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)

Application Period: January 5, 2023 - January 19, 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: Clinical Analyst

Series: AD-0601

Location(s): 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: 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 are 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 Safety, Policy, Research, and Initiatives Team (SPRIT) 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 SPRIT Team has three areas consisting of Policy, Research, and Initiatives. The SPRIT 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 SPRIT, 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 expertise in safety policy and processes to OND safety staff and consultation to key members of CDER safety staff by working closely with team leader and other stakeholders to develop and implement new policies and processes that meet the needs of OND's safety functions. Serves as a resource to CDER staff engaged in review of post market safety issues, providing guidance on the interpretation and implementation of the FDA safety authorities.
- Participates in the development and revision of post market safety related Manuals of Policies and Procedures (MAPPs), guidance, and other regulatory documents to ensure consistency. Provides subject matter expertise in coordination and consultation with OND Policy, 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.
- Conducts systematic evaluation of drug safety programs to determine the impact of safety related regulatory policies and actions. Reviews safety programs to ensure appropriate application of various safety guidelines and authorities implemented by FDA and analyzes inconsistencies in the application of drug safety policies and regulations.
- Provides clinical analysis on current and emerging complex safety issues. Conducts safety research in collaboration with internal and external subject matter experts. Compiles reports on the status for various assigned activities within the drug safety research program through interaction with program participants. Monitors timeframes, milestones, and agreed upon endpoints.
- Contributes towards the development and implementation of safety-related initiatives

and activities in OND. Organizes and/or provides training/presentations related to drug safety. Collaborates with OND Learning and Talent Development Staff and other Center programs to develop safety related training and resources to advance the understanding of post market safety science and pharmacovigilance. Responsible for establishing and maintaining effective communications and collaboration with safety staff and other offices responsible for implementation of various drug safety programs and initiatives.

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:

Clinical Analyst, **AD-0601 Series**

Degree: 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.

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.

Professional Experience:

Our ideal candidate will possess:

- Experience in the pharmaceutical industry in drug development in the relevant area.
- Experience identifying, addressing, and resolving problems and complex issues.
- Experience utilizing written communications skills to prepare a variety of written reports and documents.
- Experience utilizing verbal communications skills to provide advice and guidance.

Desired Professional Experience:

Our ideal candidate will possess:

- 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 U.S. Department of

Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/Moderate

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 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 or curriculum vitae with cover letter by **January 19, 2023,** to: ONDIORecruitment@fda.hhs.gov Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact Ericka Huntspon at ONDIORecruitment@fda.hhs.gov.

Please reference Job Reference ID: **SPRIT-002-CA.**

Announcement Contact

For questions regarding this Cures position, please contact ONDIORecruitment@fda.hhs.gov.

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