



**Information Technology Specialist
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of the Center Director (OCD)
Laboratory Quality Staff (LQS)**

Summary:

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) 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.

Overview

Area of Consideration: The Public
Open & Closing Date: August 9 – 23, 2024
Salary Range: \$117,962 - \$164,260
Band: C
Occupational Series: 2210
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band C
Supervisory Status: Non-supervisory
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

This position is located in the Laboratory Quality Staff (LQS), Office of the Center Director (OCD) in the Center for Biologics Evaluation and Research (CBER). The Information Technology (IT) Specialist will serve on or lead working groups, subcommittees, or review boards to approve and/or determine policies and procedures for IT initiatives.

Monitors and reports on the status and progress of work, checks on work in progress and reviews completed work to see that the stakeholder instructions on work priorities, methods, deadlines, and quality is met.

Serves as an IT Project Manager for various IT initiatives, managing IT projects to scope, and schedule, as well as risk and resource management. Communicates project plans, status, risks, issues and/or resource requirements to management and/or potential vendors, customers, and stakeholders. Develop ways to improve productivity and the quality of work. Plans work to be performed by team members, setting, and adjusting priorities and schedules for completion based on priorities set by the stakeholder. Negotiates with stakeholders and end-users on the details of work to be performed. Develop and maintain installation and configuration management policies and procedures. Contributes to and maintain database system standards.

Coordinates and communicates work products with impacted stakeholders as needed. Applies application version upgrades and validations in a timely manner. Configures/adds new services as needed. As the User administrator, including creating, changing, and disabling user accounts per approved policies/procedures. Works with stakeholders and process owners to deploy new modules, providing advanced training to support process owners becoming power users. Develops reports based on needs of end-users and management to enable efficient real-time reporting.

Assists in the development of training materials and responsible for creation and effective delivery of training. Performs or oversees the vendor's performance of system configuration. Manages project schedules and milestones. Participates in software testing, drafting, and executing validation test scripts with the software/solution host vendor. Develops and/or supports software design and implementation. Provides web-based and network solutions for process owner and stakeholder IT projects.

Serves as Subject Matter Expert and administrator for CBER's quality management database. Chairs and leads business owner change control board, client status meetings, requirement meetings etc. Troubleshoots system issues and reports defects to the vendor or appropriate POC in a timely manner. Monitors developments and activities in system user communities to gather important information for CBER systems strategic planning.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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. Please go to <http://www.sss.gov> for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.

- **If you are serving, or have served in the last 5 years 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.

Desired Skills/Experience:

- Project management skills and ability to manage multiple complex projects.
- Uses technical understanding to prioritize and recommend critical decisions.
- Excellent organizational, planning, and time management skills with the ability to manage multiple and changing priorities and issues of varying complexity, while meeting time-sensitive deadlines and deliverables.
- Experience maintaining and administering to Enterprise level Quality Management Software and tools.
- Experience working within and across various support teams to design, develop, test, implement and support Quality Management technical solutions.
- Experience with Database migrations and multiple database technologies. Specifically with planning, execution and post data validation(s).
- Experience with analytical reporting tools.
- Experience with systems integration including creation and update of interface documentation.

Qualifications

Basic Qualification Requirements:

- **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 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.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Education must be accredited by an accrediting institution recognized by the [U.S. Department of Education](#) in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

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 further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

How you will be Evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

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), copy of unofficial transcripts, latest PMAP (if applicable), and letter of interest with **“CURES CBER/OCD/LQS Information Technology Specialist”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **August 23, 2024**.

Announcement Contact

For questions regarding this Cures position, please contact CBERHumanCapital@fda.hhs.gov.

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FDA is an equal opportunity employer.

