



Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Medical Policy (OMP)
Immediate Office (IO)

Application Period: October 30, 2023 - November 10, 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: Senior Regulatory Health Project Manager **Series:** AD-0601

Location(s): Silver Spring, MD **Salary:** Starting at \$132,368

Work Schedule: Full-Time (Telework Eligible)

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

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 and prescription drugs, including biological therapeutics and generic drugs.

The Office of Medical Policy (OMP) is responsible for directing medical policy programs and strategic initiatives, including regulation of prescription drug promotion and advertising, through the Office of Prescription Drug Promotion, for providing leadership and scientific advice in clinical trial design, and for providing consultation and direction in policy issues related to human subject protection and good clinical practices. OMP is responsible for developing regulation, guidance documents, and procedures related to medical policy issues.

The immediate office (IO) directs the overall office to focus on high-priority policy development needs. It also leads high-profile/high-visibility initiatives, such as the real-world evidence program and clinical methodology tracks, as well as cutting edge issues including, but not limited to the incorporation of technological advances in drug development.

Duties/Responsibilities

As a **Senior Regulatory Health Project Manager**, the incumbent coordinates high-profile strategic initiatives and medical policy programs and projects primarily led by the Super Office Director, Deputy Super Office Director, or Associate Director(s).

- Serves as a regulatory-policy liaison to coordinate engagement on public health initiatives and facilitates communication on strategic policy issues.
- Interacts daily with other FDA regulatory health project managers, scientific reviewers, and Agency leaders including Center Directors, Deputy Center Directors, and Super Office Directors.
- Coordinates the development of materials that address overarching policy issues and strategic
- Initiates correspondence regarding actions, policy issues, or requests for additional information.
- Identifies project activities or situations that may adversely impact project plans; advises supervisors, team members, and OMP senior leadership of potential impact; and recommends solutions to problem areas.
- Facilitates timely completion of assigned projects and evaluates the progress of activities to assure timely solution of scientific and regulatory conflicts or problems to avoid delays achieving project goals.
- Applies extensive knowledge of FDA and CDER policies and procedures to resolve inconsistencies and make recommendations on strategic initiatives.
- Coordinates activities related to specific drug application reviews, including determining how much progress is being made and if any problems are surfacing.

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.

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, AD-0601 Series

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

Desired Education: Our ideal candidate will possess an advanced degree in public health, or another related field is preferred.

Desired Professional Experience:

Our ideal candidate would possess:

- Ability to apply professional knowledge and understanding of current FDA and Center regulations, medical and regulatory policies, and procedures pertaining to safe and effective drugs and biologics.

- Ability to apply knowledge and understanding of federal laws, scientific research methods, and regulations and FDA policies and procedures related to acquisition and procurement management.
- Demonstrated ability to independently manage and lead a diverse interdisciplinary staff towards a common goal.
- Experience utilizing skill in written and verbal communication, including expressing a thorough understanding of the regulatory and scientific contexts.
- Ability to communicate effectively with staff at different levels of the organization who have varying levels of domain expertise.
- Demonstrated ability to identify and analyze complex problems as well as evaluate possible solutions.

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/Moderate Risk

A background security investigation will be required for all appointees. Appointment will be subject to applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the 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 qualifications 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 with cover letter by **November 10, 2023**, to: lisa.champion@fda.hhs.gov and CC: debbie.begosh@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research 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-40-2-RHPM.24** in email subject line.

How I Will Be Evaluated

Candidates may be evaluated based on their cover letters and resume or curriculum vitae. Additionally, candidates may be evaluated on interview(s), review of requested work samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact Lisa Champion, Administrative Officer lisa.champion@fda.hhs.gov and CC: Debbie Begosh, Senior Management Officer (SMO) debbie.begosh@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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