Title 21 Vacancy Announcement
(Multiple Vacancies)
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of New Drugs (OND)
Office of Immunology & Inflammation (OII)
Division of Rheumatology & Transplant Medicine (DRTM)

Application Period: September 13, 2023 – October 13, 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 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: Band D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 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 Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications (NDAs), interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

Office of Immunology & Inflammation (OII) evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs/BLAs. Also, evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office of Immunology & Inflammation. Performs medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and OTC drug products regulated by other offices in the Center, as applicable. Works collaboratively with the Office of Surveillance & Epidemiology to conduct continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by IND sponsors, by NDAs applicants, and from other sources.

The Division of Rheumatology & Transplant Medicine (DRTM), in the Office of Immunology and Inflammation (OII), Office of New Drugs (OND), regulates and reviews Investigational New Drug (IND), New Drug Application (NDA) and Biologics License Applications (BLAs) for safety and effectiveness for treatment of rheumatology and transplant medicine.

Duties/Responsibilities

As **Lead Physician**, the incumbent is responsible for assisting the supervisor with administrative direction and scientific oversight. In this capacity, the incumbent leads clinical assignments related to New Drug Applications (NDAs) or Biologic License Applications (BLAs) and serves as an authority on the clinical aspects of the drug or biologic applications in the assigned therapeutic areas as it relates to marketing approval and enforcing safeguards for testing of investigational drugs and biologics in humans.

- Evaluates the proposed clinical trials for safety, appropriateness of the study population, and other study design items. Determines if human subjects in clinical research of investigational new drugs or biologics can be protected from

unreasonable risks. Reviews work for completeness of scientific, clinical, and medical content for Investigational New Drug Applications (INDs) for all drugs and biological products regulated by the FDA.

- Reviews the evaluations available regarding the pharmacology and toxicology of similar and related products (including those used as drugs and those which have been found unsuitable for use in humans). Considers the purpose of the proposed trials to assess whether the risks of the trials exceed their potential benefits.
- Ensures that the organization's strategic plan, mission, vision, and values are communicated and integrated into the team's strategies, goals, objectives, and work. In addition, communicates key milestones to the team; coaches the team in the selection and application of appropriate problem-solving methods and techniques; and leads the team in identifying, distributing, and balancing workload among employees.
- Serves as coach and facilitator in coordinating team initiatives, policy implementation, and consensus building. Prepares reports and maintains records of work accomplishments and supporting information; represents the team in dealings with the supervisor and manager to obtain resources and secure information for decisions; reports to the supervisor on team and individual work accomplishments, problems, and work processes, including individual and team training needs.
- Represents the team consensus and conveys the team's findings, reports to the team on progress in meeting team milestones and deadlines for completion of assignments. Applies a wide range of qualitative and quantitative methods to analyze and improve team effectiveness; leads the team in assessing its strengths and weaknesses.
- Serves as a professional by participating in meetings/conferences with other Center and Agency officials, academia and regulated industry related to issues pertaining to safety, health hazards, contamination, recall actions, and other matters associated with the marketing of those drugs which fall within the purview of the Division; advises other agencies of government, industry representatives, and others on medical-scientific questions, including methods and criteria for research and testing, and performance of clinical research.

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.

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 Series, AD-0602

For more information, please see: **OPM Occupational Series Qualification Requirements.**

Professional Experience:
Our ideal candidates will possess:

- Experienced and effective communicator who can drive collaboration, empower team members, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Demonstrated experience in leadership principles and concepts.

Desired Professional Experience:
Our ideal candidates will possess:

- Extensive knowledge of the therapeutic areas and associated guidance documents.
- Excellent leadership skills, capable of providing guidance to non-clinical review staff and input across OND and to other internal and external stakeholders.
- Excellent collaborative skills, capable of working with a wide range of individuals of all levels from both public and private organizations, including the Center, Office of the Commissioner, other FDA Centers, other Federal agencies, and Congress, as well as the scientific/medical community, academia, and industry, which requires tact, diplomacy and technical expertise in communicating Center/Agency policies.
- Excellent verbal and written communication skills in order to develop policy, guidance(s) to industry, internal procedures, Center-level responses to congressional inquiries, etc.
- Excellent skills in critical thinking and strategic vision, to advance OND's policies, research agenda, training, and collaboration across other divisions, offices and stakeholders.
- Solid understanding of the regulations and polices as well as experimental design, theories and practices utilized in new drug evaluation.

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.

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 a resume or curriculum vitae with cover letter by **October 13, 2023,** to Danielle Harris at Danielle.Harris1@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference source code: **OND-OII-DRTM-3477** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Danielle Harris at Danielle.Harris1@fda.hhs.gov.

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