



Title 21 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: July 24 – July 31, 2023

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: IT Specialist (Data Architect)

Series: 2210

Location(s): White Oak Campus, Silver Spring, MD

Salary: Starting at \$155,700

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band: Band E

Full Performance Band Level: Band E

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 IT Specialist (Data Architect)'s primary focus is to lead, review and approve the implementation and continuous evolution of an enterprise data architecture, governance, and knowledge management architecture. The Data Architect serves as the principal data expert with respect to CBER's data architecture and assists the ORO Office Director and other senior staff, in carrying out the diverse responsibilities related to Data Management to support science, regulatory review, and/or compliance mission of the Center. The incumbent ensures that data architecture and data management meet CBER's needs, follow best practices, and are high quality. The Data Architect will develop enterprise data architecture, participate in the solution design process, and oversee the development and implementation of CBER enterprise data solutions and technical architecture.

The Data Architect must effectively communicate with and understand the needs of stakeholders at all levels of an organizations. The Data Architect is a thought leader in existing and emerging methods to most effectively leverage data from many sources, both internal and external, and will facilitate CBER's and FDA's IT strategy and implementation roadmap(s) to achieve most effective data management and usability.

Specifically, the IT Specialist (Data Architect) will:

- Work with CBER staff and contractors to design, deploy and provide operational support for data solutions such as: data mesh, data warehouses, data marts, master data management, queries, reports, and business intelligence solutions and integration with processes and applications for CBER.
- Lead efforts to architect, develop, and document (e.g., data dictionaries, glossaries), data integration technologies (e.g., ETLs, stored procedures, materialized views), database schemas (e.g., logical, and physical), and interfaces (e.g., HL7/FHIR), ensuring fitness for purpose and adherence to architectural principles.
- Translate business requirements into actionable deliverables that reliably and accurately produce the data assets required for the business.
- Serve on CBER and FDA IT, and data committees related to technical design, architecture, and change management.
- Propose, review, approve, and develop database and information solutions to store and retrieve information, and to enable interoperability, exchange of information and sharing of data.
- Analyze the data structure requirements for new software and applications.
- Oversee the migration of data between legacy systems and new solutions.
- Collaborate to improve and optimize data system performance.
- Coordinate in and participate with IT governance to identify requirements and future needs.

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 [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.

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 Requirement:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: <https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series>

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](#).

Desired Skills:

- Certifications in database engineering, data architecture, systems engineering, data integration, and business intelligence or other related areas are preferred.
- Experience using industry standard tools to support data architecture, database design, ETL, interfaces, queries, and systems engineering.

Desired Professional Experience:

- Demonstrated experience as a data architect, data integration developer, and/or in a related technical field.
- Experience architecting information data systems including data-pipelines, application support and integration, interfaces/APIs, access, security, backup/recovery.
- Expert understanding and ability to design conceptual, logical, and physical data models using associated tools (e.g., ER-Studio, Erwin) to support enterprise data warehouse, data marts, master data management (MDM), interfaces/APIs, integration, and applications.
- Demonstrated experience leading and developing extract-transform-load tools (e.g., SSIS, Informatica) architectures, design methods and processes in both real-time and incremental load environments, and associated job scheduling.
- Familiarity with standardized terminologies, ontologies, and index (e.g., WHODrug, MedDRA, RxNorm, LOINC, CPT, ICD, SSA Death Index, CDC National Death Index, Address Doctor).
- Demonstrated experience with software development Life Cycle (SDLC) and associated quality, function, and performance testing processes and best practices.
- Experience establishing and maintaining enterprise data dictionaries, glossaries, and meta-data lineages.
- Experience with data matching, de-duplication, and merge methods and principles.
- Experience with designing and participating in data governance processes in large enterprises.

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), copy of unofficial transcript(s), SF50 (if applicable), latest PMAP (if applicable), and letter of interest with **"CURES CBER/ORO/IOD IT Specialist (Data Architect)"** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **July 31, 2023**.

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.

