



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Center Director(OCD)
Immediate Office(IO)

Application Period: March 7, 2024 - March 21, 2024

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 Analyst

Series: AD-0601

Location(s): Silver Spring, MD

Salary:

\$82,764-\$109,506 (Band A)

\$99,200-\$133,845 (Band B)

\$117,962-\$164,260 (Band C)

Work Schedule: Full Time

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

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 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 safe, and effective.

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 and prescription drugs, including biological therapeutics and generic drugs

The Office of the Center Director (OCD)(IO) provides 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 Analyst**, the incumbent works for the Controlled Substances Initiatives (CSI) team under the direction of the Supervisory General Health Scientist, providing technical expertise with developing and implementing activities related to controlled substances initiatives. The Science Policy Analyst will help enhance CDER's data-driven approach to combating the drug overdose and behavioral health crises.

Band A:

- Provides assistance with the planning, development, administration, execution, and coordination of CSI activities, initiatives, and policies related to substance use and behavioral health to equip FDA to respond to the intertwined overdose and behavioral health crises.
- Assists in the development of policy recommendations regarding current and/or emerging issues related to substance use and behavioral health and consistency with program implementation of regulations, Center policies, and precedents on substance use and behavioral health related to regulatory and health science programs.
- Gathers and synthesizes scientific information from subject matter experts, news articles, policy documents, and scientific literature in support of the development of policies and regulations related to the science of substance use and behavioral health.
- Supports the planning and implementation of projects and preparation of presentations for conferences and professional meetings related to emerging and/or current issues in substance use and behavioral health.
- Participates in meetings with key FDA and/or interagency stakeholders supporting public scientific workshops focused on topics like emerging trends in substance use and behavioral health.

Band B:

- Assists in the development of policy recommendations regarding current and/or emerging issues related to substance use and behavioral health and consistency with program implementation of regulations, Center policies, and precedents on behavioral health and substance use-related regulatory and health science program.
- Participates in consultations with subject matter experts and other policy staff concerning ongoing and established scientific studies or other projects related to substance use and behavioral health; gathers and synthesizes scientific information from subject matter experts in support of the development of policies and regulations related to the science of substance use and behavioral health.
- Supports the planning and implementation of projects and preparation of presentations for conferences and professional meetings related to emerging and/or current issues in substance use and behavioral health.
- Participates on special projects that may involve problems that require detailed understanding of Agency's public health policy and knowledge of regulatory science.

Band C:

- Leads meetings with key FDA stakeholders and/or interagency stakeholders to understand real-world experiences with substance use to inform regulatory decisions related to substance use and behavioral health.
- Conducts controlled substances-related policy analysis and monitors news articles, research publications, and social media sources to develop landscape analyses that inform program development.
- Plans, develops, administration, executes, and coordinates Controlled Substance Initiatives activities, initiatives, and policies regarding current and/or emerging issues related to substance use and behavioral health.
- Recommends policies and participates in the development of policy recommendations regarding current and/or emerging issues related to substance use and behavioral health and consistency with program implementation of regulations, Center policies, and precedents on behavioral health and substance use-related regulatory and health science programs.

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 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:

General Medical and Healthcare Series-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.

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

Position Desired Skills, Experience, or Education:

Our ideal candidate would possess:

- Mastery in identifying problems, gathering, and analyzing information, drawing conclusions, recommending solutions, preparing reports and options, and developing presentations is required.
- Ability to distill large amounts of information into specific takeaways.
- Possession of at least two years of experience in a regulatory or clinical research environment; this may include experience gained during doctoral work.
- Excellent proactive project management and problem-solving skills.
- Skill in effective/efficient meeting management.
- Strong analytical and communications skills, both oral and written.
- Knowledge of computer applications, including expertise using Microsoft Office Suite and the ability to use computer databases to conduct literature searches.
- Excellent interpersonal, analytical, organizational, and time management skills.

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

How to Apply: Submit resume or curriculum vitae with cover letter by **March 21, 2024** 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”.

Please reference **Job Reference ID: T-23-1143-Band A, B or C** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Karen Cox, Administrative Officer, CDER-OCD-OEP-Hires@fda.hhs.gov

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

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