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 the Center Director (OCD)
Professional Affairs and Stakeholder Engagement Staff (PASE)

Application Period: October 1, 2021-November 1, 2021

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: Staff Director

Series: AD-0601/0602

Location(s): Silver Spring, MD

Salary: (0601 series) Starting at $144,128, (0602 series) $195,000

Work Schedule: Full Time

Full Performance Band Level: Band E

Cures Band: Band E

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) 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. CDER is looking for leaders with a commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization.

The Director of the Professional Affairs Stakeholder and Engagement Staff (PASE) serves as the principle advisor to the Center Director and Deputy Center Director on all aspects of stakeholder engagement for patients and patient advocacy groups.

Duties/Responsibilities

Provides systematic and coordinated engagement with internal and external stakeholders to develop complementary, collaborative actions that improve medication use and increase awareness of regulatory activities. Operates as a senior level manager providing leadership, oversight and execution of CDER's stakeholder engagement activities implementing CDER's advocacy and stakeholder relations strategy regarding drug development and other CDER priorities to support FDA's mission.

Oversees the FDA's Safe Use Initiative responsible for reducing preventable harm from drugs by soliciting and funding projects that develop innovative methods to create, facilitate, and encourage research in the area of safe medication use. In this capacity, the Director leads an interdisciplinary team of professionals and oversees the Safe Use and Network of Experts programs for CDER. Manages the staff activities ensuring they effectively and efficiently collaborate, plan, and manage non-regulatory initiatives with the goal of providing a venue for external stakeholders to engage with the Center, improving the safe use of medications and reducing preventable harm from medication misuse and errors.

Creates high-value partnerships with key stakeholder groups and conducts outreach to the healthcare community, professional organizations, and patient safety and advocacy groups, to facilitate exchange of information and provide a forum for the voices of external stakeholders to be heard by Center staff. Cultivates partnerships to collect real-time information necessary to inform internal CDER decision making in the development, review, and regulation of medical products keeping senior leaders informed of program developments and status of engagement initiatives with external organizations.

Proactively monitors and identifies emerging trends to determine if there is information that could be useful to the Center related to the use of CDER-regulated products. Keeps abreast of critical and/or controversial developments in areas related to CDER strategic priorities, and shares relevant information with the Center.

Supervises contract execution of Broad Agency Agreements to support research aimed to reduce preventable harm from medication misuse and errors to support programs of the Office and the agency.

Oversees the CDER Network of Experts (NoE) program tool designed to quickly broaden staff exposure to scientific, clinical and medical viewpoints from sources outside of the federal government, especially in areas of emerging sciences. Leads and coordinates the efforts of the CDER NoE program for the Center, by forging collaborations between the Center and external stakeholders, executing signed agreements with external organizations, and providing CDER with access vetted network of organizations, including clinicians, scientists, pharmacists and engineers, who provide staff with supplemental knowledge and rapid access to up-to-date best practices with the mutual goal of having more innovative, safe, and effective medical products.

Serves as a liaison between CDER and outside entities (e.g. patient advocacy groups and health professional organizations.), concerning matters related to drug development and other relevant medical/patient care issues, of interest to the Center. Collaborates with Center officials to coordinate and prepare responses reflecting CDER's position.

Represents CDER and FDA on committees and contributes to, Department, Agency, and Center conferences on broad policy matters and complex issues related to drug development and regulation. Makes recommendations both national and international, concerning programs, policies, and the evaluation of activities within the PASE program. Receives requests from external groups for particular meetings or listening sessions and coordinates responses between the Center to participate or conduct engagement meetings.

Supervisory Responsibilities:

- Serves as first line supervisor.
- 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.
- Defines jobs, selects employees, and assigns work; defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends organization and employees work to senior management and other offices.
- Recommends employee promotions and recognition; approves leave; implements performance modifications and takes corrective actions as appropriate

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.

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: AD-0601

Candidates must meet education requirements of a 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 at the time the degree was obtained.

Education Requirement: AD-0602

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.

Candidates must meet education requirements in a scientific discipline and the Physician series 0602, directly related to the position being filled, in accordance with the Office of Personnel Management (OPM) qualification standards. For more information please see: OPM Occupational Series Qualification Requirements.

Licensure AD-602

For all grade levels and positions, 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:

- Proven ability in providing effective leadership and promoting maximum potential of a large organization with a multicultural workforce.
- Proven ability to conduct in-depth research and analysis to develop and implement stakeholder engagement strategy.
- Demonstrated previous senior leadership experience, strong interpersonal skills, and sound judgement.
- Ability to function within a regulatory environment and problem solve to meet challenging demands.
- Experience as a leader in a complex organization managing, planning, directing, and evaluating multidisciplinary activities of significant scope and effect.
- Demonstrated ability to build strong working relationships among external organizations with diverse interests and/or opinions, such as, professional, public health, patient safety or patient/consumer organizations, and other federal agencies.,
- Ability to establish an organizational vision and to implement it in a continuously changing environment.
- Ability to provide an inclusive workplace that fosters the development of others, facilitates cooperation and teamwork, and supports constructive resolution of conflicts.
- Facilitates relationships in a manner that motivates others to maximize their abilities, skills, and knowledge to affect the desired outcomes.
- Ability to identify strategic objectives in support of the organizational mission and lead staff towards reaching established goals. Project management experience within a health or regulatory organization is a plus.

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 resume or curriculum vitae with cover letter by **November 1, 2021** to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring officials 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 Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov. Please reference Job Reference ID: S-21-478-E.

Announcement Contact

For questions regarding this Cures position, please contact Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov.

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