Title 21 Vacancy Announcement
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)
Division of Clinical Evaluation Hematology (DCEH)
Benign Hematology Branch (BHB)

Application Period: 05/22/2023 – 07/03/2023

Area of Consideration: The 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: Clinical Pharmacologist Reviewer

Series: 0405 (Pharmacologist)

Location(s): White Oak Campus, Silver Spring, MD. 24145-0031.

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: 25 % or less

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 the Clinical Pharmacologist Reviewer for the Benign Hematology Branch (BHB) within the Division of Clinical Evaluation Hematology (DCEH). This position falls under the Office of Clinical Evaluation (OCE) within the Office of Therapeutic Products (OTP). This position reports to a Branch Chief in DCEH. The Clinical Pharmacologist Reviewer provides clinical pharmacology 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 reviewer, provide scientific expertise as a member of multi-disciplinary scientific teams engaged in review, evaluation, and making recommendations regarding approvability of regulatory submissions containing investigations with human drugs and biological products.
- Lead, plan, schedule, and carry out major studies and projects concerned with the analysis and clinical pharmacology evaluation of biological products under the purview of Division of Clinical Evaluation Hematology.
- Analyze, study, and make recommendations pertaining to clinical pharmacology studies in the therapeutic area of hematology products and evaluate scientific validity of investigations.
- Resolve unique, far-reaching, and previously unsolved problems, design and recommend studies concerning specific product issues and consult with other professionals both within and outside the Division, Office, Center, and Federal Government as necessary.
- Serve as a member of task forces and study groups assembled by the Division, Office or Center to consider general problems or specific solutions for issues surrounding products regulated by the Division of Clinical Evaluation: Hematology.
- Provide expert assessments 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 regarding clinical pharmacology and biopharmaceutics issues.
- Apply expert knowledge of the design and analysis of human pharmacokinetic and pharmacodynamics studies to reviews and evaluations of approvability of regulatory submissions.
- Ensure that rapid advances in translational science such as quantitative clinical pharmacology and pharmacogenomics are incorporated into regulatory reviews.
- Stay abreast of complex, long-range, and emerging problems of drug study, efficacy, and dosing, as applied to the products being regulated.
- Ensure that senior leaders are aware of crucial or precedent-setting cases, scientific and clinical interpretations, or analyses under review within the Division, Office and in the regulated industry.
- For submission-related meetings with sponsors and applicants, ensure that advanced preparations are made to address meeting agendas that clearly and comprehensively express the position of the Division/Office on scientific issues in clinical pharmacology.
- Maintain close personal contact with other pharmacology reviewers and the current "state of science and therapeutics" to ensure that Division and Office programs incorporate the most advanced theories and practices in the clinical pharmacology field.
- 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.

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 Professional Experience:

- Ability to assess, analyze or evaluate study designs, data models, analyses, and conclusions in pharmacology or biopharmaceutics sections submitted within IND, NDAs and BLAs to support development and approval of biological and drug products.
- Past service as a recognized authority in clinical pharmacology.
- Experience with design, evaluation, and recommendations for clinical pharmacology studies, including pharmacokinetics, pharmacodynamics, and pharmacogenomics studies.
- 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 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.

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 PMAP (if applicable), unofficial transcripts, and letter of interest with ***"CURES CBER/OTP/OCE/DCEH Clinical Pharmacologist Reviewer"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through July 3, 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.