



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)
Program Management and Analysis Branch (PMAB)

Application Period: 9/16/24 – 9/27/24

Area of Consideration: 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 (IT Project Manager)

Series: 2210

Location: Remote Eligible position

Salary: Starting at \$165,648

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band: Band D

Bargaining Unit: 3591

Travel Requirements: 25% or less

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.

ORO, DIT, Program Management & Analysis Branch (PMAB) is responsible for CBER activities regarding planning and evaluation of programs, functional activities, and resource utilization related to regulatory review and governance of regulatory, information technology (IT), data and other regulatory operations. ORO manages the CBER Managed Review Process, maps processes develop

guidance, regulations, standard operating procedures, job aids, and tools associated with the regulatory review process. Promotes and coordinates the development and management of regulatory data standards for review of regulatory submissions and represents CBER in several areas of national and international data standards formulation/implementation. DIT works with the CBER managers and staff in carrying out activities and projects related to meeting the Center's specific IT goals by providing a high level of support to CBER customers while effectively managing IT change. This position is at the GS-2210-14 full performance level.

Duties/Responsibilities

The incumbent serves in the Program Management & Analysis Branch (PMAB), Division of Information Technology (DIT) in ORO.

Specifically, the Information Technologist (IT Project Manager) will:

- Participate in oversight of CBER IT projects that encompass all aspects of Center operations and are intended to optimize and modernize the various CBER Regulatory Review legacy systems and reduce the number of systems a CBER Reviewer needs to use while providing more user-friendly IT tools.
- Leads in efforts to develop policies and procedures and implement process improvements to enhance the efficiency and effectiveness of DIT/PMAB operations.
- Participate in reviews and assessments throughout the PMAB with primary focus on the following areas: IT Program Management, contract management and oversight, IT contract creation and oversight, communications management, adherence to DIT standards, data oversight and planning, and Independent Verification and Validation (IV&V).
- Develop, recommend, coordinate, and implement PMAB program wide processes promote standardization, minimize risks and improve DIT work quality.
- Develop, Maintain, and revise the Quality Management Plan, Risk Management Plan, applicable documentation, and SOPs to incorporate process improvements and updates to the IT program and IT systems.
- Help manage IT project risk & issues.
- Review IT projects for consistency and adherence with the regulations and CBER IT procedures and standards.
- Support CBER IT Project Managers and stakeholders in planning and executing projects, during all phases of the HHS Enterprise Lifecycle Project management (EPLC).
- Verify that IT Project deliverables meet standard and help with remediations as necessary, as well as updating documents and templates to reflect identified process improvements.

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 later.

Professional Experience/Desirable Qualifications:

- Proven track record in working with Quality Management Plans for IT program and projects
- Proven track record in working with Risk Management Plans for IT program and projects
- Project Management certification

Other 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:

2210 Series (Information Technologist)

Education: A bachelor’s degree or higher in 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 IT program/project management.
- Experience that demonstrates knowledge of Quality Assurance and/or Independent Validation or Verification (IV&V) processes.
- 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.
- 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 Project Manager, Quality Assurance specialist, 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](#).

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.

Additional Information

If you are serving, or have served in the last 5 years (from 12/01/2023) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment. You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

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/DIT/PMAB Information Technologist (IT Project Manager)** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **9/27/24**.

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.

