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: December 9, 2022 - December 19, 2022

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, Epidemiology I & II

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: This is a non-bargaining unit position

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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the respective divisions in the Office of Pharmacovigilance and Epidemiology is to protect the public using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics by detecting, assessing, and evaluating the safety and effectiveness of drugs and biologics using observational methods; and conducting drug and biologic safety and effectiveness surveillance and research using the best available epidemiologic methodologies.

Duties/Responsibilities

The mission of Division of Epidemiology (DEPI) is to protect the public using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics by detecting, assessing, and evaluating the safety and effectiveness of drugs and biologics using observational methods; and conducting drug and biologic safety and effectiveness surveillance and research using the best available epidemiologic methodologies.

As an **Associate Director**, the incumbent serves as the principal scientific advisor to the DEPI Directors on all pharmacoepidemiology, drug safety and effectiveness, and regulatory science-related matters. The incumbent serves as an authoritative resource on the epidemiological assessment of DEPI and CDER programs and provides critical guidance, scientific oversight, and expert consultation to DEPI Team Leaders, and other DEPI staff members and fellows in all activities within DEPI's scope of responsibility. This includes, but is not limited to, epidemiological reviews, regulatory research projects, procurement of database resources, Sentinel-related activities, mentoring, participation in the division strategic planning activities, and participation in Office and Agency-wide work-groups. This responsibility requires the Associate Director to maintain close personal contact with the current science in the field of pharmacoepidemiology in order to inculcate the most advanced theories and practices in the scientific field into the Division and the Office programs.

The Associate Director:

- Provides critical scientific leadership, direction, planning, strategy, and management of the Division's program, and providing scientific support for various projects and assignments in the Division. Initiates decision-making processes and documents and participates in discussions and decisions concerning Division, Office, and Center plans, programs, and activities. Develops short- and long-term vision, priorities and plans to strengthen the epidemiology program including staff development and training, improving computational infrastructure, analytic tools, and database access.

- Serves as the subject matter expert and as an authoritative resource on pharmacoepidemiology research tools and methods, to carry out the mission of the Division as well as to address and solve highly complex, unusual, and often precedent setting problems associated with the Division programs. This includes providing technical direction and scientific oversight to the design and execution of research projects, development of good epidemiological standards and research practices and processes to foster a high-quality science-based epidemiological program to assess drug safety and effectiveness and real-

world evidence (RWE) questions, participating in procurement activities for database resources and ensuring that all research activities and project conducted under his/her guidance adhere to Federal and institutional regulations, policies, and procedures for the protection of human subjects.

- Advises the DEPI Directors on methodologically challenging and/or controversial issues. Provides critical scientific leadership and develops guidelines, standards, and methods utilized to gather research and data for DEPI's drug safety and effectiveness and RWE regulatory research/investigation programs. Concentrates on complex, long range, and emerging problems and conflicts in the scientific field as applied to the programs for which the Division is responsible. The incumbent keeps fully abreast of the crucial and precedent-setting epidemiological studies under review within the Division.

- Advises and collaborates with professionals (scientists, team leaders, reviewers) and officials (e.g., directors) in CDER, other Centers and other Agencies or regulatory bodies on pharmacoepidemiology issues, original research projects, best practices, guidances, legislative initiatives, and SOPs related to DEPI program areas. This requires continuing knowledge of both research in the scientific discipline and in regulated industry as those studies impact on the area of science for which the incumbent is responsible.

- Prepares reports and maintains records of work accomplishments and administrative information, as required. Coordinates the preparation, presentation, and communication of work-related information for the supervisor.

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:

General Medical and Healthcare Series, AD - 0601 Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for General Health Series (0601) https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0600/general-health-science-series-0601/

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:

- Demonstrated knowledge of the Food and Drug Administration Amendments Act, regulations, policies, and procedures related to the regulation and evaluation of drugs and biologic products.
- Demonstrated knowledge and experience applying science (e.g., biology, regulatory science, drug safety, pharmacoepidemiology)
- Demonstrated experience in managing, planning, organizing, monitoring, and providing

expert advice and leadership on regulatory program segments, functions, and activities to a highly trained and skilled staff of health professionals, scientists, and/or multi-disciplinary professionals in a regulatory program.

- Demonstrated experience applying expertise in advanced professional theories, principles, concepts, standards, and methods of drug regulatory process using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics.
- Demonstrated leadership and knowledge of the many scientific areas important to post marketing drug safety and effectiveness including assessment of potential concerns with drugs and therapeutic biologics. Advance scientific knowledge of different past and present data source systems used to monitor the effectiveness and safety of the various classes of drugs.
- Demonstrative experience and/or training in the application of the most advanced clinical and scientific practices used in the field of pharmacoepidemiology.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive

Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

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

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 by **December 19, 2022,** to: OSE-PMAS-Admin-Team@FDA.HHS.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". Please reference **Job Reference ID: DEPIIDEPDIR0822**

Announcement Contact

For questions regarding this Cures position, please contact OSE-PMAS-Admin-Team@FDA.HHS.gov.

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