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)
Office of Scientific Investigations (OSI)

Application Period: January 10, 2022 – January 31, 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: Branch Chief (Supervisory Physician)

Series: AD-0602

Location(s): Silver Spring, MD

Salary: Starting at $180,000

Work Schedule: Full time

Cures Band(s): Band D

Full Performance Band Level: 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 (OTC) 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).

The Good Clinical Practice Assessment Branch Chief (GCPAB) within OSI reports to the Director of the Division of Clinical Compliance Evaluation (DCCE). The Branch Chief has full responsibility for managing a staff of approximately 15 highly skilled professionals responsible for designing and operating a surveillance program of clinical drug product investigations supporting New Drug Applications (NDA) and Biologics License Applications (BLA). This includes oversight of clinical investigators, sponsors, and other entities with relevant regulatory responsibilities to verify the quality, data integrity, and protection of human subjects in clinical trials of safety and efficacy.

Duties/Responsibilities

- Serves as a technical and scientific authority in the area of Good Clinical Practice (GCP), including data integrity and clinical trial conduct, evaluating the reliability of clinical data relating to the safety and effectiveness of a broad range of drugs pending approval before CDER. Reports to the Division Director on emerging issues or problems.
- Develops and implements policies, surveillance activities, compliance strategies and administrative actions under the Agency's Bioresearch Monitoring (BIMO) Program to: 1) protect the rights, safety, and welfare of human research subjects; 2) ensure the reliability and interpretability of data submitted in support of NDAs and BLAs; and 3) assess compliance with the laws and regulations governing clinical research and GCP compliance.
- Provides oversight and management of multiple highly complex programs handled by GCPAB:
    - Responsible for the effective discharge of program responsibilities, and recommendations are expected to be scientifically sound and responsive to program needs.
    - Directs the work of the branch, assigns incoming documents and providing second level signoff for outgoing documents; responsible for providing review on draft guidance documents and regulations; participates in and leads regulatory projects; responsible for drug assessments and regulatory mandates; directs and supports implementation of new laws and regulations; and provides technical and non-technical guidance to internal and external senior level officials and stakeholders.
    - Evaluates relevance of inspectional findings from clinical and scientific perspectives as applicable, recommends GCP compliance action, and assesses potential impact on effectiveness and safety of a medical product based on inspection results.

    - Provides leadership, oversight, and review of the assessment of inspectional reports, development, and issuance of correspondence to the inspected party, and involvement in administrative and regulatory corrective measures, as necessary.
    - Recommends GCP compliance action and assesses potential impact on effectiveness and safety of a medical product based on inspection results.
    - Strengthens collaborations with foreign regulatory counterparts, including European Medicines Agency, and Health Canada, and encourages GCPAB staff participation of collaborative GCP inspections that are relevant to GCPAB activities.
- Develops and presents educational outreach and training programs for regulated industry, professional societies, academic research institutions, and foreign regulatory authorities in area of GCP.

Supervisory Responsibilities:
Directly supervises and evaluates approximately 15 staff members who serve as experts in their field. These include scientific, professional, technical, and administrative personnel ranging in grade from GS-12 to GS-15 and includes Band D Team Leaders. Manages multiple projects, providing leadership and management oversight to branch. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives for the organization.

The incumbent will also be responsible for the below supervisory duties:

- **Organizational Management**
- **Program Management**
- **Resource Management**
- **Personnel Performance Management**:
- **Human Capital Management**:

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.
- THIS POSITION IS SUBJECT TO EXECUTIVE ORDER 14043 MANDATING COVID-19 VACCINATION FOR FEDERAL EMPLOYEES. See section titled Vaccination Requirements for more Conditions of Employment for this position.

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:

Physician 0601

Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

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, a fifth pathway certificate for Americans who completed premedical

education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination. For more information please see: OPM Occupational Series Qualification Requirements

Licensure
Applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Professional Experience:

Priority will be placed on candidates with:

- Demonstrated experience in identifying and analyzing problems; weighing relevance and accuracy of information; generating and evaluating alternative solutions; and making recommendations.
- Demonstrated experience in leadership principles and concepts.
- Effective and experienced communicator who can drive collaboration, empower staff, and is committed to the Public Health mission.
- Knowledge of the Food, Drug and Cosmetic Act and related regulations applicable to human drugs that are administered by the FDA.
- Knowledge of the processes and procedures employed in FDA's BIMO program as well as the ability to converse with stakeholders in the associated scientific, clinical, and technical fields.
- Knowledge of regulatory compliance involving GCP compliance, technical programs and projects that impact upon and affect top priority agency programs. Some knowledge of science-based management of bio-research monitoring for multiple categories of drug trials.
- Knowledge in the areas of risk management, policy development, and strategic planning and implementation to support scientific GCP management activities.

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

Security Clearance: 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

As required by Executive Order 14043, Federal executive branch employees are required to be fully vaccinated against COVID-19 regardless of the employee's duty location or work arrangement (e.g., telework, remote work, etc.), subject to such exceptions as required by law. If selected, you will be required to be vaccinated against COVID-19 and submit documentation of proof of vaccination by November 22, 2021 or before appointment or onboarding with the agency (if later than November 22, 2021). The agency will provide additional information regarding which forms of documentation can be accepted and how you can request a legally required exception from this requirement.

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 31st, 2022 to: CDEROC-OSI-Recruit@fda.hhs.gov. **Note: Candidate's resume/curriculum vitae must include MM/YYYY for each position.** 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 taurean.washington@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact Taurean Washington, Administrative Officer at email taurean.washington@fda.hhs.gov.

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

FDA is an equal opportunity employer.