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 Compliance (OC)
Division of Enforcement and Postmarketing Safety (DEPS)
Office of Scientific Investigations (OSI)
Postmarket Safety Branch (PSB)

Application Period: January 3, 2022 to January 14, 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: Lead Pharmacologist

Series: AD-0405

Location(s): Silver Spring, MD

Salary: Starting at $122,530

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

Full Performance Band Level: Band D

Travel Requirements: 25% 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 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 or Agency) 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 Office of Scientific Investigations (OSI) within the Office of Compliance (OC) is to ensure CDER-regulated products are safe and effective for the life of the product, through oversight and enforcement activities involving: the reliability of safety and efficacy data submitted to FDA, the application of human subject protections in clinical trials, and compliance with the laws and regulations governing research, adverse event reporting, Risk Evaluation and Mitigation Strategies (REMS), and Postmarketing Requirements (PMRs).

Duties/Responsibilities

The incumbent serves as Team Lead in the Postmarketing Safety Branch (PSB), Postmarketing Adverse Drug Experience (PADE) Compliance Team. The PSB within OSI's Division of Enforcement and Postmarket Safety assigns, directs, and coordinates onsite inspections in collaboration with the Office of Regulatory Affairs in order to monitor adherence to regulations and statutes governing Postmarket Adverse Drug Experience reporting requirements and REMS. The Team Lead provides guidance and direction to a team of employees responsible for carrying out Team activities associated with PADE compliance.

- Serves as a source of informed opinion and information on medical and scientific matters related to CDER's adherence to regulations and statues governing postmarket adverse drug experience reporting requirements. Makes independent scientific and regulatory judgments on violative PADE cases, relying on their thorough knowledge of the theories, principles, practices and knowledge of clinical pharmacokinetics and pharmaceutics in the pharmacology discipline.
- Serves as a recognized authority in scientific matters related to pharmacological, compliance, and inspectional findings. Guides and mentors subordinate team members in the evaluation of inspectional reports (EIR), makes determination on whether corrective action is necessary, and initiates administrative and regulatory corrective action as needed.
- Collaborates within CDER's Office of Medical Policy, Office of Regulatory Affairs, and Office of Surveillance and Epidemiology on highly complex, long-range, and emerging compliance and postmarketing safety issues.
- Maintains high quality inspection standards that meets timelines set to ensure Center goals related to regulated products are met. Ensures that team complies with applicable federal laws and regulations and FDA and OSI policies and guidance governing work performed. Assures the rights, safety, and welfare of human subjects are protected.
- Collaborates with international regulatory agencies to conduct and observe inspections and appropriately applies knowledge of International Counsel for Harmonization Guidance and other guidelines.
- Develops and presents educational outreach and training programs for regulated industry, professional societies, academic research institutions, and foreign regulatory counterparts to help improve industry's compliance with federal law and regulations.

- Represents FDA/CDER at professional meetings with regulated industry and other regulatory counterparts. Represents FDA/CDER and participates on internal and external working groups, scientific symposia, and public workshops.

Team Leader Duties: The incumbent leads a multidisciplinary team of a minimum of four professionals, and (1) 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; (2) 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; (3) leads the team in identifying, distributing and balancing workload and tasks among employees in accordance with established work flow, skill level and/or occupational specialization; adjusting the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks; and ensuring that each employee has an integral role in developing the final team product; (4) provides input on the training needs of team members and works with the division management to arrange specific administrative and/ or technical training to accomplish tasks or projects; (5) 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; (6) serves as facilitator in coordinating team initiatives and in consensus building activities among team members; (7) represents the team is dealings with the supervisor and manager to obtain resources and secure information for decisions; and (8) reports to the supervisor on team and individual work accomplishments, problems, and work processes, including individual and team training needs.

Supervisory responsibilities: None

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.

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:
Pharmacology Series, 0405

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

For more information please see: OPM Occupational Series Qualification Requirements

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: No national security duties

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 (**resume and curriculum vitae must have the MM/YYYY for each position**) with cover letter by 1/14/2022 to: CDEROC-OSI-Recruit@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 Monica.Lewis@fda.hhs.gov. **Please reference Job Reference ID: T-21-531-D in the subject line.**

Announcement Contact

For questions regarding this Cures position, please contact Monica.Lewis@fda.hhs.gov

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