



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)

Application Period: December 20, 2023 – January 17, 2024

Area of Consideration: 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 Program Manager (IT Specialist)

Series: 2210

Location(s): Remote Eligible

Salary: Salary is commensurate with Education and experience and starts at \$132,368.00

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position requires less than 25% of travel

Bargaining Unit: 3591

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 mission of the Center for Devices and Radiological Health ([CDRH](#)) is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. The [Office of Strategic Partnerships and Technology Innovation | FDA](#) (OST) provides leadership for all scientific collaborative and emerging technology related activities at CDRH. We represent

CDRH with a broad and diverse array of national and international entities including other government agencies, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations, with mutual interests in medical devices and radiation-emitting products.

Duties/Responsibilities

The incumbent applies new methods and approaches incorporating state-of-the-art theories and applications. Heads projects expanding emerging best practices and advances in technology with responsibility for gathering information, identifying, and analyzing issues, and making recommendations through development of detailed plans identifying goals, objectives, and milestones.

Manages resources that provide CDRH and its information technology (IT) partners with delivery and project support services to help CDRH implement, operate, and optimize current and future technology systems, processes, and procedures. Recommendations regularly involve impact assessments of how planned computer systems upgrades can best be incorporated into organizational and process design. Performs business and systems analysis to identify business opportunities, defining detailed technical and business process requirements, including adoption and implementation of current and emerging best practices and applicable technology. Identifies unprecedented alternative approaches expanding past practice. Defines, maintains, and manages system requirements, and maintains requirements traceability. Heads development of Level of Effort (LOE) estimates for requirements analysis work, participating in the planning for systems requirements development and artifacts completion often as a project technical authority. Uses advanced business analysis principles, concepts, methods, standards, and practices to develop business requirements and implement business processes leveraging a broad range of enterprise information technologies aimed at connecting data, workflow, and analytics.

Schedules, participates, and leads Requirements Review meetings. Identifies and clarifies requirements for other functional groups providing expert recommendations for establishing approach, goals, and methods that may include untried methods, incorporation of emerging changes to health science testing methods, or emerging best practices. Elicits requirements from project stakeholders serving as an expert resource providing options and alternatives for defining requirements and applying established and emerging technology and methods. Works closely with the various customers and the internal development teams to embrace change that can be suggested to the customer as well as validate requirements were met serving as an expert resource for addressing emerging and ongoing issues and problems providing options for incorporating new practices and techniques.

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

Qualified applies to all candidates for Cures appointments. The FDA OTS will use the Alternative Qualifications Standards below as a baseline for comparing experience levels and other candidate attributes for relevant positions.

- a. **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

- b. **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 agency 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 administration, programmer, program analyst, or other positions that required the management of, use, or adaptation of computer programs and systems.

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 above **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.

Desired Professional Experience:

- Expertise and skill in applying advanced IT systems principles, concepts, methods, standards, and practices to govern existing IT systems and identify potential needs and improvements in the way IT is applied to key business functions for the Center.
- Expert knowledge of working with both the information management systems and business processes
- Ability to develop workable solutions that meet user and organizational needs
- Strong analytic and problem-solving skills
- Able to communicate across all levels of the organization and work with diverse projects and teams.
- Ability and desire to regularly learn and adopt new technologies and methodologies into their work.

How to Apply

Submit resume or curriculum vitae, transcripts with cover letter, **in one (1) combined PDF document**, by **January 17, 2024**, to CDRHRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please include the following Job Reference ID in the subject line of your email submission: **CDRH/OST IT Program Manager PBM-3960**

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Officers must follow the instructions for how to apply and include their most recent orders in addition to the required documents. If selected, candidates will be referred to (CC) personnel and not as candidates for a Cures appointment.

Educational 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](#).

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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: This position requires a *Public Trust* security clearance.

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

Equal Employment Opportunity Policy

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

Reasonable Accommodation Policy

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.

Announcement Contact

For questions regarding this Cures position, please contact Mariela Mercedes at mariela.mercedes@fda.hhs.gov

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FDA is an equal opportunity employer.

