Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Immediate Office of the Center Director (IOD)

Application Period: June 21 – July 5, 2023

Area of Consideration: 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: Senior Advisor (Regulatory Counsel)

Series: 0301

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

Salary: Starting at $132,368

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 25%

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.

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.

Duties/Responsibilities

The incumbent serves as a Senior Advisor within the Office of the Center Director (OCD), concerning the coordination of the Center's activities and resource management, including providing information to the Agency and other Centers on regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. In collaboration with other staff, the incumbent organizes, and coordinates matters brought to the attention of OCD.

As a recognized Agency and government-wide regulatory expert in the legislation, policies, and procedures relevant to the issuance of FDA regulations, the Senior Advisor applies a wide range of qualitative and quantitative methods to the management of complex FDA/CBER programs characterized by boundaries that are extremely broad and sometimes difficult to define.

Specifically, the Senior Advisor will:

- Collaborate with CBER and work to develop policies and programs involving the most complex and highest priority matters affecting the regulation of biological products, and for drafting or critically reviewing documents embodying policy and program proposals and decisions on these products.
- Evaluate the content of new or modified legislation and regulations for projected impact upon current and future Agency programs and resources, and translates basic legislation into organizational program goals, actions, and services.
- Work with the CBER OCD staff in advising and counseling CBER Office Managers and staff of the Center Director's views and priorities regarding developing and implementing compliance policy and strategic enforcement initiatives concerning biological products consistent with risk management principles and risk based strategic problem solving.
- Resolve a broad range of issues concerning the application of any of FDA's enabling legislation, pertinent regulations and/or general legislation affecting the operation of the FDA or the Federal Government, particularly with respect to provisions in the Public Health Service Act and the Federal Food Drug and Cosmetic Act that impact CBER products.
- Lead working groups to resolve difficult and controversial issues raised by regulatory concerns associated with policy development, guidance, regulations, or petitions, such as citizen petitions, petitions for stay of action, and/or petitions for reconsideration.
- Prepare and review of replies to correspondence and/or inquiries from the regulated industry, Congress, and other interested persons on issues that are industry-wide in scope or have broad health policy implications and that concern precedent setting interpretation of FDA policy.
- Provide guidance and/or training to regulatory specialists and other professionals within FDA on matters relating to the incumbent's regulatory expertise, and for the development of regulatory documents and other written statements of FDA policy.
- Represent the Center and FDA on task forces and committees mandated by Congress, Health and Human Services (HHS), Public Health Service (PHS), FDA and the Center, and serves as the OCD representative and a spokesperson to various individuals and groups that interact with the Center on regulatory policy issues.

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.
- 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.
- 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:
A graduate or professional degree (Ph.D., M.D., LL.B., or J.D.)

Desired Professional Experience:
- Excellent interpersonal skills to deal effectively with multi-disciplinary teams and diverse stakeholders
- Outstanding oral and written communication skills
- Strong scientific background related to the review, development, manufacture, and testing of biologic products
- Knowledge and experience regarding FDA scientific and review policies is desirable

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.

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), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CURES CBER/IOD Senior Advisor (Regulatory Counsel)*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through July 5, 2023.**

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.