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)

Application Period: 08/12/24 – 08/23/24*
Initial cut-off period for first-referral consideration is 08/16/24.

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: Division Director

Series: 2210

Location(s): Remote

Salary Range: $181,551 - $260,823 and is set commensurate with education and experience.

Work Schedule: Full Time

Cures Band(s): F

Full Performance Band Level: F

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) 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; records, 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 Director for the Division of Information Technology (DIT) within the Office of Regulatory Operations (ORO) and manages daily operations of the Division. This position reports to the Director of ORO. As the Division Director, the incumbent oversees the development and management of the CBER Information Technology (IT) Investments in review, scientific, and administrative areas. As a key leader of the CBER Modernization team, the incumbent brings their knowledge and expertise to lead the informatics component in modernizing CBER's operations to support new practices and business processes.

Specifically, the Division Director will:

- Develop and implement a Center information technology strategy which supports and aligns with the Center's emerging needs for review of the human biological products and the Agency's strategic plans for technology.
- Advance the modernization and digital transformation of the Center Information Technology Plan. The incumbent will manage, and ensure quality of CBERs information technology operations, programs, functions, and activities; lead the CBER IT Governance function.
- Identify, evaluate, and integrate IT solutions, that solve current and future business needs with consideration for advanced technology. Maintains currency on new technologies and platforms.
- Ensure IT capabilities for CBER are delivered reliably, sustainably, cost effectively and securely and with agility based on changing business objectives, goals and strategies.
- Provide leadership and direction in modernization and digital transformation of the CBERs Information Technology and in scientific and regulatory modernization initiatives for CBER.
- Provide strategic direction and oversight for the design, development, operation and support of IT systems and programs that fulfill the needs of the business, including enterprise architecture management, application management, security and risk management, and infrastructure and operations support management.
- Direct cross-functional teams responsible for planning, designing, and developing approaches to addressing business needs, and identifying long-term, best-in-class architecture and technology that will provide enhanced support across CBER.
- Oversee the development of the Center's IT annual budget, to ensure the investment in technologies is consistent with the enterprise's overall strategic objectives and is within plan. Oversee the preparation of information technology investment reporting, defends systems proposals and budgetary requirements.
- Direct and coordinate contract support activities in the development, operation, maintenance, and enhancement of Center information technology programs.
- Plan and establish long-term goals and schedules for the work of the Division, assures implementation by subordinate supervisors (or team leaders) and organizations of the goals and objectives of the Division, determines goals and objectives that need additional emphasis, determines the best approach and solution for resolving budget problems, and plans for long-range staffing needs.
- Manage a staff of approximately 30 employees in two Branches (Program Management and Analysis Branch (PMAB), and Technology Integration and Delivery Branch (TIDB)); supervise, manage, and exercise full and final technical authority over highly professional work with some work involving extreme urgency and controversy.
- Serve as an Associate Deputy Chief Information Officer (ADCIO) in the FDA-wide Information Technology organization.

Supervisory Responsibilities:

Organizational Management: Manages a division.
Program Management: Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.
Resource Management: Monitors and reports on resources needed to run a Division in the Center.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies employee competency gaps.

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.
- 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 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 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/Graduate Training 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 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 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.

Desirable Professional Experience:

- Extensive technical understanding and demonstrated application of technologies, in areas relevant to responsibilities described.
- Ability to develop formal and informal relationships, drive organizational change and build capabilities that effectively support the organization.
- Experience leading and managing similar sized IT organizations.
- Experience developing and executing IT strategy, and a record of timely delivery of effective IT solutions.
- Experience leading Information Technology modernization, including migration to the Cloud.
- Ability to prioritize, make critical decisions and adjust to organizational and program information and changes with minimal impact.
- Excellent verbal and written communication skills, including the ability to explain digital concepts and technical solutions in terms that meet the needs of the affected audience.
- Familiarity with IT governance, federal government reporting requirements, federal government contract acquisition process.
- Ability to develop, direct, mentor and reinforces team members in line with the mission, vision, values, goals, and performance standards of formal and informal teams.
- Ability to manage and foster collaboration among diverse staffs (e.g., FTE and contractor) in geographically diverse locations.

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.*

Application Procedures

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 your transcripts (unofficial), SF50 (if applicable), latest PMAP (if applicable) and letter of interest with ***"Cures CBER/ORO/DIT Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **The initial cut-off for first referral consideration is August 16, 2024, at 11:59 p.m. (ET); applications received after this date will be given consideration only if there is a need for further applicant review, until a selection is made or on the closing date.**

Learn more about disability employment and reasonable accommodations or how to contact an agency.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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