Pharmacologist and Associate Director for Drug Development Innovation
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: $163,964 - $251,125 and is set commensurate with education and experience.
Band: E
Occupational Series: 0405

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 E
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 Drug Development Innovation in the Immediate Office of the Director (IOD) within the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to the Office Deputy Director of OBPV. The incumbent serves as a nationally authoritative regulatory review scientist for drug development innovation. The incumbent provides authoritative and technical leadership and guidance for regulatory activities in the area(s) of vaccines, blood products, recombinant protein therapeutics, cellular and gene therapy products for the development and application of new methods and tools for improving clinical trials, observational epidemiological studies, data mining, and comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products for innovative drug development.

Specifically, the Associate Director for Drug Development Innovation will:

- Use expertise in reviewing analytical and/or clinical issues in the following area(s): preclinical toxicology, clinical pharmacology and drug development. Maintain knowledge of recent and innovative advances in biotechnology have dramatically expanded the types of biologic products evaluated in clinical studies. Identify and analyze areas for which new policies must be formulated and evaluate complex regulatory issues to meet the increased volume and variety in CBER's regulated products and conduct in-depth reviews of a variety of products, specifically, on clinical pharmacology. Analyze clinical trials and/or analytical studies of preclinical and clinical pharmacology issues related to drug development innovation, and provide guidance to reviewers when specific regulations, guidance or procedures are not available or apparent.
- Be responsible for resolving particularly complex or controversial issues in study design, protocol review, first-in-human dose selection, and benefit-risk analysis of pharmacokinetic studies and exposure-response analyses. Advise and consult on the development of novel model-based data analyses, especially as they concern an assessment of safety and effectiveness.
- Serve as a subject matter expert with innovative methods for enhancing regulatory decision tools to support drug development such as model informed drug development (MIDD), benefit-risk assessment in decision making, and enhancing drug development tools qualification pathway for biomarkers.
- Identify and assess emerging complex program operations and management issues and advises OBPV Director, internal and external stakeholders of potential and emerging problem areas and strategies for issue resolution for drug development innovation.
- Serve as the OBPV expert in drug development innovation, provides information and consultation to individuals, federal agencies, private industry, universities, and/or foreign governments on consumer safety issues. Keep abreast of the latest drug development innovation developments reported in medical literature, guides and other references to apply an authoritative, critical judgment to developments

reported. Identify requirements and expected outcomes for new or existing initiatives, and the measurements of success for drug development innovation

- Utilize communication and interpersonal skills to represent CBER at meetings, workshops and Agency and Department discussions concerning innovative drug development. Manage OBPV's application of drug development innovation across the office to support regulatory and public health missions. Coordinate and communicate program initiatives and outcomes with CBER and FDA leadership. The incumbent establishes collaborations both within and outside the Center, FDA, and the government.
- Collaborate as a recognized expert with officials and representatives of higher departmental echelons, counterpart government departments or agencies, national and international organizations, the scientific, medical community, and related industries concerning the innovative drug development for scientific and research programs and activities.
- Resolve problems and controversial issues affecting relevant CBER regulated products, programs and activities; reviews and makes recommendations pertaining to legislative proposals, congressional testimony and materials related to implementing, amending or modifying FDA laws and regulations.
- 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 bachelor's degree or higher in toxicology, pharmacology, pharmaceutics, environmental sciences, medicinal chemistry, pharmaceutical sciences, or related sciences. The degree must be from an accredited program or institution.
  OR
- American Board of Toxicology certification
  OR
- Experience: Experience in administering, advising on, supervising, or performing research, analytical, advisory, or other professional and scientific work in the discipline of pharmacology. Such work requires the application of a knowledge of the history, sources, physical and chemical properties, biochemical, toxic, and physiological effects, mechanisms of action, absorption, distribution, metabolism, biotransformation and excretion, and therapeutic and other uses of drugs as well as modern pharmacological techniques such as in vitro cell based assays and leveraging mathematical models for quantitative analysis. The work could include the design, development, and performance of pharmacodynamic modelling and simulation studies as well as the development of Model-Informed Drug Development (MIDD) approaches to facilitate the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources.

Desired Professional Experience, Skills, or Education:

- Master's or doctoral degree in an appropriate biological, medical, veterinary, or physical science, or in pharmacy with a focus in pharmacology.
- Knowledge and experience drug development innovation such as the FDA Model-Informed Drug Development (MIDD) Program, pharmacology/toxicology, benefit-risk assessment in decision making, and enhancing drug development tools qualification pathway for biomarkers for CBER-regulated products.
- Demonstrated experience in written and oral communications techniques required to prepare and deliver reports and presentations on study results and other critical data and information.
- Demonstrated experience communicating highly technical information in a clear matter.

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 Drug Development Innovation (Pharmacologist)"*** 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.