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 Surveillance and Epidemiology (OSE)

Application Period: January 9, 2023 - February 21, 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: Lead General Health Scientist, DMEPA I

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $126,233

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Will not be paid.

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 Divisions of Medication Error Prevention and Analysis I (DMEPA I) is responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, product design and Human Factor Studies to identify, evaluate, and minimize the potential for medication errors and use errors for CDER-regulated products.

Duties/Responsibilities

The **Lead General Health Scientist** is responsible for serving as advisor planning, coordinating, and evaluating drug safety programs and activities to explore and/or confirm signals and to assess risk. The incumbent will be responsible for the following major duties:

- Applies a wide range of qualitative and quantitative methods to analyze and improve team effectiveness. Leads the team in assessing its strengths and weaknesses; resolves simple and informal complaints of employees and refers others to an appropriate management official.
- Maintains close personal contact with the "state of the science" in order to inculcate the most advanced theories and practices in the programs.
- Serves as a recognized authority in the area of scientific expertise, receives for resolution unique, far-reaching, and previously unresolved problems.
- Provides consultations, opinions, and endorsements regarding the area of regulatory expertise and attends meetings both within and outside the Federal government.
- Addresses professional groups, such as Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation and Advanced Medical Technology Association (AdvaMed), on the area of regulatory expertise as that area affects the mission for which the Division/Staff is responsible.

Team Leader Functions:

- Leads a team of a minimum of four other interdisciplinary professionals, and ensures that the organization's strategic plan, mission, vision, and values are communicated and integrated into the team's strategies, goals, objectives, and work.
- Articulates and communicates to the team the assignment, project, problem to be solved, actionable events, milestones, and/or program issues under review, and deadlines and time frames for completion.
- Coaches the team in the selection and application of appropriate problem-solving methods and techniques, provides advice on work methods, practices, and procedures, and assists the team and/or individual members in identifying the parameters of a viable solution.
- Balances workload and tasks among employees in accordance with established workflow, skill level and/or occupational specialization; adjusting the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks and ensures that each employee has an integral role in developing the final team product.

- Monitors and reports on the status and progress of work, checking on work in progress and reviewing completed work to see that the supervisor's instructions on work priorities, methods, deadlines, and quality have been met.

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.
- 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 Series, AD - 0601

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply knowledge of the Food, Drug and Cosmetic Act, Code of Federal Regulations, and other Agency guidelines and policies pertaining to review of drug and therapeutic biologic applications.
- Ability to apply knowledge of scientific areas important to premarket and post marketing safety.
- Ability to apply knowledge of the medication use process, and clinical effects, of medications.
- Ability to apply initiative, resourcefulness, and knowledge of the area of regulatory expertise to interpret and apply appropriate guidelines to address pre and post marketing drug safety and human factor review issues.
- Skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods of pharmacy and/or drug regulatory process sufficient to serve as expert to resolve difficult problems and issues, as well as plan, design, monitor and evaluate complex projects.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.

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 **February 21, 2023,** 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: **DMEPATLGHS1022.**

Announcement Contact

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

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