



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)
Immediate Office (IO)

Application Period: September 6th, 2021- October 4th, 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: Associate Director for Counter-Terrorism and Emergency Preparedness (CTEP) **Series:** AD-0602, AD-0601

Location(s): Silver Spring, MD **Salary:** Starting at \$199,213 (0601)
\$235,000 (0602)

Work Schedule: Full Time

Cures Band(s): Band G **Full Performance Band Level:** Band G

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

organization.

The Associate Director for Counter-Terrorism and Emergency Preparedness (CTEP), provides oversight, direction, and supervision to the Counter-Terrorism and Emergency Coordination Staff (CTECS) which includes a staff of scientists, physicians, and program managers. CTECS is responsible for collaborating with sponsors to develop countermeasures against chemical, biological, radiological and nuclear (CBRN) threats prior to the pre-Investigational New Drug Application (IND) stage. In addition, CTECS is the FDA point of contact for the Strategic National Stockpile (SNS) which is maintained by the Centers for Disease Control and Prevention (CDC). CTECS is also responsible for coordinating emergency preparedness and response for CDER. The incumbent is responsible for the management of scientific, regulatory and policy drug development initiatives relating to medical countermeasures, and coordination of emergency activities involving CDER regulated products

Duties/Responsibilities

Incumbent serves as an advisor and technical expert to the Center and Deputy Center Directors in making public health impact decisions on medical countermeasures (MCM) in the event of potential public health emergencies stemming from national and international threats. Responsible for policy formulation and planning, coordinating and implementing activities related to preparedness which includes work related to medical countermeasures for counter-terrorism as well as fostering advanced manufacturing processes, which ultimately contribute to national security and preparedness, to support CDER response readiness.

Oversees the management, coordination, and tracking of public health emergency issues, ensuring that the Center's response and/or handling of the issues are appropriate and timely, and to the extent anticipated. Oversees the management and implementation of the Preparedness program by performing substantive activities related to the planning, development, administration, tracking, execution, and coordination. More specifically, Identifies, initiates, coordinates, and participates in all issues regarding preparedness that require the development of policies and procedures. Assures that all essential issues are identified and resolved. Assures the appropriate people are involved in the development of these policies and procedures. Assures that appropriate time lines are developed and adhered to. Participates and contributes to Center-level and inter Center-level discussions and meetings on the formulation and development of policy. Oversees all CDER activities related to both domestic and international critical missions such as: the facilitation of the development of MCMs for CBRN threat agents and emerging infectious diseases; works with strategic stockpiles – the SNS under the Assistant Secretary for Preparedness and Response (ASPR) and states - for the availability of MCMs; and the preparedness and coordination of public health responses for emergencies related to CDER-regulated products and facilities.

Oversees the development and implementation of guidance and procedures related to MCM development under the Animal Rule (a regulation for the development and testing of drugs and biologicals in animals to reduce or prevent serious/life-threatening conditions caused by exposure to lethal or permanently disabling toxic agents, when human efficacy trials are not feasible or ethical), oversees collaboration with internal and external stakeholders surrounding expertise provided on the use of Animal Rule Emergency Use Authorization (a regulatory mechanism to facilitate the availability and use of investigational medical countermeasures, including vaccines, during certain public health emergencies), the Public Readiness and Emergency Preparedness Act (PREP) (which provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of

countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency).

Advises the Commissioner, Center Director, senior FDA and HHS officials, and others on matters involving the drug development initiatives relating to CBRN threats and military counter-terrorism measures. The incumbent is required to be an authoritative expert not only in preparedness but also on all areas of regulation and regulatory policy. Fosters and facilitates the special drug development issues relating to counterterrorism and force protection, such as animal models, and the development and labeling of drugs for CBRN threat agents that have an impact on policy development and execution and long-range programs goals.

Represents the Center, Agency, and Department on committees or at meetings and conferences related to drug development initiatives involving medical countermeasures, and coordination of emergency activities involving CDER-regulated products, both within and outside the government. Represents the Center on external committees, task forces, and working groups for the Preparedness program. Convenes meetings with professional organizations, industry, academia, and other groups, as needed to explore issues surrounding preparedness and develop plans to enhance the program.

Identifies significant weaknesses/problems in CDER's coordination activities related to emergency situations involving CDER-regulated products or facilities, the Animal Model Qualification Program (AMQP), emergency preparedness and response activities, advising the Deputy Center Director, or determining/initiating/taking corrective action independently.

Advises and interacts with the regulated industry, the clinical, scientific, and government agencies to communicate current CDER policy developments and to exchange information with various stakeholders.

Maintains at least a Top Secret (TS) national security clearance and assumes the responsibility and oversight for ensuring that CDER leadership receive and maintain clearances for access to classified documents and submissions; to maintain a secure email account and allows for the discussions with TS level colleagues in FDA, Health and Human Services (HHS), Department of Defence (DoD) and other federal agencies on MCMs and CBRN threats.

Supervisory Responsibilities: The Associate Director for CTEP serves as the second line supervisor for the staff in CTECS and directly supervises the Director of CTECS and any additional staff assigned within OCD. Provides overall leadership, direction and planning for all scientific, regulatory and policy drug development initiatives relating to the preparedness, coordination and response of MCMs, and coordination of emergency activities. Manages the Center's CTEC staff and program activities. Plans and sets long-range plans and schedules for the work of CTECS. Provides occupational-specific technical and administrative direction and supervision 25 percent or more of the time to subordinate supervisors and staff performing the work and functions of the organizational unit. Determines goals and objectives of CTECS, and the best approach and solution for resolving issues. Obtains resources and identifies strategic objectives for the organization and plans for long range budget, staffing, and other needs.

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-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

Education Requirement: AD-0601

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.

At a minimum, the candidate must possess a doctoral-level degree from an accredited institution of higher learning, including: Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academia as equivalent to a Ph.D.

Professional Experience:

- Experience formulating and establishing strategies and influencing strategy and policy relating to counter-terrorism and emergency response preparedness, compliance, enforcement, or import activities, both within the FDA and across the broader US landscape.
- Expert knowledge necessary to develop and implement practices/procedures and policies related to the FDA counterterrorism responses, including medical product development and response coordination.
- Proven ability in providing effective leadership and promoting maximum potential of a large organization with a multicultural workforce.
- Demonstrated previous senior leadership experience, strong interpersonal skills, and sound judgement.

Desired Professional Experience:

- An understanding of the medical specialty (infectious diseases) which will aid in consultative and development efforts of MCMs as well as emerging infections.
- Regulatory knowledge and experience acquired through a regulatory agency or through industry.
- Knowledge of agency-wide occupational safety and health program policies and procedures that address the wide range of hazardous and high-risk activities within the FDA.

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:

This position requires a *Top Secret* security clearance and the incumbent has access to documents related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of top secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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 **October 4th, 2021** to: CDER-OCD-OEP-Hires@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 Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov. Please reference Job Reference ID: E-21-626-G.

Announcement Contact

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

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

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