Title 21 Vacancy Announcement
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)
Immediate Office (IO)

Application Period: September 16, 2024 - September 27, 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: Safety Regulatory Health Project Manager

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $139,395

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: up to 25%

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 or Agency) 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 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 over-the-counter (OTC) drug products.

The mission for the Office of Oncologic Diseases (OOD) is to review notices of claimed investigational exemptions for Investigational New Drugs (INDs) and biologics within hematology and oncology products and recommends appropriate action with respect to safety and effectiveness of clinical trials. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biological License Applications (BLAs) for hematology and oncology products and evaluates supplements that propose changes in the conditions upon which NDA and BLA approvals are based.

Duties/Responsibilities

As a **Safety Regulatory Health Project Manager** for all post marketing safety activities (such as those related to FDA's Safety First and Safe Use Initiatives), in an assigned Office of New Drugs (OND) Division. In this capacity, the incumbent serves as a focal point and coordinator for all activities related to post marketing safety including required post marketing studies and other voluntary commitments. These activities will improve the safety process that span post marketing activities OND and other offices, such as the CDER/Office of Surveillance and Epidemiology (OSE) and Office of Translational Sciences (OTS) to better meet their respective missions and achieve the Center for Drug Evaluation and Research's (CDER) objectives. The following duties are performed in regard to managing, tracking, and coordinating the post marketing safety activities.

- Develops and coordinates material to contribute to the division being able to address individual safety issues, but also development of materials for briefing Congressional staff, reports in the Federal Register, and the safety applications in the system of record and post marketing commitment safety database. In order to accomplish these activities, the incumbent is required to interface and interact on a daily basis with other regulatory health project managers and scientific reviewers in the assigned division.
- Meets with other FDA components, consumer and healthcare professional liaisons and counterparts in other Federal agencies such as the National Institute of Health (NIH), Center for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), Department of Defense (DoD), Department of Administration (DOA), Veterans

Affairs (VA), advocacy groups, officials in academia, professional societies, regulated industry, and Congress.

- Develops, tracks, and maintains new safety applications in the system of record.
- Manages the flow of post marketing safety consult requests, OSE safety reviews, and division responses to the OSE within tracking system. Coordinating the interface between assigned clinical Division and OSE counterparts. Notifying the respective OSE Regulatory Health Project Manager about safety issues that do not warrant OSE consults or do not invoke regulatory intervention under Food and Drug Administration Amendments Act (FDAAA) (e.g., minor safety labeling changes, post marketing safety studies by sponsors that are not required studies or clinical trials).
- Monitors the status of post marketing safety issues including reviews of periodic regulatory submissions.
- Coordinates and tracks consultation requests for Specific Post marketing Safety Regulatory Documents. These consultations are initiated by the primary Medical Officer, in collaboration with the Medical Officer team leader and the Regulatory Health Project Manager.
- Consultations may address safety issues related to post marketing studies or clinical trials (required or voluntary commitments under FDAAA), including Risk Evaluation and Mitigation Strategies (REMS) that may include proposed plans, amendments, sponsor status reports, and evaluations of existing plans.
- Designs epidemiologic study changes to (i) medication guides and patient labeling involving safety; (ii) professional labeling for products in which OSE was previously involved in a safety issue; and (iii) professional labeling involving precautions and warnings not previously reviewed by OSE.
- Discusses the scope and objectives with an OSE safety evaluation/epidemiologist, in conjunction with the respective Medical Officer, prior to preparing the request and ensures the request contains appropriate documentation then enters into DARRTS and forwards to OSE.
- Coordinates and tracks discretionary consultations requests to OSE. These consultation requests are for items such as annual reports for New Drug Applications (NDAs)/Biological License Applications (BLAs), Periodic Safety Reports (PSRs), NDA/BLA supplements with clinical trial data, safety-related post marketing studies from sponsors with clinical trial data; information related to safety and marketed drugs arising from IND activities, PSRs, CBE label changes involving safety issues that do not rise to the level of precautions/warnings, and literature reports.
- Coordinates, reviews, and decides on the appropriate action, including approval or disapproval of all applications for Over-the Counter (OTC) drug products, OTC drug monographs, prescription drug switches to OTC drug status, and other OTC-related drug products, except for generic drug applications.
- Coordinates the development and implementation with the Deputy Division Director for Safety in the assigned division, of staff training on programs and initiatives to support the Center's policies related to post marketing safety.
- Issues are handled by the Safety Regulatory Health Project Manager (SRPM) at this level often have broad, controversial, sensitive, and complex implications for FDA programs

and the public health. As a result, the SRPM is called upon to engage in extensive interface with technical experts throughout various Center components, as well as sensitive coordination with other Agency components. The incumbent is required to be an authoritative expert not only on the post marketing safety activities and post marketing commitments but also on all areas of drug regulation and regulatory policy.

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.
- 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 Experience:
Our ideal candidate will possess:

- Ability to identify and analyze complex problem; and evaluates alternative solutions.
- Expert ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to organize time effectively, determine priorities and move work forward.

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

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.

This position requires a security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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 or curriculum vitae with cover letter by **September 27, 2024,** to ONDStaff4Recruitment@fda.hhs.gov**.** Candidate resumes may be shared with hiring official within 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: **CDER-OND-IO-1012** in the email subject line.

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

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

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

FDA is an equal opportunity employer.