**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 Surveillance and Epidemiology (OSE)**
**Office of Medication Error Prevention and Risk Management (OMEPRM)**

**Application Period:** September 10, 2024 – September 24, 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:** Deputy Office Director

**Series:** AD - 0601

**Location(s):** Silver Spring, MD

**Salary:** Starting at $181,551

**Work Schedule:** Full Time

**Title 21 Pay Table & Band:** Band F

**Full Performance Band Level:** Band F

**Travel Requirements:** Up to 25%

**Bargaining Unit:** This is a non-bargaining unit position (8888)

**Relocation Expenses Reimbursement:** Will not be paid

**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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Medication Error Prevention and Risk Management (OMEPRM) is to increase the safe use of drug products and improve public health by minimizing use error related to the naming, labeling, packaging, or design of drug products; and developing effective and efficient Risk Evaluation and Mitigation Strategies (REMS) for certain drug products that ensure the benefits outweigh its risks. OMEPRM is responsible for the post-marketing evaluation of adverse event reports and industry safety submissions that pertain to medication errors, and provides medication error risk assessment support (including review of proposed proprietary names, non-proprietary name suffixes, container labels and carton labeling, and potentially error prone aspects of product design) to enhance the safety of medical products. In conjunction with the Office of New Drugs, OMEPRM is responsible for evaluating the need for, and review, of all proposed Risk Evaluation and Mitigation Strategies (REMS) and REMS modifications; OMEPRM evaluates proposed REMS assessment methodologies and reports of the performance of the REMS in meeting its risk mitigation goals for all products with approved REMS.

As the Deputy Office Director, the incumbent supports the Office Director by providing leadership and direction to the OMEPRM Immediate Office and four subordinate Divisions: Medication Error Prevention and Analysis I and II, Risk Management, and Mitigation Assessment and Medication Error Surveillance.

## Duties/Responsibilities

As the **Deputy Office Director,** the incumbent is expected to provide regulatory and technical direction; oversight to programs and operations; and develop policy and strategic goals for the Office. Specific duties include the following:

• Provides technical and administrative direction in the development and implementation of complex regulatory matters relating to medication error prevention and analysis, including issues involving product design, labels, labeling, packaging and human factors assessment, and risk mitigation, including REMS and REMS assessments.

• Assists the Office Director in managing a diverse professional staff which conceives and develops scientific methods, in conjunction with other CDER offices, to measure, evaluate, and provide continuous surveillance of marketed drugs, particularly medication error reports, and implements the provisions of the Federal Food, Drug, and Cosmetic Act concerning REMS.

• Oversees the establishment of policy and program objectives for OMEPRM review divisions.

• Supports the Office Director in providing the OSE Director with authoritative information on the status of ongoing Office-wide work and issues and advises on appropriate actions.

• Reviews, evaluates, and researches needs and regulatory requirements on a continuing basis for program adjustments and cost efficacy to meet the Center's mission, needs, and priorities.

• Serves as scientific advisor and consultant to the Office Director, OSE Director, the Center Director, and/or higher-level Agency officials on functions, programs, and problems of functional areas covered by OMEPRM.

• Represents the Center and FDA on committees and at professional meetings, both national and international. Makes suggestions and recommendations concerning programs, policies, and evaluation of activities, as well as commitments within areas of responsibility. Supports the Office Director in preparing briefing materials and testimony that are presented by CDER Center Director and/or the Commissioner to Congress. Presents information regarding OMEPRM programs to the OSE Director, CDER Center Director, the Commissioner, and outside bodies (e.g., academic bodies; trade groups representing regulated industry) as needed.

**Supervisory Responsibilities**: Provides occupational-specific technical and administrative direction and supervision 25% or more of the time to subordinate supervisors and/or staff performing the work and functions of the organizational unit. Provides authoritative and professional expertise in health sciences, including medication error prevention and risk management related to the regulation of drugs and therapeutic biological products. Obtains resources and identifies strategic objectives for the organization.

## 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: 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's Desired Skills, Experience, or Education:**
• Demonstrated skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods of pharmacy and/or drug regulatory process sufficient to serve as expert to resolve difficult problems and issues, as well as plan, design, monitor, and evaluate complex projects.
• Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals. Demonstrated skills in building and maintaining relationships with disparate stakeholders; and ability to work with staff at all levels of the organization and varying levels of domain expertise.
• Demonstrated ability to identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.
• Demonstrated experience managing, planning, organizing, monitoring, and providing expert advice and leadership on regulatory program segments, functions, and activities to a highly trained and skilled staff of health professionals, scientists, and/or multi-disciplinary professionals in a regulatory program.
• Experience managing teams and/or large projects.
• Successful experience in organizational change management.
• Demonstrated knowledge of the Food and Drug Administration Amendments Act, regulations, policies, and procedures related to the regulation and evaluation of drugs and biologic products.

## 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 September 24**,** 2024, to: OSE-PMAS-Admin-Team@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: **Job ID: OSE-OMEPRM-0924-DDIR**

## Announcement Contact

For questions regarding this Cures position, please contact OSE-PMAS-Admin-Team@FDA.HHS.gov.

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*FDA is an equal opportunity employer.*