



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: December 19, 2022 – January 5, 2023

Area of Consideration: The 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): White Oak Campus, Silver Spring, MD

Salary: Starting at \$168,914

Work Schedule: Full Time

Telework Eligible: Yes

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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.

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 protects and advances the public health by ensuring that biological products are safe and 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 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.

The Division Director oversees the activities in DIT's Program Management and Analysis Branch (PMAB) which is responsible for IT program management, contract management and oversight, the Contractor Officer Representative (COR), IT contracts creation, and procurement evaluations and also oversees activities in DIT's Technology Integration and Delivery Branch (TIDB) which establishes a Development, Security and Operations (DevSecOps) environment, culture, and platform to integrate development, security, and operations priorities throughout the entire IT lifecycle.

Specifically, the Division Director will:

- Develop and implement a Center information technology strategy which supports and aligns with the Center and Agency's strategic plans for technology and data.
- Oversee the development of the Center's IT annual budget, 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, prioritize, manage, and ensure quality of all the Centers information technology operations, programs, functions, and activities, leads the CBER IT Governance function and is responsible for the modernization and digital transformation of the Center Information Technology.
- Direct and coordinate contract support activities in the development, operation, maintenance, and enhancement of Center information technology programs.
- Plan and set long-range 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.
- Responsible for a staff of technical employees; and for supervising, managing, and exercising full and final technical authority over highly professional work at the GS 13 - 15 level with some work involving extreme urgency and controversy.

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.
- 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.
- 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.

Basic Qualifications:

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: <https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series>

Professional Experience/Desirable Qualifications:

- Leadership coaching experience training, or certification;
- Technical understanding, certification, training in areas as described;
- Demonstrated experience managing similar size organizations ;
- Familiarity with information technology governance;
- Experience leading Information Technology modernization;
- Ability to build and work effectively within teams;
- Ability to work collaboratively with diverse staffs (e.g., FTE and contractor) and stakeholders; and
- Ability to prioritize and make critical decisions.

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](#).

Vaccination Requirements:

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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.

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 **“CBER/ORO/DIT Division Director – Cures Announcement”** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **January 5, 2023**.

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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