



**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 Translational Sciences (OTS)**

**Application Period:** December 14, 2022 – December 28, 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:** Computer Scientist

**Series:** AD-1550

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

**Salary:** Starting at \$106,823

**Work Schedule:** Full-Time

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

**Full Performance Band Level:** Band C

**Travel Requirements:** None

**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 FDA's 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 a **Computer Scientist**, the incumbent provides mission-critical informatics initiatives in support of OTS's regulatory operations by assisting in the development of software systems that form the basis of the modern computing environment for management activities which support the scientific review of human drugs and therapeutic biologics.

- Serve as a member of a multi-disciplinary team that designs, develops and/or modifies existing software to address scientific computing problems. Participate in establishing system design and characteristics to meet user requirements. Participate with team to complete phases of projects by developing subsystems or components. Participate in the design and monitoring of the execution of software testing and implementation plans; and conducts postimplementation evaluations of systems in the areas of graphics and distributed file systems. Prepare software documentation, technical reports, and presentations related to assigned projects.
- Apply scientific computing techniques to computationally intensive tasks that are encountered in regulatory and scientific applications. These activities may involve graphics, prototype database development, modeling and simulation, and data display and presentation.
- Establishes the functional requirements through discussion with customers and observations of their methods and business processes and investigates software architectures and development of methods to improve software reusability and portability.
- Develop design strategy for major systems, anticipating changing workloads and program directions. Develop timetables and coordination controls to ensure the integrity of the system design and the phases of its implementation. Develop recommendations to change system requirements to meet the needs of multiple users and/or alternatives for consideration when problems arise.
- Develop program specifications which set forth parameters such as inputs and outputs, decision rules, hierarchical structure, interface plans, file layout, control requirements, processing and timing requirements, test plans, and program interrelationships.
- Monitor the data integrity and security of the database, supporting backup and recovery procedures.
- Conduct computer analysis and in-depth investigations to identify the most feasible approaches to hardware/software/networking system design and development problems.
- As a technical and subject matter expert, designs, develops and/or modify existing software to help solve routine, novel, and difficult computing problems.
- Analyzes business and IT challenges in regulatory operations and designs a comprehensive solution that integrates effectively into the computing environment.

- Initiates and evaluates the provision of critical technical support and collaborates closely with peers, scientists, and engineers (including the CDER community) to solve complex computing problems for one or more diversified and complex workstreams.
- Establishes the functional requirements through discussion with customers and observations of their methods and business processes and investigates software architectures and development of methods to improve software reusability and portability.
- Independently applies advanced methods and tools in project management, change management, and operations management, providing Information Technology (IT) project management support for complex technical projects through planning, organizing, and implementation. This includes coordinating complex production releases and rollouts.
- Applies expert knowledge of advances in IT industry to advise on technical trends and techniques used to improve the development of solution design.
- Participates and attends symposia relates to the application of software development and computer technologies and reviews other research and development efforts to keep abreast of innovative computing developments.

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:**

[Computer Science Series 1550 Basic Requirements](#)

**Desired Professional Experience:**

Our ideal candidate should possess:

- Ability to apply advanced computer science principles, concepts, methods, standards, and practices, information theory, programming languages operating systems, modeling, computer systems architecture sufficient to develop and interpret policies, procedures, and strategies governing the planning and delivery of services.
- Knowledge of computer science concepts, principles, laws, programs, and precedents sufficient to develop, propose, and recommend substantial developmental and/or program innovations, significant program changes, and alternate courses of critical management action. Ability to apply the most current technical advances and research findings in the public health informatics field to resolve statistical and/or data management issues.
- Knowledge in computer hardware and software resources with awareness of current developments in the LAN/WAN, Client/Server, and informatics field to provide assistance in the selection of possible alternatives for new or emerging technologies.
- Experience in programming languages (e.g., Java and Perl). Mathematical and statistical software and libraries (e.g., Matlab, SAS and R) and interfacing
- Ability to assess and demonstrate the effectiveness of new concepts and ideas in the area of informatics and to evaluate technological trends and establish the more promising approaches for achieving highly significantly advancements in informatics.
- Experience and skill to apply the latest developments in the computer science field to scientific and regulatory data.
- Knowledge of written and oral communication techniques to serve as subject matter expert and present findings and deliver briefings, explain, and justify recommendations

used as the basis for management and budget decisions.

## 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 level investigation, and the incumbent has access to documents and facilities.

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 later.

## 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

Applicants should submit a letter of interest (cover letter) and current resume by December 28, 2022, to: [CDEROTSHires@fda.hhs.gov](mailto: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 Computer Scientist' 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](mailto:CDEROTSHires@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.*

