



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: May 06, 2022 - June 03, 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: Science Policy Advisor

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at:
\$126,233 (AD-0601)
\$176,294 (AD-0601)

Work Schedule: Full Time

*Starting salary is minimum of band and may be set higher, commensurate with experience.

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 mission of the Office of the Center Director (OCD) is to provide leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

Duties/Responsibilities

As a **Science Policy Advisor**, the incumbent acts as a public-health focused subject matter expert supporting the Associate Director for Controlled Substances on strategic controlled substances programs and policies, serves as a key liaison to Agency-level staff, other Federal agencies, industry, and academia on controlled substances issues, represents the Center on internal and external committees, task forces and working groups, and presents Center policies and procedures in public forums. Facilitates intra- and inter-agency interactions to develop and implement strategy and policies that require coordination and negotiations among stakeholders.

Proactively identifies and assesses emerging complex public health issues or problem areas with controlled substances, advises the Associate Director for Controlled Substances, and other senior management in the Center, including the Center Director, of these issues or problem areas and the need to formulate appropriate program responses to minimize risks associated with problematic use of controlled substances.

Provides analysis and advice on agency-wide programs or issues involving controlled substances and public health.

Pursues proactive stakeholder engagement to increase awareness among internal and external stakeholders of emerging issues with controlled substances and ongoing FDA initiatives and proactive policies, in coordination with strategic partners CDER OCOMM and PASE and with FDA professional staff from other Centers or Offices as necessary.

Serves as a project manager responsible for independently overseeing and influencing a high-level portfolio of initiatives, task forces, and program responses to address emerging issues involving problematic use of controlled substances or substances with potential for abuse.

Develops, recommends, coordinates, and implements program improvements and new procedures designed to enhance program performance on controlled substance activities

broadly throughout CDER.

Supervisory Responsibilities: N/A

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.

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:

Science Policy Advisor (General Medical and Healthcare), AD-0601 Series

Degree: A Bachelor's degree that focuses on the medical field, health sciences or allied sciences.

For more information, please see: [OPM Occupational Series Qualification Requirements](#).

Professional Experience:

Our ideal candidate will possess:

- Experience and leadership in programmatic drug safety and drug development activities.
- Experience in leading and overseeing initiatives or strategies in support of programmatic drug safety activities.
- Demonstrated previous senior leadership experience, and sound judgement.
- Ability to function within a regulatory environment and problem solve to meet challenging demands.
- Identifies the internal and external politics that impact the work of the organization. Perceives organizational and political reality and acts accordingly.
- Builds and manages workforce based on organizational goals, budget considerations, and staffing needs. Ensures that employees are appropriately recruited, selected, appraised, and rewarded; takes action to address performance problems. Manages a multi-sector workforce and a variety of work situations.

Desired Professional Experience:

- Mastery of a professional or administrative field to make decisions or recommendations significantly changing, interpreting, or developing important public policies or programs
- Knowledge of FDA regulations and laws, historical and legal precedents, regulations, guidelines, policies, and procedures for that may be relevant for controlled substances.
- Knowledge of data gathering methods and analytical/evaluative techniques to conduct assessments of health communication strategies and to draw valid conclusions.
- Understands and keeps up to date on local, national, and international policies and trends that affect the organization and shape stakeholders' views; is aware of the organization's impact on the external environment.
- Ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solutions; makes recommendations.
- Ability to lead people towards meeting the organization's vision, mission, and goals.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 **June 03, 2022**, to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact Karen D. Smith at Karend.Smith@fda.hhs.gov. **Please reference Job Reference ID: T-20-198-D.**

Announcement Contact

For questions regarding this Cures position, please contact Karen D. Smith, Management Officer, Karend.Smith@fda.hhs.gov.

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

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