Title 21 Vacancy Announcement
Clinical Pharmacologist Reviewer
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 Clinical Evaluation (OCE)
Immediate Office of the Director (IOD)

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: The Public
Open & Close Dates: December 27, 2024 – January 27, 2025
Salary: Starting at $117,962 and is set to commensurate with education and experience
Band: C
Occupational Series: 0405
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full-Time
Competitive Service: Yes
Promotion Potential: Band C
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

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 Clinical Pharmacologist Reviewer for the Office of Clinical Evaluation (OCE) within the Office of Therapeutic Products (OTP). This position reports to the OCE Office Director. The Clinical Pharmacologist Reviewer provides clinical, clinical pharmacology and non-clinical review and recommends appropriate action on investigational new drug applications (INDs), biologics license applications (BLAs), investigational device exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview. The incumbent provides interpretation and policy recommendations on clinical pharmacology, programs intended to support IND, BLA, IDE, PMA, and 510(k) submissions.

Specifically, the Clinical Pharmacologist Reviewer will:

- Serve as a senior reviewer, provide scientific expertise as a member of multi-disciplinary scientific and medical teams engaged in review, evaluation, and decision-making regarding approvability of submissions and applications requesting FDA regulatory consideration of clinical research, testing and manufacture of human drugs and any other related regulatory submissions.
- Conceive and develop valid approaches, make decisions that impact Office policy and procedures, serve on task forces and study groups and authoritatively recommend standards of excellence to enhance programs of the Division, Office or Center.
- Analyze, study, and make recommendations pertaining to clinical pharmacology studies in the therapeutic area for which the reviewer is responsible for scientific validity and for potential influence on organizational objectives and program goals of the Division, Office or Center.
- Apply expert knowledge of the design and analysis of human pharmacokinetic and pharmacodynamics studies to reviews and evaluations of approvability of regulatory submissions.
- Provide expert assessments incorporating the most advanced theories and practices in the specific therapeutic area and convey critical scientific findings during the review process, both verbally and in writing, to other scientists and clinicians engaged in the review process.
- Provide expert advice to the Branch chief, Division Director and Office Director in a specified therapeutic area and professional and scientific guidance to the junior clinical pharmacology reviewers regarding clinical pharmacology and biopharmaceutics issues.
- Stay abreast of complex, long-range, and emerging problems of drug study, efficacy and dosing and of conflicts in the therapeutic area as applied to the products being regulated.
- Ensure that rapid advances in translational science such as quantitative clinical pharmacology and pharmacogenomics are incorporated into regulatory reviews.
- Apply current knowledge of research in clinical pharmacology and therapeutic areas and research conducted by the regulated industry in the area of therapeutic responsibility in order to advise organizational leadership of interrelated programs, current developments, and problems related to products under review.
- Ensure that senior leaders are aware of crucial or precedent-setting cases, scientific and clinical interpretations, or analyses under review within the Division, in the regulated industry, and related cases in the Office.
- Meet with representatives of the regulated industry to discuss issues pertaining to the specific therapeutic area and maintain clear communication in these meetings.
- Attend professional meetings both within and outside the Federal Government and make presentations in abstract or podium format.

- Ensure timely and effective communication with the sponsors and timely completion of reviews according to Good Review Management Principles (GRMP) timelines.

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 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 ***requirements:***

- 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
  - When there is no experience statement, follow the job family description.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

- Ideal candidates should have a Doctorate or a Ph.D. in a biological, medical, veterinary, pharmacology, or physical science field.
- Experience assessing, analyzing or evaluating study designs, data or conclusions submitted by sponsors of pharmacology or biopharmaceutics submissions associated with IND, NDAs and BLAs to support marketing of a drug.
- Experience serving as a recognized authority in a specific therapeutic area to resolve unique, far-reaching, and previously unsolved problems.
- Experience designing and recommending studies concerning specific drug issues.
- Thorough knowledge of the mission, goals structures, policies, functions, interrelationships, and activities of the Division and Office, and of those other Agency organizations related by function and mission in order to ensure that rapid advances in translational science such as quantitative clinical pharmacology and pharmacogenomics are incorporated into regulatory reviews.
- Clear written, oral, and visual communication skills to speak and write with clarity and tact to communicate findings, advocate positions, make formal presentations, convey information related to a wide range of pharmaceutical regulatory issues, and effectively interact with agency staff and stakeholders.

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** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable)**, **latest PMAP (if applicable)**, **unofficial transcripts**, **Foreign Credit Evaluation (if applicable), copy of your active medical license/s (if applicable**), **copy of your board certification/s (if applicable)**, and **letter of interest (Word or PDF)** with ***"Title 21 CBER/OCE/IOD Clinical Pharmacologist Reviewer"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through January 27, 2025.**

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.