Title 21 Vacancy Announcement
U.S. 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)

Application Period: April 13, 2023 – April 24, 2023

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: Safety Clinical Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $132,368

Work Schedule: Full-Time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: 25% or less

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) 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 (OTC) and prescription

drugs, including biological therapeutics and generic drugs.

Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications, interactions with the pharmaceutical industry, and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multidisciplinary organization engaged in the oversight of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLAs) for marketed drugs and therapeutic biologics in this country, and in regulating OTC drug products.

The Immediate Office (IO) in OND is responsible for advancing New Drugs Regulatory Program (NDRP) modernization by directly supporting and advancing new postmarket safety processes, facilitating integration of available data on safety signal status for a portfolio of products, and enhancing communication within OND and across CDER to support awareness and resolution of safety issues.

Duties/Responsibilities

As a **Safety Clinical Analyst**, the incumbent provides direct support for New Drugs Regulatory Program (NDRP) Postmarket Safety Initiatives (e.g., Drug Safety Teams (DST), Pharmacovigilance Strategies (PVS), Integrated Safety Assessment (ISA) template use, Periodic Safety Report (PSR) review process).

- Serves as a core member of their assigned DST(s). Provides direct support to DSTs, including project/program management. Integrates and synthesizes safety data from all sources across a portfolio of drugs in a therapeutic area, for DST discussion, and oversees emerging and ongoing safety issues.

- Serves as the primary focal point and coordinator for assigned OND clinical office(s) for all activities related to NDRP; interfacing and interacting frequently with DST members to facilitate interdisciplinary collaboration within review teams participating in DST, PVS, and Newly Identify Safety Signal (NISS) evaluation/ ISA completion and enable robust and efficient decision-making based on the totality of evidence.

- Tracks NISS and PVS status to support evaluation and resolution of safety issues.

- Responsible for DST knowledge management activities including assigning submissions to DST through written communications; Oversight and maintenance of DST charter and procedural documents; DST dashboard and informatics support.

- Researches, learns, and applies a wide range of qualitative and/or quantitative methods to identify, assess, analyze, and improve team effectiveness, efficiency, and work products; takes a leadership role in assessing DST strengths and weaknesses, exploring alternatives, and determining what improvements can be made.

- Provides NDRP postmarketing drug safety guidance, assistance with interpretations, and

recommendations to the OND safety staff, senior OND management, RPM staff, and medical/scientific medical staff. Under the direction of the OND Deputy Office Director for Safety - in conjunction with the OND IO Associate Director for Safety – facilitates OND interactions with other CDER offices, including OSE, OGD, and OPQ to support collaboration and coordinated review of postmarketing safety submissions and activities at the DST meetings.

Supervisory Responsibilities: None

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 Series, AD-0601

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

Desired Education:
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.

Desired Skills and Experience:
Our ideal candidate will possess:

- Experience applying knowledge of regulatory expertise and drug safety review.
- 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 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 U.S. Department of Education website for Foreign Education Evaluation.

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 these 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 qualifications is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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 or curriculum vitae and unofficial transcripts with cover letter by **April 24, 2023** to: CDER-OND-Leadership-Employment@fda.hhs.gov Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research (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: **ONDIO-SCA-001**.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OND-Leadership-Employment@fda.hhs.gov

The U.S. Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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