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 Regulatory Operations (ORO)
Division of Regulatory Operations and Programs (DROP)
Regulatory Programs Branch (RPB)

Application Period: December 14, 2023 – December 20, 2023

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: Biologist (Senior Advisor)
*Limited to the first 150 applicants or the closing date, whichever occurs first

Series: 401

Location: Remote Eligible

Salary: Starting at $132,368

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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.

The Office of Regulatory Operations (ORO) is responsible for managing the review process and associated activities used to support CBER in facilitating the regulation and review of biological products, drugs, devices, and combination products. These responsibilities include development and governance of regulatory business processes; data standards; regulatory data analysis; program evaluation; resource utilization; user fee management; electronic submission management; and special

initiatives. ORO manages CBER's Information Technology investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

Duties/Responsibilities

The Biologist (Senior Advisor) serves as the principal liaison for CBER staff with respect to CBER's medical device review program, and assists the ORO Office Director, also known as the Associate Director for Review Management (ADRM), in carrying out the diverse responsibilities related to the science, regulatory review, and/or compliance mission of the Center and in performing special assignments.

The incumbent provides medical device review expertise, vision, and direction to CBER staff conducting medical device reviews and leads CBER in activities related to the Medical Device Use Fee Act (MDUFA).

Specifically, the Biologist (Senior Advisor) will:

- Develop, recommend, and implement Center operational, science, regulatory review, and/or compliance policies and procedures for medical devices designed to ensure consistency and balance throughout the Center.
- Interpret and guide the overall Center operational science, regulatory review, and/or compliance policy and special issues which can cross organizational lines within the Center pertaining to medical devices.
- Serve as the principle liaison for CBER staff with respect to CBER's medical device review program and assist the ORO Director in carrying out the diverse responsibilities related to the science, regulatory review, and/or compliance mission of the Center, and in performing special assignments for medical devices.
- Implements activities and goals in MDUFA, reviews reports Monitor MDUFA performance reports to track and measure progress, identify critical areas of concerns with medical device submissions and performance, and facilate solutions to address resource needs to implement and improve CBER's policy and business process development, training requirements, and review performance.
- Identify and assess emerging, standing, complex, or precedent-setting issues impacting on Center science, regulatory review, and/or compliance operational science, regulatory review, and/or compliance operational procedures, policies, activities, and resources for medical devices.
- Work closely with the ORO Director and CBER leadership in guiding, coordinating, and controlling the overall science, regulatory review, and/or compliance workload and work products of the Center pertaining to medical devices.
- Advise the ORO Director and CBER leadership on potential and emerging policy issues and the need to formulate appropriate program responses in support of new initiatives for medical devices.
- Initiate necessary actions and interactions between the ORO Director, the office and division directors, and other appropriate officials in identifying and agreeing upon Center positions and decisions pertaining to medical devices.
- Work with the ORO Director in meeting Agency priorities on work products by assuring that the Center work meets the standards of quality of the ORO Director, addresses all relevant issues, represents credible Center courses of action or response, and input has been secured from all appropriate organizations.
- Be responsible for developing, recommending, and implementing Center operational (science, regulatory review, and/or compliance) policies and procedures, SOPPs, Job Aids and other review tools designed to ensure consistency and balance throughout the Center.
- Coordinate and provide interpretation and guidance on overall Center operational (science, regulatory review, and/or compliance) policy and special issues which can cross organizational lines within the Center.
- Perform special assignments. Study the background of assigned projects, research appropriate sources of information, propose and justify solutions. Develop briefing papers providing the probable consequences of the various courses of action along with recommendations. Prepares and delivers presentations covering all issues involving or impacting on the Center for presentation These assignments can include interrelationships with other Agency components, other Federal, State, and local agencies, the regulated industry, academia, and health professionals.

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: Advanced degree in health, life sciences degrees or medical/ biomedical fields.

Desired Professional Experience:
- Familarity with laws, regulations, and guidance pertaining to regulation of medical devices.
- Demonstrated experience in development, evaluation and implementation of legislation, regulations and guidance for medical devices.
- Experience in review of device regulatory submissions and regulation of medical devices
- Demonstrated experience in solving complex management problems and administering these solutions.
- Ability to create and administer a wide variety of programmatic activities.
- Experience in conducting timely analysis and writing comprehensive reports.
- Experience negotiating to consolidate positions and to resolve differing points of view.

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.

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), SF50 (if applicable), latest PMAP (if applicable), copy of unofficial transcript(s), and letter of interest with ***"CURES CBER/ORO/DROP/RPB Biologist (Senior Advisor)"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **December 20, 2023**. 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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