



**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 Compliance (OC)**

**Application Period:** October 18, 2022 – November 4, 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:** Physician

**Series:** AD-0602

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

**Salary:** Starting at \$165,000

**Work Schedule:** Full Time

**Cures Band(s):** Band C

**Full Performance Band Level:** Band C

**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 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 CDER Office of Compliance (OC) is to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. CDER OC strives to be a model of efficiency, innovation, and operational excellence. Guided by law and science, the Office makes strategic and risk-based decisions, communicates clearly with all stakeholders, fosters global collaboration, promotes voluntary compliance, and takes decisive action.

The mission of the Office of Scientific Investigations (OSI) within the Office of Compliance (OC) is to ensure CDER-regulated products are safe and effective for the life of the product, through oversight and enforcement activities involving: the reliability of safety and efficacy data submitted to FDA, the application of human subject protections in clinical trials, and compliance with the laws and regulations governing research, adverse event reporting, Risk Evaluation and Mitigation Strategies, and Postmarketing Requirements.

## Duties/Responsibilities

As a **Physician**, the incumbent serves as a physician reviewer on an assigned team and reports to the Branch Chief of the Good Clinical Practice Assessment Branch within OSI's Division of Clinical Compliance Evaluation (DCCE).

- Designs, operates, directs, and participates in inspections in collaboration with the Office of Regulatory Affairs (ORA) to verify the quality, data integrity, and protection of human subjects (rights, safety, and welfare) in clinical trials of safety and efficacy. Provides study data acceptability recommendations to the Center for Drug Evaluation and Research, Office of New Drugs (OND).
- Serves as a resource in medical and scientific matters related to the assessment of data reliability and protection of human subjects (rights, safety, and welfare) in clinical trials. Provides subject matter expertise for a wide variety of pre-market compliance programs.
- Reviews and evaluates industry's compliance with investigational new drug (IND) regulations, new drug application (NDA) and biological licensing application (BLA) regulations for the protection of human research participants and the accuracy and reliability of marketing data submitted to FDA as governed by the Compliance Program Guidance Manuals.
- Investigates allegations of GCP noncompliance related to the conduct of clinical trials. Directs inspections of clinical investigators, sponsors, monitors and contract research organizations using a risk-based approach. Participates in inspections as subject matter expert, as needed, for example, in clinical trials with complex trial designs or data management plans, or specific data integrity concerns.
- Evaluates inspectional reports to assess data integrity and the adequacy of human subject protections, evaluates the potential impact of inspectional findings on the effectiveness and safety findings of a medical product.

- Provides Good Clinical Practice (GCP) compliance recommendations to OND on the conduct of the clinical trial(s) and reliability of the data submitted in an NDA, BLA, or a supplement.
- Participates on internal and external working groups, scientific symposia, and public workshops. Maintains skills through continuing education and professional development, by literature research and writings, and by staying abreast of the state-of-the-art technologies and emerging scientific advances.

**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:**

**Physician, AD-0602 Series**

Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

**Licensure:** Applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

**Professional Experience:** N/A

**Desired Professional Experience:**

Priority will be placed on candidates who possess:

- Knowledge of the Food, Drug and Cosmetic (FD&C) Act and related regulations applicable to human drugs that are administered by the FDA.
- Experience in clinical and scientific regulatory reviews.
- Ability to converse with stakeholders in associated scientific, clinical, and technical fields.
- Knowledge of regulatory compliance involving Good Clinical Practice. Some knowledge of FDA’s Bioresearch Monitoring program.

## 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: 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

How to Apply: Submit resume or curriculum vitae (**note: resume/curriculum vitae must include MM/YYYY for each position**) with cover letter by **November 4, 2022**, to: [CDEROC\\_recruit@fda.hhs.gov](mailto:CDEROC_recruit@fda.hhs.gov). Please mention **“Physician for OSI”** upon submission. Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. For questions, please contact the [CDEROC\\_recruit@fda.hhs.gov](mailto:CDEROC_recruit@fda.hhs.gov).

## Announcement Contact

For questions regarding this Cures position, please contact [CDEROC\\_recruit@fda.hhs.gov](mailto:CDEROC_recruit@fda.hhs.gov).

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

*FDA is an equal opportunity employer.*

