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 the Center Director(OCD)
Immediate Office (IO)

Application Period: December 20, 2024- January 21, 2025

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 RWE Analytics

Series: AD-0601/0602

Location(s): Silver Spring, MD

Salary: Starting at:
$213,491 (AD-0601)
$235,000 (AD-0602)

Work Schedule: Full Time

Cures Band(s): Band G

Full Performance Band Level: Band G

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 safe, and effective.

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 and prescription drugs, including biological therapeutics and generic drugs.

The Office of the Center Director (OCD) Immediate Office (IO) provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

Duties/Responsibilities

As the **Associate Director for Real World Evidence (RWE) Analytics**, the incumbent leads CDER's RWE program and provides strategic vision and direction for the agency's effort to evaluate and promote the use of real world evidence to advance efficient drug development, including for chronic diseases that impact many Americans and for which RWE can promote efficient evaluation of the safety and effectiveness. Resource management at this level involves major decisions and actions which have a direct and substantial effect on the organizations and programs managed but also on the technology development, clinical and epidemiologic strategies, and regulatory convergence in the broader drug development community and internationally.

In this capacity, the incumbent is responsible for the following:

- Serves as the principal external spokesperson for the Center for RWE, as well as a senior spokesperson for related efforts to increase the efficiency and utility of clinical trials through use of real world data, artificial intelligence, digital technology and advanced analytics.

- Communicating with international regulators through leadership of the FDA, European Medicines Agency (EMA), and RWE Cluster and related international regulatory liaison mechanisms.

- As the Chair RWE Senior Advisory Committee , the incumbent provides strategic and clinical guidance for agency review of RWE submissions by managing input from senior Center for Drug Evaluation and Research (CDER), Oncology Center of Excellence (OCE), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) staff, and any future bodies that would coordinate, guide, and advise on RWE submissions, policies, and projects. Provides technical assistance to other professionals in the organization on the use of real-world evidence to evaluate the effectiveness and safety of medical products.

- Provides matrixed leadership for guidance development and workgroups composed of staff from multiple CDER Offices, as well as CBER and CDRH to identify and address scientific and policy challenges.

- Provide strategic direction for investment in regulatory science related to RWE and oversee contracts and grants totaling millions of dollars.

- Leverages prior FDA review and technology transfer experiences as well as input from other CDER offices to identify key gaps preventing wider adoption of RWE. Reviews existing resources initiates internal and external partnerships and directs staff who evaluate, and initiate demonstration projects designed to close these gaps in the areas of real-world data utilization, real world evidence generation, and submission standards for FDA.

- Keeps the Center Director, and Principal Deputy Commissioner and other officials fully informed of programs, resources, and related considerations that would impact the Agency's evaluation of real-world evidence and the implementation of relevant portions of the Agency's Technology Modernization Action Plan.

- The Associate Director for RWE Analytics will work closely with CDER experts, as well as relevant staff across FDA (e.g., in other centers or in the Office of the Commissioner) to optimize opportunities for external engagement and communication, and internal communication and integration. Because of the important ongoing programs throughout CDER, this individual is expected to integrate and align with leadership in these programs to assure seamless internal and external efforts. They will coordinate with ongoing scientific, regulatory policy and communication efforts, assuring close partnership with the relevant programs within CDER.

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.

In order 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:

AD-0601 Series: General Medical and Healthcare Series:

Degree: 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.

At a minimum, the candidate must possess a doctoral-level degree from an accredited institution of higher learning, including Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph.D.

Physician, AD-0602 Series:

Degree: From an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Desired Professional Experience:
Our ideal candidate will possess:

- Demonstrated leadership ability in a regulatory, pharmaceutical company, or academic organization with a focus on generation of RWE to support drug development.
- Ability to lead the development of large surveillance and real-world evidence generation systems.
- Expertise in clinical informatics with experience and knowledge of clinical trial protocols, electronic health records systems, disease and patient registries, and medical claims data is desirable.
- Experience overseeing the development of study protocols involving real world evidence.
- Experience with benefit risk assessments and FDA labeling.
- Experience and/or knowledge of the procedures of other global regulators, such as the European Medicines Agency.
- Experience launching and scaling analytical solution and digital health platforms to meet regulatory needs.

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 resume or curriculum vitae with cover letter by **January 21, 2024**, to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions, please contact CDER-OCD-OEP-Hires@fda.hhs.gov.
Please reference Job ID: **Associate Director for RWE Analytics** in the email subject line.

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

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