**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 Translational Sciences (OTS)**
**Immediate Office (IO)**

**Application Period:** June 14, 2023 – June 28, 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:** Deputy Super Office Director for Science

**Series:** AD-0601

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

**Salary:** Starting at $177,123

**Work Schedule:** Full-Time

**Cures Band(s):** Band F

**Full Performance Band Level:** Band F

**Travel Requirements:** 25% or less

**Bargaining Unit:** 8888

**Relocation Expenses Reimbursement:** Relocation expenses 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) 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 and prescription drugs,

including biological therapeutics and generic drugs.

The mission of the Office of Translational Sciences (OTS) is to empower a diverse, collaborative, and high performing workforce to champion innovation and advance global human drug development.

## Duties/Responsibilities

As **Deputy Super Office Director for Science**, the incumbent is responsible for management review of short- and long-range plans and programming generated at the Staff level related to broad regulatory science responsibilities; and is assigned specific authority on an ongoing basis.

- Participates in overall management of the Office with emphasis on science matters and administration of science and research programs.
- Supervises OTS staff within the Immediate Office (OTSIO) engaged in science and research activities, overseeing all projects, and coordinating efforts across CDER offices, with other FDA Centers and with the Office of the Commissioner.
- Oversees development of quality management systems and supporting tools for processes related to scientific prioritization, oversight, review, and reporting.
- Leads planning and reporting on Regulatory Science required under the FDA Science and Innovation Act (FDASIA), section 1124.
- Oversees the management of CDER science governance committees.
- Leads the development and implementation of major CDER initiatives to identify science needs, set science priorities, develop tools to track and report on science projects, review the quality and outcomes of CDER science programs, and manage competitive intramural funding programs, including Critical Path, Regulatory Science and Review Enhancement (RSR).
- Advises on the formulation of policy directives that form the framework for management of OTS and CDER science programs.
- Represents the Super Office Director on committees and working groups at Center and higher levels on scientific research matters of major significance to the Agency.
- Represents FDA at meetings of medical, scientific, and professional groups and consortia within and outside the Federal government regarding science, research, policies, and evaluation of activities within his or her areas of responsibility.
- Represents the Super Office Director on senior CDER governance and scientific committees, ensuring that office interests are clearly represented, and important outcomes are communicated to the Super Office Director and OTS senior leadership.
- Represents CDER on senior agency science policy committees, including the Science and Innovation Strategic Advisory Council, the Research Involving Human Subjects Committee and the Cooperative Research and Development Agreement Review Board.
- Ensures that CDER Senior Leadership and members of the CDER science committees are apprised of science initiatives within the Office of the Commissioner.
- Acts as the CDER Liaison to the FDA Research Involving Human Subjects Committee.
- Provides oversight for all CDER research involving human subjects and is accountable to

the CDER Director for ensuring compliance with all relevant federal regulations and FDA policies governing human subject research.

- Responds for the Super Office Director to inquiries from other Offices, Centers (e.g., Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Research (CBER), and etc.), Office of the Chief Scientist, Congress, and external stakeholders (e.g., pharmaceutical industry, etc.) about CDER's science and research programs and projects.
- Reviews and evaluates proposed position papers reflecting the official viewpoint of OTS on science and research program matters.
- Provides recommendations and decisions on particularly complex issues including research related to drug development, drug safety and drug manufacturing, as well as policies related to effective implementation of scientific research programs both within FDA (e.g., Immediate Office, Office of Biostatistics, Office of Clinical Pharmacology, Office of Study Integrity and Surveillance, and Office of Computational Science) and in collaboration with other federal agencies (e.g., National Institute of Health (NIH), Agency for Healthcare Research and Quality (AHRQ) and etc.), academia, and the pharmaceutical industry.

**Supervisory Responsibilities:** Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate employees (including supervisors and team leads, if required). Provides leadership to a group of employees performing the work and functions of the organizational unit, including scientific, professional, technical, administrative, and clerical support personnel (ranging in levels from senior management to entry levels).

## 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 Requirements:**
**General Medical and Healthcare Series, AD-0601**

Degree: A 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.

**Desired Professional Experience:**
Our ideal candidate will possess:

- Doctoral-level degree from an accredited institution of higher learning, including Ph.D., MD., DVM., DDS., D.MD, Sc.D. or other research doctoral degree widely recognized in U.S. academe as equivalent to a Ph.D.
- Skilled in collaborating with internal and external stakeholders.
- Possession of a scientific background in translational science with strong fundamental understanding of drug regulatory review processes in the areas of clinical pharmacology, biostatistics. computational science and inspectional review practices.
- Ability to function within a regulatory environment and problem solve to make challenging demands.
- Ability to apply understanding of Federal Regulations related to the work of CDER.

- Experience serving in a leadership capacity. Prior senior leadership experience. Demonstrated ability to provide leadership and promote maximum potential of a diverse staff.

## 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 level

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 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

Applicants should submit a letter of interest (cover letter) and current resume by **June 28, 2023,** to: CDEROTSHires@fda.hhs.gov. Please adhere to the following submission protocol:

- Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name.
- Reference **'OTS IO Deputy Super Office Director for Science'** in the subject line of the email.

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".

## Announcement Contact

For questions regarding this Cures position, please contact CDEROTSHires@fda.hhs.gov.

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*FDA is an equal opportunity employer.*