Title 21 Vacancy Announcement
Office Director
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products (OTP)
Office of Pharmacology/Toxicology (OPT)

Summary:

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.

Overview:

Area of Consideration: FDA-Wide/HHS-Wide/The Public
Open & Close Dates: October 9, 2024 through November 8, 2024
Salary: Starting at $213,491 and is set to commensurate with education and experience
Band: G
Occupational Series: AD-0401
Duty Location: White Oak Campus, Silver Spring, MD. 24145-0031.
Remote Job: No
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band G
Supervisory Status: Yes
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.

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

Duties:

The incumbent serves as the Office Director for the Office of Pharmacology/Toxicology (OPT) within the Office of Therapeutic Products (OTP) and manages daily operations of the Office. This position reports to the OTP Super Office Director. OTP is a newly established Super Office within CBER which is responsible for the continued safety, purity, potency, and effectiveness of cellular, tissue, and gene therapies, plasma protein therapeutics, and other products regulated by OTP. The Office Director provides leadership, management, and regulatory oversight to the regulatory activities of the Office. The Office Director reviews policy and program objectives of the Office.

The Director is responsible for ongoing policy activities related to products subject to Office oversight and oversees changes in policy and/or procedures necessary to improve the efficiency and responsiveness of the Center's regulatory responsibilities and research programs to other FDA and Department of Health and Human Services (DHHS) organizations. The Office Director makes management decisions pertaining to changes in course of approach, degree of program emphasis, allocation of resources, internal cooperative ventures, and similar matters. The Office Director serves as a principal adviser to the Super Office Director and Center Director on all matters related to the responsibilities of the Office and works collaboratively with staff from other FDA Centers, other government institutions, academia, contractors and other public and private sector organizations.

Specifically, the OPT Director will:

- Develop guidance, policies and procedures governing the non-clinical review and evaluation of cellular therapies, gene therapies, plasma protein therapeutics, and other products regulated in OTP, in keeping with the provisions of the Public Health Service Act and applicable provisions of the Federal Food Drug and Cosmetic Act.
- Evaluate non-clinical pharmacology and toxicology evidence, and proof-of-concept studies, to facilitate the design of appropriate clinical trials and protect the safety of study subjects, in collaboration with other offices in OTP.
- Evaluate non-clinical pharmacology and toxicology evidence to support marketing applications for cellular therapies, gene therapies, plasma protein therapeutics, and other products regulated in OTP.
- Develop and refine pathways for non-clinical evaluation of products regulated in OTP.
- Apply a knowledge of administrative and program management principles and skills to carrying out the mission of the Office.

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.
- 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.

- 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.
- One year supervisory 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:

Professional Experience/Desirable Qualifications:

- Candidates would ideally have an advanced scientific degree
- An experienced scientist with a strong scientific background in the design and interpretation of non-clinical studies
- Strong leadership and skill in strategic planning, problem solving, and making policy and programmatic decisions
- Knowledge and experience regarding FDA scientific and review policies in the pharmacology/toxicology areas is desirable
- Supervisory experience is desirable
- Skilled at building partnerships and collaborations with internal or external stakeholders

Basic Qualification Requirements: There are no Individual Occupational Requirements for this series. https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

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

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), unofficial transcripts and letter of interest with ***"CURES CBER/OTP/OPT Office Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through November 8, 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.