Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Surveillance and Epidemiology (OSE)

Application Period: April 6, 2021– April 20, 2021

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: Epidemiologist

Series: 0601

Location(s): Silver Spring, MD

Salary: Starting at $103,960

Work Schedule: Full Time
Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 10% or less

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 compensated 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 Center for Drug Evaluation and Research (CDER), is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotional activities; review, monitoring and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply

with the law.

This position is in the Divisions of Epidemiology (DEPI I and II), Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), CDER. The mission of these divisions are to protect the public using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics and evaluate observational methods and analytical approaches of real-world evidence for drug efficacy. The divisions in collaboration with other disciplines, accomplish this by detecting, assessing, and evaluating safety signals of drugs and biologics; conducting and evaluating drug and biologic safety and effectiveness surveillance research using the best available epidemiologic methodologies across OSE and CDER.

Duties/Responsibilities

- Provides regulatory expertise in the use of various data sources and methodologies to assess and inform drug safety and the observational aspects of drug efficacy/effectiveness evaluations. Data evaluated by the divisions may include evidence generated from clinical trials data as well as evidence generated from non-randomized studies including observational studies using various population sources and study designs
- Provides expertise in the use of data such as computerized electronic medical records, claims, managed care data, as well as other data sources such as prospective data collection to conduct epidemiologic evaluations
- Coordinates and conducts epidemiologic analyses and reviews required for the assessment of the safety and efficacy/effectiveness of medical products for use in the United States; efforts include specification of regulatory research questions, selection of adequate population or data sources to inform regulatory questions, implementation of data management strategies and preparation of analytical datasets, development and implementation of appropriate study, design and analytical methodologies, and provision of adequate interpretation of results considering the strength of evidence to inform regulatory recommendations
- Provides technical assistance and participates fully in the scientific review of new drug and biologic applications when safety concerns are identified, or epidemiologic expertise is needed; provides an evaluation of the advantages and limitations of utilizing observational population/data sources, study designs, and analytical strategies to evaluate safety concerns post-marketing, provides required assessments for issuance of post-marketing studies under the Food and Drug Administration Amendments Act (FDAAA); provides scientific and technical assistance in the development of drug specific post market safety surveillance plans, post-marketing requirements or post-marketing commitments

- Coordinates and conducts epidemiological and statistical studies in drug safety and effectiveness, conducting and coordinating safety surveillance, signal evaluation, and risk assessment of pharmaceutical products using epidemiologic approaches
- Provides technical assistance to other professionals in the organization on the use of complex statistical and epidemiologic methodologies to monitor and evaluate post-marketing drug safety issues and for the epidemiologic aspects of efficacy submissions utilizing real world data or relying on real world evidence; examines reports and articles prepared by others within the organization as part of the peer review process; serves as technical expert in study design, analytical methodologies utilized and interpretation of epidemiologic studies
- Maintains contact with consumers of work products, usually professional personnel of government and non-governmental organizations; shares scientific findings of epidemiologic assessments at CDER briefings, other internal meetings and with external groups such as professional societies, presents review findings and provides scientific advice at Sponsor or Industry meetings, FDA advisory committee and professional meetings and conferences where the subject under consideration is concerned with the projects assigned to the incumbent; prepares manuscripts for submission and publication
- Prepares comprehensive reports of study protocols and results. These include discussion of the research objectives, assessment of the adequacy and validity of the data used in the analyses, assessment of the methodologies, results, and the regulatory and public health relevance of the findings; disseminates results of research projects in a wide range of venues including publications, peer-reviewed journals, summaries, manuscripts, and special reports. Presents results to the scientific community at professional meetings and conferences

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.

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:

Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for OPM Occupational Series Qualification Requirements.

Desired Education: 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 (https://www.ed.gov/) at the time the degree was obtained.

Professional Experience:

- Knowledge of multiple and appropriate data sources for drug safety assessment and the conduct of observational pharmacoepidologic studies
- Knowledge of Federal laws and FDA regulations and related guidances for industry including regulations pertaining to the legal and ethical conduct of human subjects research; and strong analytical, negotiation, and communication (writing and oral) skills
- Demonstrated leadership, interpersonal skills and knowledge of the many scientific areas important to postmarketing safety

Desired Professional Experience: Possession of post-graduate epidemiology training and relevant epidemiology research experience.

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.

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 by **April 20, 2021** to: David Moeny David.Moeny@fda.hhs.gov or Simone Pinheiro Simone.Pinheiro@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”. For questions please contact Amy Garvin amy.garvin@fda.hhs.gov. Please reference Job Reference ID: 21EPI002.

Announcement Contact

For questions regarding this Cures position, please contact amy.garvin@fda.hhs.gov.

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