



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)
Division of Informatics (DI)
Regulatory Information Branch (RIB)

Application Period: February 1, 2024 – February 15, 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: Business Informaticist (Data Integration)

Series: 0301

Location: Remote Eligible position

Salary: Starting at \$132,368 is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Title 21 Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 investments throughout their lifecycle to support and ensure CBER's review, scientific, and administrative needs are met.

Duties/Responsibilities

The incumbent serves as the Business Informaticist (Data Integration) for the Regulatory Information Branch (RIB) within the Division of Informatics (DI) under the Office of Regulatory Operations (ORO). This position reports to the RIB Branch Chief. The Business Informaticist is a critical part of the Center for Biologics Evaluation and Research (CBER) data team; responsible for design, development, and maintenance of Extract, Transform, Load (ETL) processes that ensure availability and accuracy of data for analytics and reporting. Personnel will collaborate with business users, Data Architect(s), Enterprise Architect, Information Technology Team(s), and other CBER stakeholders and data components in the delivery of quality solutions that will enable data-driven decision making across the Center.

Specifically, the Business Informaticist will:

- Design, develop, and maintain ETL processes to extract data from various sources, transform it into a usable format using enterprise platforms, and load into data warehouses or data lakes.
- Integrate and consolidate data from multiple sources utilizing data integration tools (e.g., Informatica, DataBricks, AWS Glue, AWS Kinesis, Redshift), ensuring consistency and accuracy of data.
- Identify and resolve performance issues within ETL processes to ensure efficient data extraction and transformation. The incumbent implements data quality checks and validation procedures to maintain data integrity.
- Create and maintain data models using available data modeling tools (e.g., Erwin, SPARX, Prolaborate).
- Create and maintain documentation of ETL processes and data/meta-data lineage.
- Understand and apply Master Data Management (MDM) concepts to data domains. Utilize skills in match-merge, text matching, ontologies, and standard terminology libraries/crosswalks to mature MDM activities.
- Collaborate with business users to understand data requirements and ensure ETL solutions meet business needs.
- Manage and make recommendations for improvement of the ETL framework to support scalability and sustainability. As well as resolves ETL-relates issues in a timely manner.

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 Title 21 (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 Title 21 appointments. The FDA OTS will use the basic requirements defined in the below Education/Graduate Training 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:

Education: A bachelor’s degree or higher in business administration or business analytics, computer science, systems engineering, information systems, operations management. The degree must be from an accredited program or institution.

OR

Experience: Comparable work in technical analysis, data analysis, analyzing and interpreting data, developing information systems that support the collection, sharing, standardization, or integration of program related data.

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](#).

Position’s Desired Skills, Experience, or Education:

- Education: A bachelor’s degree in computer science, Information Technology, or related field.
- Proven experience as an ETL Developer or similar role.
- Proficiency in ETL tools and technologies (e.g., Informatica, DataBricks, AWS Glue, AWS Kinesis, Redshift).
- Strong SQL and scripting skills for data manipulation and transformation.
- Experience with data modeling and warehousing concepts.
- Strong knowledge of data integration best practices and techniques.
- Strong analytical and problem-solving skills.
- Excellent communication and teamwork skills.
- Attention to detail with a commitment to data accuracy and quality.

Technical Skills:

- Ability to adapt to changing working conditions and work assignments, motivated to learn and adapt new ideas and concepts, and to work independently or as part of the team to work on multiple tasks.
- Capable of clear and sound reasoning, with a demonstrated ability to use sound judgement in practical matters.
- Ability to multi-task and provide deliverables within fixed timelines, as well as the ability to work well in a dynamic environment and meet overall objectives.
- Working knowledge of the principals of Systems/Software Development Life Cycle (SDLC).
- Demonstrates experience with fundamentals, principals, and processes related to change control for information systems.
- Working knowledge of basic analytics/statistical principles, and the ability to synthesize complex information into an easy-to-understand manner.
- Knowledge of business workflow and associated terminologies, and the ability to document them with industry standard tools such as Visio or PowerPoint.
- Creating and maintaining consistent reference data and integrate data from various homogenous and heterogeneous source system, including the creation and maintenance of data dictionaries, entity relationship diagrams, and business glossaries.
- Experience analyzing and testing enterprise data for quality and consistency and working with stakeholders to reconcile data issues across data repositories.
- Knowledge of project and system development methodologies (e.g., Waterfall, Agile) and the demonstrated ability to apply and adopt methodologies to align with project needs and drivers.
- Ability to maintain detailed project plans that include milestones, tasks, and target/actual dates of completion.

- Ability to create technical and business documentation including white papers, knowledgebase articles, system diagrams, workflow diagrams, and presentations.
- Experience with workflow analysis and process redesign to improve efficiency and performance.
- Demonstrates ability to develop metrics and reporting frameworks to measure efficiency and effectiveness, facilitate appropriate resource allocation, and increase the maturity of programs.

Communication Skills:

- Possess outstanding communication (written and verbal), listening and interpersonal skills; and able to quickly establish credibility and rapport with a board set of stakeholders.
- Proven track record of collaboration and relationship building across diverse teams.
- Ability to prepare and give presentations, and to communicate (written and verbal) complex technical content to technical and non-technical stakeholders.
- Ability to work with customers to conduct detailed requirements gathering and analyze information to translate customer objectives into a detailed technical implementation plan.

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), unofficial transcripts and letter of interest with **“CURES CBER/ORO/DI/RIB Business Informaticist (Data Integration)”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **February 15, 2024**.

Announcement Contact

For questions regarding this Title 21 (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.

