Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Immediate Office (IO)
Safety, Policy, Research, and Initiatives Team (SPiRIT)

Application Period: March 25, 2024 – April 5, 2024

Area of Consideration: 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: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $139,282

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You will not 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) 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 mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential

public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a super office within CDER responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The mission of the Immediate Office (IO) is to facilitate the ongoing availability of new drugs that are safe and effective for their intended use and meet established quality standards.

The Safety, Policy, Research, and Initiatives Team (SPiRIT) supports all areas of drug product safety within OND and CDER, through the development of methods, policies, and procedures that ensure a consistent and unified approach to drug safety. The SPiRIT Team has three areas consisting of Policy, Research, and Initiatives. SPiRIT works collaboratively with the OND Clinical Offices, Office of Surveillance and Epidemiology, and other Center and Agency offices to support continuing surveillance and medical evaluation of drug safety, including clinical reports submitted by IND sponsors, New Drug Applications (NDA) applicants, Biological Licensing Applications (BLA)s and from other sources.

Duties/Responsibilities

As a **Clinical Analyst** within SPiRIT, the incumbent participates in the development and implementation of programs and initiatives to support policies, procedures, research, and operations related to the postmarket drug safety program. The incumbent will perform the following duties:

- Provides expert advice and consultation to senior leadership and other key members of OND and CDER staff. Works closely with team lead and other stakeholders to advise, mentor, and assist in defining, formulating, and ensuring successful implementation and effectiveness of new policies, processes, and various initiatives that meet the needs of OND's safety functions.
- Serves as a regulatory expert for safety-related laws and regulations; applies knowledge of FDA and CDER policies and procedures to identify and resolve complex issues and inconsistencies and make recommendations on strategic safety initiatives, ensuring cohesive implementation of changes.
- Facilitates and coordinates consistent regulatory approaches to the oversight of postmarket drug safety review to support drug product safety within OND. Serves as a resource to CDER staff engaged in review of postmarket safety issues, providing direct guidance on the interpretation and implementation of the FDA safety authorities. Provides expertise during the development and revision of post market safety related MAPPS, guidance's, and other regulatory documents to ensure consistency in oversight. Provides subject matter expertise in coordination and consultation with OND Policy,

Office of Surveillance and Epidemiology (OSE), Office of Regulatory Policy (ORP), Office of Chief Counsel (OCC) and other offices, as appropriate, on post market safety related inquiries to formulate cohesive responses as well as provide guidance for precedent setting safety issues.

- Provides scientific and technical subject matter expertise and input in developing, implementing, and analyzing the effects of drug safety programs and the establishment of safety research projects. Researches and analyzes safety issues, reviews projects to ensure appropriate application of various safety guidelines and authorities implemented by FDA, resolves inconsistencies in the application of drug safety policies and regulations requiring innovative approaches, and makes recommendations on strategic plans for drug safety.
- Analyzes and provides appropriate recommendations pertaining to the conduct of studies from pilot programs and other post marketing safety initiatives on internal procedures for the purpose of finding ways to improve efficiency and ensure consistency in OND's approaches to the evaluation and management of drug safety issues.
- Coordinates, conducts, leads, and facilitates the development of new research projects, time frames, milestones, and agreed upon endpoints.
- Monitors and complies reports on the status for various assigned activities within the drug safety research program through interaction with program participants. Develops and compiles necessary background data pertinent to OND and CDER programs, through a wide variety of qualitative and quantitative methods to prepare special reports related to drug safety.
- Provides expert clinical analysis on current and emerging complex safety issues and programs and provides input of viable solutions on these issues to the Supervisory Associate Director and/or Team Lead.
- Organizes and/or provides training/presentations related to drug safety in collaboration with OND Learning and Talent Development Staff and other Center programs to develop and provide oversight of safety related training, curriculum, and resources to advance the understanding of postmarket safety science and pharmacovigilance if applicable.
- Responsible for establishing and maintaining effective communications and collaboration with safety staff and other offices and centers responsible for implementation of various drug safety programs, and initiatives.
- Provides subject matter expertise and represents the CDER/OND/SPiRIT on committees, task forces, and other forums related to the planning, development, administration, and coordination of drug safety initiatives.
- Serves as a liaison to external entities such as industry, professional organizations, academia, other regulatory agencies, and the public in the gathering of information to guide plans for the development of the post marketing safety initiatives and policies.

Supervisory Responsibilities: N/A

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.
- One-year probationary period may be required.
- 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.

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:

General Medical and Healthcare, AD-0601 Series:
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. This

degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Professional Education and Experience:
Our ideal candidate will possess:

- Advanced degree in life or biomedical sciences, pharmacology, epidemiology, or a related field (including Pharm.D., Ph.D.); (ii) specific training in health outcomes research; (iii) experience reviewing applications in FDA; or (iv) experience in the pharmaceutical industry in drug development in the relevant area.
- Experience identifying, addressing, and resolving problems and complex issues.
- Experience utilizing written and verbal communications skills to provide advice and guidance to senior management and employees as well as prepare a variety of written reports and documents.
- Experience applying knowledge of regulatory expertise and drug safety.
- Experience applying knowledge of clinical and research data and activities.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov).

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High-Risk

If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a

background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

Equal Employment Opportunity Policy

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

Reasonable Accommodation Policy

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

Submit resume with cover letter and unofficial transcripts by **April 5, 2024,** to Keya Whitaker at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

Please reference **Job Reference ID: IO-24-036** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Wright at Danielle.Wright@fda.hhs.gov.

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