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)
Safety, Policy, Research, and Initiatives Team (SPRIT)

Application Period: May 05, 2023 - May 10, 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: Lead Clinical Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $132,368

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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a super office within the Center for Drug Evaluation and Research 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.

Duties/Responsibilities

As **Lead Clinical Analyst**, the incumbent serves as principal advisor to the Office of New Drugs' senior management and other Center Managers performing professional and scientific work related to initiatives to establish safety research projects related to safety policies and standards for drug product manufacturers and identifying problems in drug regulation.

- Provides authoritative post-marketing drug safety guidance, assistance interpretations, and recommendations to the Deputy Director for Safety in OND Immediate Office (IO), senior OND management, Regulatory Health Project Management staff, scientific and medical staff, Agency representatives, and others. Under the direction of the OND IO Deputy Director for Safety, facilitates OND interactions with other CDER offices, including OSE, OGD, and ORP, to facilitate collaboration and coordinated review of post-marketing safety submissions and activities.

- Represents the CDER/OND on external committees, task forces and working groups for post-marketing safety initiatives. Serves as a liaison to external entities such as industry, processional 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.

- Ensures that the organization's strategic plan, mission, vision, and values are communicated and integrated into the team's strategies, goals, objectives, and work; communicates to the team milestones.

- Leads the team in identifying, distributing and balancing workload and tasks among employees in accordance with established workflow, skill level and/or occupational specialization; making adjustments to accomplish the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks; and ensuring that each employee has an integral role in developing the final team product.

- Trains or arranges for the training of team members in methods and techniques of team

building and working in teams to accomplish tasks or projects and provides or arranges for specific administrative or technical training necessary for accomplishment of individual and team tasks.

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:
Lead Clinical Analyst, AD-0601 Series

Bachelor's 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.

A health sciences/allied health sciences degree or completed medical school (MD, DO, PharmD, or OD degree) or specific training in biochemistry, epidemiology, health services or health outcomes research, measurement, educational research, or behavioral/social science research is preferred.

This position requires several years of regulatory experience reviewing applications in FDA and/or experience in the pharmaceutical industry in drug development in the relevant area.

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

Professional Experience:
Our ideal candidate will possess:

- Mastery of advanced clinical theories, practices, and techniques as applied to drug evaluation.
- Leadership experience in an area of regulatory expertise.
- Knowledge of the Federal Food, Drug, and Cosmetic (FD&C) Act and the regulations and policies promulgated under the statute.
- Knowledge of experimental design, theories, and practices utilized in new drug evaluation.
- Knowledge of literature and current clinical and research data and activities.
- Ability to communicate in writing in order to develop policy, guidance(s) to industry, internal procedures, and Congressional inquiries.
- Skill in working with a variety of officials of all levels from both public and private organizations.

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

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 qualifications 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 electronic resume or curriculum vitae (clearly describe duties performed, number of years for employment using month and year, training completed, SF50 (if applicable), latest PMAP (if applicable), to ONDIORecruitment@fda.hhs.gov Attn: Ericka Huntspon by **May 10, 2023.** Candidate resumes may be shared with hiring officials with a similar job vacancy. Candidates can opt out of this proves by annotating resume with “do not share”.

Please reference **Job ID: ONDSPRIT23-69** and use CDER/OND/IO/SPRIT/Lead in the subject line.

Announcement Contact

For questions regarding this Cures position, please contact Ericka Huntspon at ericka.huntspon@fda.hhs.gov.

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