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 Strategic Programs (OSP)
Office of Business Informatics (OBI)

Application Period: January 19, 2024 - April 19, 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: Computer Scientist

Series: AD-1550

Location(s): Silver Springs, MD

Salary:
$82,764 - $109,506 (Band A)
$99,200 - $133,845 (Band B)
$117,962 - $164,260 (Band C)

Work Schedule: Full-Time

Cures Band(s): Band A/B/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 compensated 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of Strategic Programs (OSP) is responsible for quantitative and qualitative data analysis, program evaluation, business process modernization, decision support services to facilitate effective operations, consultation to Center Offices in developing strategic and operational plans for CDER, cross-center management and coordination of work on Center-wide governance and special initiatives, and the implementation of IT solutions to meet CDER's business needs. OSP provides essential expert support and enabling services for CDER to meet its mission objectives.

The Office of Business Informatics (OBI) supports CDER's regulatory decision-making by identifying, implementing, and managing CDER-wide informatic systems to meet business needs. OBI collaborates with CDER stakeholders to modernize and continually improve CDER's business operations with state-of-the-art tools to facilitate activities related analysis, management, performance tracking, and execution of the Center's regulatory commitments while continuing to protect public health. Additionally, OBI develops analytic approaches and conducts analyses for regulatory operations to inform CDER's strategy and policy position on emerging trends and streamline review operations.

This position is located in the Division of Business Management Services and Solutions (DBMSS), Office of Business Informatics (OBI).

Duties/Responsibilities

- As a **Computer Scientist,** the incumbent works to meet mission-critical informatics initiatives in support of CDER's regulatory operations by assisting in the development of software systems that form the basis of the modern computing environment for scientific review of human drugs and therapeutic biologics. Participates in the requirements analysis of architecture solutions and products for big data, research and scientific analysis that are aligned with industry best practices.
- Responsible for ensuring successful on-time delivery of informatics projects and effective planning for lifecycle maintenance to support Prescription Drug User Fee Amendments (PDUFA), Generic Drug User Fee Amendments (GDUFA), and Over-the-Counter Monograph User Fee Amendments (OMUFA) regulatory activities.

Band A

- Works with the supervisor or senior staff to design and deliver architecture solutions and software applications for research and scientific analysis that are aligned with the latest industry trends and standards for the implementation of electronic submissions, workflow management, and data analytics tools. Assists with the design and

implementation of analytics tools to facilitate the regulatory decision-making for pre-market review and post-market surveillance.

- Assists with technical support needs and collaborates closely with peers, scientists, and engineers (including the CDER community) to solve computing assigned problems.
- Works with senior computer scientist or senior specialists to identify and report on technical trends and techniques and apply them to the development of solution design.
- Assists with the provision of Information Technology (IT) project management support for technical projects by working with project leads to plan, organize, and implement technical projects.
- Assist project lead coordinate production releases and rollouts. Work with project lead to identify task to delegate contractors and collaborate with project lead to present on project's progress and results.

Band B

- Meets duties and responsibilities outlined in Band A above.
- Contributes to the design and delivery of architecture solutions and software applications for big data, research and scientific analysis that are aligned with the latest industry trends and standards for the implementation of electronic submissions, workflow management, and data analytics tools. Participates in the design and implementation of analytics tools to facilitate the regulatory decision-making for pre-market review and post-market surveillance.
- Provides technical support and collaborates closely with regulatory staff and software engineers to solve computing problems for easily solvable workstreams.
- Applies scientific computing techniques to computationally intensive tasks that are encountered in research and management applications.
- Collaborates with technical and subject matter expert, to design, develop and/or modify existing software to help solve routine, novel, and difficult scientific computing problems.
- Collaborates with technical and subject matter expert, provides Information Technology (IT) project management support for technical projects by planning, organizing, and implementing technical projects. Coordinate production releases and rollouts. Works with the supervisor on tasking the necessary contracting team and presenting on project's progress and results.

Band C

- Meets duties and responsibilities outlined in Band B above.
- Designs and delivers architecture solutions and software applications for big data, research and scientific analysis that are aligned with the latest industry trends and standards for the implementation of inbound management, information management, electronic submissions, workflow management, and data analytics tools. Coordinates the design and implementation of analytics tools to facilitate the regulatory decision-making for pre-market review and post-market surveillance.

- Analyzes business and IT challenges in regulatory operations and designs a comprehensive solution that integrates effectively into the scientific computing environment.
- Applies scientific computing techniques to computationally intensive tasks that are encountered in research and management applications.
- Designs, develops and/or modifies existing software to help solve routine, novel, and difficult scientific computing problems.
- Independently provides Information Technology (IT) project management for complex technical projects by planning, organizing, and implementing technical projects. Coordinate complex production releases and rollouts. Delegating Works with the supervisor to delegate multiple tasks to the necessary contractors and presenting on project's progress and results.

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:
Computer Scientist, AD-1550 Series
Degree: A bachelor's degree or higher in mathematics, statistics, computer science, data science, information systems, software engineering, or computer engineering. The degree must be from an accredited program or institution.
OR
Experience: Relevant work in designing, analyzing, or developing computer systems, may also include the application of mathematical and statistical sciences to computer system design and development.

Specialized Experience: N/A

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/Low Risk (A/B) or Medium Risk (C)

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

Submit resume with cover letter and transcripts by **April 19, 2024,** to: CDEROSPRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact CDER OSP Recruitment Team at CDEROSPRecruitment@fda.hhs.gov.

Please reference ***"Computer Scientist and OBI -DBMSS"*** in the subject-line when applying or submitting questions.

Announcement Contact

For questions regarding this Cures position, please contact CDEROSPRecruitment@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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