Physician and Associate Director for Regulatory Affairs
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Immediate Office of the Director (IOD)

Summary

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.
At the Department of Health and Human Services (HHS) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

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.

The mission of the Office of Biostatistics and Pharmacovigilance (OBPV) involves evaluating the safety and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, pharmacoepidemiology, medicine, genomics, statistics, risk analysis, public health, and related scientific areas.

Overview

Area of Consideration: FDA-Wide
Open & Closing Date: August 6, 2024 – August 12, 2024
Salary Range: $210,000 - $325,066 and is set commensurate with education and experience.
Band: F
Occupational Series: 0602

Duty Location: White Oak Campus, Silver Spring, MD
Remote Job: No
Telework Eligible: Yes – as determined by agency policy.
Travel Required: 25% or less
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band F
Supervisory Status: Non-Supervisory
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

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.

Duties

The incumbent serves as the Associate Director for Regulatory Affairs in the Immediate Office of the Director (IOD) within the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to the Office Director of OBPV. The Associate Director for Regulatory Affairs serves as the principal regulatory advisor to and spokesperson for the Office Director and provides staff leadership and direction by performing substantive activities related to the planning, development, administration, execution, and coordination of regulatory programs and policies in Office. The Associate Director for Regulatory Affairs initiates, coordinates, and participates in the development and implementation of regulatory programs, policies, standards and criteria, procedures, and guidelines applicable to the operations of the Office.

Specifically, the Associate Director for Regulatory Affairs will:

- Direct special projects, studies, or activities of concern to the Office Director and/or Center Director. These projects may involve the coordinated effort of other Center and/or Agency components. Such projects may involve operational matters on biologic policy and may result from a public health emergency or congressional initiative. Perform such projects or activities individually or establish committees and work groups as needed. Develop and present recommendations for action.
- Monitor, coordinate, and advise on new and/or revised regulatory policies and programs involving sensitive, controversial, and critical problems and complex and precedent-setting issues of particular concern to the Office, Center Director, or FDA Commissioner. Apply extensive knowledge of FDA and CBER policies and procedures to identify and resolve inconsistencies and to make recommendations on strategic initiatives. Exercise leadership in expediting resolution of policy issues and ensuring standardization between multiple Office components.
- Serve as the OBPV expert in regulatory affairs, provides information and consultation to individuals, federal agencies, private industry, universities, and/or foreign governments on consumer safety issues. Provide authoritative advice, guidance, interpretation, and recommendations to the Office Director/Deputy Director, Division Directors, scientists, Agency representatives, and others in areas such as: the development of new policies; addressing questions, critical problems and controversial issues affecting Office programs and activities; legislative proposals, Congressional testimony, materials related to implementing, amending, or modifying FDA laws and regulations; and integration of Office programs to implement new or modified legislative and statutory authorities and program responsibilities.
- Assist the Office Director in appraising Office-wide biologic safety and biologic safety-related products and policies in the review and analysis of program reports, proposals, and other correspondence that either impact upon or affect the operation of the regulatory review process in the Office.
- Work collaboratively with FDA Centers, federal agencies, and international entities on projects for OBPV's surveillance programs. Conduct outreach for stakeholders within CBER, FDA and externally to advance

CBER and OBPV regulatory safety, effectiveness, and surveillance programs and to further FDA's public health mission.

- Identify and assess emerging complex program operations and management issues and advise OBPV Director, internal and external stakeholders of potential and emerging problem areas and strategies for issue resolution for regulatory affairs.
- Keep abreast of the latest in regulatory affairs for biological product review and surveillance developments reported in medical literature, guides and other references to apply an authoritative, critical judgment to developments reported.
- Perform other duties as assigned.

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.
- 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. Please go to http://www.sss.gov for more information.
- 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 **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: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the

United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.
AND

- Graduate Training In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Desired Professional Experience, Skills, or Education:

- Possess an active medical license in at least one state or U.S. federal jurisdiction.
- Knowledge and experience in biological product development and related regulations.
- Demonstrate effective oral and written communications skills.
- Experience with OBPV's premarket review as well as post-market surveillance systems and a deep understanding of how they relate to regulatory affairs.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Education must be accredited by an accrediting institution recognized by the U.S. Department of Education in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

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.

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), copy of unofficial transcripts, latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OBPV/IOD Associate Director for Regulatory Affairs, Band F"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **August 12, 2024.**

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.