



Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Operations (ORO)
Immediate Office of the Director (IOD)

Application Period: May 7, 2024 – May 21, 2024

Area of Consideration: The Public

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: Information Technologist (Enterprise Architect)

Series: 2210

Work Schedule: Full Time

Salary: Starting at \$181,551

Telework Eligible: Yes – as determined by agency policy

Location: Remote Eligible position

Title 21 Band: F

Full Performance Band Level: F

Travel Requirements: 25% or less

Bargaining Unit: 8888

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 safe, and effective.

The Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The Office of Regulatory Operations (ORO) is responsible for managing the review process and associated activities used to support CBER in facilitating the regulation and review of biological products, drugs, devices, and combination products. These responsibilities include development and governance of regulatory business processes; data standards; regulatory data analysis; program evaluation; resource utilization; user fee management; electronic submission management; and special initiatives. ORO manages CBER's Information Technology (IT) investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

Duties/Responsibilities

The Information Technologist (Enterprise Architect) of the Office of Regulatory Operations (ORO) reports to the ORO Director. The Information Technologist (Enterprise Architect) develops and facilitates the implementation of a CBER enterprise informatics architecture as captured in associated roadmaps and other documents. The incumbent provides technical understanding of information technology to business staff, technical staff and others, to drive a CBER-wide enterprise architecture modernizing CBER's business, data and information technology. The Information Technologist (Enterprise Architect) understands business issues and needs and translates these into future state Enterprise Architecture solution. The incumbent designs a high-quality enterprise solution architecture that contributes to our IT strategic planning, IT systems and infrastructure design.

The Information Technologist (Enterprise Architect) develops and oversees the Centers enterprise architecture design strategies, models, projects and program. The incumbent supports IT modernization, by leading the effort to transform existing business capabilities contained in legacy IT systems to modern information technology solutions using an enterprise architecture approach. The Information Technologist (Enterprise Architect) leads enterprise architecture projects incorporating business processes, data management, and information technologies through the complete project life cycle.

Specifically, the Information Technologist (Enterprise Architect) will:

- Provide expert advice and guidance when technical interpretation, opinion, or decisions related to enterprise architecture and information management are solicited.
- Interpret and apply information contained within the IT architecture to inform a range of business improvement activities, particularly those involved in the design, development, enhancement, and maintenance of Center IT systems.
- Coordinate strategic activities of IT projects with appropriate contacts to ensure program operations are consistent and comply with goals and plans.
- Perform analyses on applying technologies to needed business capabilities, prepares reports or presentations outlining technical solution alternatives including risks, benefits, and costs with recommendations.
- Identify and align business, data sources and technical capabilities needed to support business capabilities and strategies.
- Create, maintain, and manage IT architecture models and their lower level components for current state and future state.
- Develop and maintain an enterprise architecture based on established EA frameworks.
- Create and manage enterprise architecture repositories using an industry recognized enterprise architecture tool such as Sparx Enterprise Architect, or Erwin EA.
- Serve as the Center liaison for industry, the Agency, the Department, and other Agencies on enterprise information management coordination.
- Monitor emerging enterprise architecture trends, and information technology trends and directions and make recommendations accordingly.
- Educate staff on the relationship between business, data, applications, and technology architectures.

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.
- 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 below Education/Experience Requirements 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/Experience Requirements:

A bachelor's degree or higher in a computer science, cybersecurity, information science, information systems management, technology, engineering field. The degree must be from an accredited program or institution.

OR

Experience requirements include at least one of the following:

- Experience that demonstrates knowledge of the software design, development, and testing lifecycle.
- Experience that demonstrates knowledge of enterprise architecture, business architecture, systems architecture, service-oriented architecture, or data architecture; or frameworks of the same.
- Experience that demonstrates knowledge of IT management, IT helpdesk support, system integration, IT project management, IT Finance or IT Acquisitions.
- Experience that demonstrates knowledge of managing IT transformation programs, managing IT innovation programs, or implementing disruptive technologies.
- Experience that demonstrates basic knowledge of technology and data processing functions, data extraction, transformation, loading, automation, and other aspects of data management.
- Demonstrated ability to meet the standards of a skills assessment test to be administered by the agency during the candidate process (i.e., preemployment).
- Experience that demonstrates knowledge of the user experience design, development, and testing lifecycle.

Experience may have been gained in work such as CIO/CTO/other IT executive, IT manager, IT services manager, enterprise transition manager/planner, enterprise architect, business analyst, systems integrator, systems administrator, programmer, program analyst, or other positions that required the management of, use, or adaptation of computer programs and systems.

Position's Desired Skills, Experience, or Education:

- Proven track record of developing enterprise architect solutions that achieve business goals.
- Proven track record in leading highly effective teams in strategic planning, enterprise and systems architectures and design/development of strategic business solutions.
- Mastery of Enterprise Architecture Frameworks, architecture repositories and architecture patterns; mastery of any architecture modelling tools specific to domain, personal productivity tools.
- Enterprise architecture certifications; business and requirements management certifications.
- Mastery of systems and solutions architecture.
- Knowledge of data architecture approaches (e.g., TOGAF), industry standards, and best practices (e.g., DMBOK).
- Strong working knowledge of regulatory business at a process level, where applicable, e.g., application architecture.
- Strong collaboration skills, effectively working closely with data and software architects, business analysts and project teams, and business stakeholders.
- Ability to effectively explain technical topics in non-technical terms; ability to effectively communicate and collaborate with stakeholders at all levels of the organization.
- Demonstrates deep analytical skills recognizing organization strategy, business process and technology specifics.

- Experience in managing organizational change.
- Demonstrates successful project and resource management experience focused on business results and demonstrated understanding of how to achieve them according to given timeframes and resources.
- Demonstrates leadership and influence skills across organizational levels and functions.
- Strong negotiating skills.
- Strong organizational skills.
- Excellent communication skills, both oral and written.

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: 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.

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

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

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

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), latest PMAP (if applicable), copy of unofficial transcript(s) and letter of interest with **“Title 21 CBER/ORO Information Technologist (Enterprise Architect)”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **May 21, 2024**.

Announcement Contact

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

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

FDA is an equal opportunity employer.

