Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of New Drugs (OND)
Office of Oncologic Diseases (OOD)

Application Period: June 23, 2023 – July 7, 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: Associate Director for Safety

Series: AD-0602

Location(s): Silver Spring, Maryland

Work Schedule: Full Time

Salary: $195,000

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

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.

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

The Office of Oncologic Diseases (OOD) is responsible for making safe and effective drugs for cancer available to the U.S. public. OOD oversees development, approval, and regulations of drug treatments for cancer, therapeutic biologic treatments for cancer, therapies for prevention of cancer, and products for treatment of malignant hematologic conditions.

Duties/Responsibilities

As **Associate Director for Safety (ADS)** within the Office of New Drugs/Office of Oncologic Diseases, the incumbent provides professional leadership and scientific direction to subordinate staff involved in the review and coordination of postmarket safety activities.

- Serves as a leader and facilitator of safety initiatives and projects from the pre-Investigational New Drug (IND) through the post-marketing phase within the Office of Oncologic Diseases' (OOD) purview. This includes the review and evaluation of various types of data in clinical trial applications and reports submitted in initial INDs and subsequent amendments, New Drug Applications (NDAs)/Biologics License Applications (BLAs), and supplemental NDAs/BLAs for regulatory and research initiatives.

- Provides oversight, coordination and technical medical expertise, and consultative services on the postmarketing safety activities typically involving the broadest and most controversial, sensitive, and complex subjects that can have a potential impact on FDA programs and the public health.

- Provides post marketing safety related medical expertise and consultative assistance to Physician Team Leader(s) and Physicians, as well as interdisciplinary scientific and staff members in addressing individual postmarketing safety concerns for individual products, as well as collectively across multiple products in the division and in collaboration with other OND divisions.

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 supervisory 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:

Associate Director for Safety, AD-0602

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

Professional Experience:

Our ideal candidate will possess:

- Significant experience in identifying, articulating, addressing, and resolving unique, far-reaching and/or previously unresolved and precedent-setting problems and complex issues.
- Professional knowledge of, and skill in applying theories, concepts, principles, and practices of medicine sufficient to serve as a recognized technical authority and consultant in a specialized technology and broad program that affects national and international interests, including the well-being of the American public.
- Strong interpersonal and expert written and verbal communications skills to provide advice and guidance to senior management and employees and prepare a variety of written reports and documents.
- Expert analytical, fact-finding, and investigative techniques and skills to carry out the Division's mission.

Desired Professional Experience:
Our ideal candidate will possess:

- Mastery professional knowledge and understanding of current FDA, Center and OND regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Ability to mentor reviewers in the Division on various aspects of the evaluation of safety during the entire drug-development cycle. This includes general approach to safety review (including pre-IND meetings, 30-day IND review, protocol review, NDA/BLA application review, and post-market safety activities).
- Expert knowledge of scientific methods and techniques related to the review and evaluation of various types of data in various regulatory applications, pertinent laws, regulations, and Agency policy. Competence to make authoritative evaluations of drugs, chemicals, and toxic agents regarding their effect on product labeling changes related to safety.
- Expert knowledge of broad operating programs to advise senior colleagues and agency officials.
- Ability to manage significant projects that represent an important segment of the agency's operating programs.

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 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 a resume or curriculum vitae with cover letter to Alexander.Levillain@fda.hhs.gov by **July 7, 2023**. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Source Code: OND-ADS-1002** in the email subject line of your submission.

Announcement Contact

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

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