



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 Information Technology (DIT)
Technology Integration and Delivery Branch (TIDB)

Application Period: September 29, 2023 – October 8, 2023

Area of Consideration: FDA-Wide

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 Project Manager (Digital Transformation)

Series: 2210

Location: Remote Eligible position

Salary Range: \$132,368 - \$184,868

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy

Cures Band: Band D

Full Performance Band Level: Band D

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 incumbent serves as the IT Project Manager (Digital Transformation) for the Technology Integration and Delivery Branch (TIDB) within the Division of Information Technology (DIT) under the Office of Regulatory Operations (ORO). The IT Project Manager's primary focus is to lead, review and approve the implementation and continuous evolution of the enterprise modernized digital transformation, governance and knowledge management. This includes program management, development around CBER's digital transformation projects and tasks. The IT Project Manager oversees the technical development, integration, and application of new technologies, developing assessments, assessing architecture, and other technical duties. The incumbent manages integrated teams with oversight of technical approaches. This position reports to the TIDB Chief.

Specifically, the IT Project Manager (Digital Transformation) will:

- Work with CBER Staff and contractors to lead CBER's modernized digital transformation objectives in a DevSecOps environment.
- Work with CBER, FDA and IT leadership to develop the overall digital transformation strategy and specific plan(s) for the technical implementation and new technology initiatives leveraging CBER's established methodology and tools, and implementing new technologies and approaches.
- Support the creation and implementation of user acceptance/validation campaigns for initiatives including technical implementations, digital transformation, and emerging technologies.
- Inform executive leadership about concepts related to digital enablement and the ramifications of enabling cloud technology.
- Understand and recommend solutions that take key digital transformation requirements into account and manage the conversion of business needs into the corresponding technical requirements.
- Possess a full understanding of CBER's technical environment and how it integrates with the FDA Enterprise environment.
- Inform CBER leadership on technical developments and best practices that will affect CBER IT as the organization implements the digital solutions.
- Deliver technical solutions using Agile Systems Development Life-Cycle (SDLC) techniques to improve quality, allow for flexibility, and discover new growth possibilities.
- Connect digital transformation activities with security, data and business and ensure they adhere to the overall timeframe of CBER's strategic objectives and major milestones on an as needed basis.
- Manage the work plan for the digital transition, provide weekly status reports, locate problems, and identify and manage risks.
- Establish and maintain communication with key customer decision-makers and, as necessary, lead and coordinate action teams.
- Contribute to business development activities, such as client presentations, proposal creation, budget formulation, and Statements of Work

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.
- 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 Education/Experience Requirements below 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 and/or Experience Requirements:

2210 Series (Information Technologist)

Education: 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: 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 gency during the candidate process (i.e., pre-employment).
- 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.

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:

- Experience in facilitating IT modernization, the introduction of new IT systems into existing digital environments and integrating modern systems with legacy systems.
- Experience with selecting and using industry standard tools and processes to support IT modernization.
- Demonstrated Senior-level experience (10+ years) in IT systems design, engineering, and implementation.
- Possession of excellent verbal and written communication skills, including briefing executive personnel.
- Possession of excellent analytical, consultative and project management skills.
- Ability to interact and interface with all levels within the organization, including executive leadership.
- Ability to provide leadership, guidance, and mentorship to members of the program, project, and administrative teams.

Desired Professional Experience:

- Experience with IT systems management, including infrastructure, software, database management, and cloud migration, integration, and hosting.
- Experience architecting information systems including application support and integration, interfaces/APIs, data-pipelines, access, security, backup/recovery.
- Demonstrated experience with software development Life Cycle (SDLC) and associated quality, function, and performance testing processes and best practices.
- Experience with planning, establishing, and maintaining enterprise systems.
- Experience with managing multiple priorities, meeting deliverable timelines, and reporting on status of multiple

- workstreams.
- Knowledge of government contracting, and FDA regulated industry.
- Demonstrated experience as a systems integrator, developer, and/or in a related technical field.

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](#).

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), SF-50 (if applicable), latest PMAP (if applicable), and letter of interest with **"CURES CBER/ORO/DIT/TIDB IT Project Manager (Digital Transformation)"** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **October 8, 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.

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