysis in order to draw valid conclusions. This includes establishing specific objectives, determining the approach, planning, scheduling, and carrying out all work associated with the assignments.
- Provide technical leadership and guidance for regulatory activities in the area of preventive and therapeutic bacterial, viral, and parasitic vaccines for infectious disease indications, allergenic products, live biotherapeutic products and microbiome-related products, including the evaluation of relevant manufacturing information, preclinical test results and clinical trial protocols to determine whether it is appropriate to initiate or continue clinical studies of biological products in humans.
- Be responsible for authoritative regulatory review, of which such regulatory review expertise is relied upon and utilized throughout the Office and Center's functional areas, e.g., review and regulatory functions, etc.
- Present Center and/or Agency concerns or positions to committees and/or other regulatory meetings such as pre-IND and pre-BLA, working groups, etc., concerning questions arising about product safety.
- Coordinate the review of INDs and amendments, Master Files (MFs) and amendments, BLAs and their amendments and supplements and the review of product labeling.
- Advise sponsors on the design of clinical and analytical studies and makes recommendations on the manufacture and formulation of the product.
- Counsel, train, and mentor Team members. This includes: explaining critical and significant scientific and regulatory concepts, regularly reviewing work products, and providing recommendations to the Branch Chief.

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.

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 respective OPM Qualification Standards or 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.*

0401 Series (Biologist)

Basic Requirements

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

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 in A above, plus appropriate experience or additional education.

0403 Series (Microbiologist)

Education: A bachelor's degree or higher in biology, microbiology, or virology. The degree must be from an accredited program or institution.

0696 Series (Consumer Safety Officer)

Basic Requirements

The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education(external link) at the time the degree was obtained.

Applicants must meet one of the following requirements.

A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Experience

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills,

abilities, and competencies necessary to perform at the grade level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

1320 Series (Chemist)

Education: A bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

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.

Desired Professional Skills and Experience:

- Mastery of a scientific discipline and associated disciplines enough to allow the incumbent to review a variety of complex biological products.
- Mastery of knowledge of recent developments in the scientific discipline and associated disciplines; applicable FDA laws, regulations, policies, guidelines, and the regulated industry.
- Knowledge of biology, including cell culture, recombinant DNA technology, recombinant protein production and purification, immunology, and biochemistry as relevant to the development of bacterial and parasitic vaccines, live biotherapeutics and allergenic products.
- Detailed knowledge of the Federal Food, Drug and Cosmetic Act as it relates to regulation of biological products.
- Detailed knowledge of the sections of the Act and of the Public Health Service Act that relate to INDs, MFs, BLAs, and other regulatory submissions.
- Ability to apply Agency guidelines to the latest developments and changes in the area of preventive and therapeutic bacterial, viral, and parasitic vaccines for infectious disease indications, allergenic products, live biotherapeutic products and microbiome-related products.
- Ability and skill to accomplish work with others, when necessary, at different levels within the Center and/or Agency, and with other organizations.

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), latest PMAP (if applicable), and letter of interest with ***"Title 21 CBER/OVRR/DRMRR Interdisciplinary Scientist (Team Lead)"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through June 5, 2024.

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.

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