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)
Office of Drug Evaluation Science (ODES)
Division of Biomedical Informatics, Research & Biomarkers Development (DBIRBD)

Application Period: October 19, 2023 - November 1, 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: Science Policy 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 WILL NOT 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 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 Office of Drug Evaluation Science (ODES) promotes innovative approaches to drug evaluation through the promotion of novel drug development tools, standardized drug evaluation approaches, and regulatory science research, focusing on: Clinical Outcome Assessment (COA), Biomedical Informatics and Regulatory Review Science (BIRRS), research, biomarkers, and innovative technologies.

The Division of Biomedical Informatics, Research & Biomarkers Development (DBIRBD) works closely with all Office of New Drugs (OND) offices and divisions as well as CDER, Center of Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH) on cross cutting scientific review and policy initiatives concerning biomarker development and regulatory science activities. The Division oversees the Biomarkers Qualification program and the recently developed pilot program, Innovative Science and Technology Approaches for New Drugs (ISTAND), that will help expedite the development of promising therapeutics to address unmet medical needs.

Duties/Responsibilities

As a **Science Policy Analyst** within DBIRBD, the incumbent serves as an advisor to the Division Director of Biomedical Informatics, Research, and Biomarker Development (DBIRBD) and the Office of Drug Evaluation Science (ODES) leadership on matters that have a direct effect on the review and evaluation of biomarkers and other Drug Development Tools (DDTs). The incumbent is responsible for assessing safety risks of new drugs or artificial intelligence/machine learning based tools.

- Monitors and coordinates the development and implementation of guidance, workshops, research projects, grants, and stakeholder engagement designed to facilitate, support, and accelerate the development of drugs and therapeutic biologics.
- Provides scientific expertise in the development of policies, procedures, and activities to ensure consistency in the application of biomarkers in regulatory decision-making, new drug application reviews, and reviews of submissions to the Drug Development Tool (DDT) Qualification Programs.
- Reviews submissions to the biomarker qualification and Innovative Science and Technology Approaches for New Drugs (ISTAND) pilot programs for drug development tools seeking

qualification.
- Presents research findings and recommendations while serving as a subject matter expert (SME) to CDER and FDA committees regarding the use of biomarkers in drug development.
- Informs stakeholders, such as biomarker developers in industry and academia and clinical review divisions, on the direction and maturation of regulatory science by keeping abreast of the progress in biomarker advancements through reviewing scientific literature, attending conferences, participating in workshops, and attending staff seminars.

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:

General Medical and Healthcare, AD- 0601 Series

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

Desired Professional Experience:
Our ideal candidate will possess:

- Skill in applying clinical and scientific expertise to complex multifaceted clinical problems.
- Ability to apply knowledge and understanding of advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply to unique circumstances and develop an understanding of these new circumstances, and to determine appropriate actions.
- Ability to resolve unique or novel problems and conditions, thereby addressing complex and challenging problems in the context of regulatory review of medical products.
- Ability to work independently, proactively identify priorities and complete assignments with minimal oversight.
- Ability to provide authoritative guidance to assist an organization in meeting defined vision, mission, and goals.
- Experience and knowledge of clinical and scientific literature and current clinical activities relating to the application of biomarkers to drug development programs for drugs and biologics.

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 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 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 with cover letter and unofficial transcripts by **November 1, 2023,** to Kenisha Salvary at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the 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: ES-23-017** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Wright at Danielle.Wright@fda.hhs.gov.

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