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 Tissues and Advanced Therapy (OTAT)
Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)
Malignant Hematology Branch (MHB)

Application Period: October 24 – November 14, 2022

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 Analyst

Series: 0601

Location(s): White Oak Campus, Silver Spring, MD

Salary: Starting at $106,823

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: Up to 25%

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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.

The Office of Tissues and Advanced Therapies (OTAT) plans and conducts research related to the development, manufacture, and testing of cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products in order to develop and maintain a scientific base for establishing standards for safety, purity, potency, and effectiveness.

The Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) develops and maintains the Office's Clinical, Clinical Pharmacology, and Pharmacology/Toxicology Review Programs. Provides clinical, clinical pharmacology and non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview. Provides recommendations on clinical, clinical pharmacology, and non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

Duties/Responsibilities

The incumbent serves as the Clinical Analyst in the Malignant Hematology Branch (MHB), DCEPT, OTAT and reviews clinical regulatory submissions for the Division. This position reports to the MHB Branch Chief.

Specifically, the Clinical Analyst will:

- Conduct clinical reviews for OTAT regulatory submissions, to include but not limited to: Initial Targeted Engagement for Regulatory Advice on CBER Products (INTERACT) meeting packages, pre-Investigational New Drug (IND) meeting packages, new INDs applications and amendments, IND meeting packages, Investigational Device Exemptions (IDEs) and supplements/amendments, Biologics License Applications (BLAs), New Drug Applications (NDAs), supplemental BLAs and NDAs, Premarket Approval Applications (PMAs) and supplements, and single patient INDs.
- Develop timely recommendations for regulatory decisions related to the Office submissions for regulated products.
- Exhibit thorough knowledge of complex FDA policies and regulations throughout the review process and during interaction with Agency officials and representatives of the related industry.
- Compile data to prepare reports related to the Office and develop pertinent background data that influence the organizational mission when required.
- Participate in science related meetings, conferences, symposia, and workshops to stay abreast in the scientific field and exchange ideas with other industry professionals.
- Integrate research, problem analysis, data collection, and clinical program requirements to deliver analysis and advice on complex issues.
- Create innovative analytical techniques to evaluate research findings and make recommendations that are generally accepted because of the expertise associated with the position.
- Collaborate with other Center officials and the industry to ensure the development of drugs addresses related scientific issues in a fair and equitable manner.
- Investigate resources and stimulate the development of methods to improve human drugs and biologics services.
- Represent the Office within the scientific community nationally and internationally in meetings, colloquia, and venues requiring knowledge and presentation of novel research findings as the activities affect the related area; respond and prepare related correspondences from the Agency, Congress, and Consumer Groups; and organize various types of meetings.

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:

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. 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:

- Expert knowledge in the science industry including new developments and clinical theories, combined with advanced judgment, planning, analysis and evaluation, administration, management, and coordination of programs within the Center.
- Mastery knowledge of broad FDA/CBER operating programs to advise senior officials to support the mission of the Agency.
- Experience with developing, participating in and/or reviewing and evaluating clinical trial protocols and reports supporting regulatory decisions in support of the assessment of safety and effectiveness of human drugs and biologics and knowledge of drug development.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status

of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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), and letter of interest with ***"CURES CBER/OTAT/DCEPT Clinical Analyst"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **November 14, 2022.**

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.