Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research(CDER)
Office of Strategic Programs (OSP)
Office of Business Informatics (OBI)

Application Period: May 30, 2024 – June 27, 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: Office Director (Supervisory Business Informaticist)

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at $231,491

Work Schedule: Full-time

Full Performance Band Level: Band G

Cures Band(s): Band G

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.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential

public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter (OTC) and prescription drugs, including biological therapeutics and generic drugs. The Office of Strategic Programs (OSP) serves the Center Director, and the super office directors who lead major operations involved in regulatory oversight of human drugs. OSP's functional capabilities include strategic planning and management, negotiation with major external stakeholders over future work commitments and resource commitments, and process and program design and management.

The Office of Strategic Programs (OSP) is responsible for quantitative and qualitative data analysis, program evaluation, business process modernization, decision support services to facilitate effective operations, consultation to Center Offices in developing strategic and operational plans for CDER, cross-center management and coordination of work on Center-wide governance and special initiatives, and the implementation of IT solutions to meet CDER's business needs. OSP provides essential expert support and enabling services for CDER to meet its mission objectives.

The Office of Business Informatics (OBI) provides leadership and coordination of enterprise level informatics activities across CDER, makes recommendations that support long-term strategic goals, builds strategic partnerships with internal clients and other Center/Agency stakeholders, collaborates closely with CDER's Business Informatics (BIG) Governance Board and its Program Management Office (PMO) to establish and execute strategic roadmaps that address business informatics needs. OBI translates business priorities and provides implementation and program management expertise to fulfill a center-wide portfolio of informatics initiatives that are delivered through these strategic partnerships.

Duties/Responsibilities

As the **Office Director (Supervisory Business Informaticist),** for the Office of Business Informatics (OBI) the incumbent is charged with leading the informatics development to modernize CDER's drug regulatory operations, through application of rigorous planning and analysis to support new practices and business processes.

- Provides scientific and operational leadership to the demand for world-class technical and operations management driving transformation.
- Provides leadership and direction for CDER's informatics delivery and operations to ensure that the OBI functions are aligned with the emerging needs of the U.S. human drug review program. The incumbent represents CDER's IT needs and objectives in the larger FDA IT environment, strategic partnering with FDA's Office of Digital Transformation (ODT)and FDA's National Center for Toxicological Research (NCTR) to drive overall effective and efficient operations of the FDA enterprise.
- Provides leadership to drive a highly effective development and implementation environment, driving breakthrough technology innovation delivery to support CDER scientific

- operations, and establish and execute plans to deliver regulatory compliance for all IT Systems in an FDA regulated environment. Incumbent serves as Center representative to the FDA Technology Council and provides consultation and expert advice on biomedical informatics issues to the Office of the Commissioner, other Centers in the FDA, other government agencies, foreign governments, and international organizations.
- Actively models and leads CDER's Office of Business Informatics (OBI) in an environment of partnership and transparency with business leaders and staff to implement IT solutions that meet business needs and priorities. The incumbent develops and promotes excellent business analysis skills within OBI to ensure that business needs are fully understood, and business owners are actively engaged in product delivery.
- Provides leadership and direction in support of the implementation of scientific and regulatory modernization initiatives sponsored by CDER and FDA. The incumbent fully supports and contributes expertise to develop CDER's strategic IT vision for a modern, efficient, all-electronic science based regulatory agency of the future.
- Collaborates with the CDER Informatics PMO (iPMO) to identify informatics challenges and opportunities, makes recommendations for optimal technical means of making biomedical information accessible and usable for problem solving and decision making, issues report on scientific findings to the BIG Board, and to regulated industry, as appropriate. Reviews and approves articles and papers prepared by Division and Staff members intended for external publication and policy statements to be published in the Federal Register.
- Provides expert advice and counselthat identifies, interprets, and develops alternative options to resolve complex informatics and data analysis questions across the human drug review program. The incumbent independently applies proper analytical resources to uncover the root cause of program issues, recognizes if there is any potential overlap between ongoing work, and, engages in aspects of problem-solving methods and/or processes.
- Leads cross-functional teams responsible for planning, designing, and developing unprecedented approaches to addressing business needs, provides expert input to the CDER's Architecture Review Board (ARB) on architectural issues and opportunities.
- Provides leadership and direction for CDER's informatics delivery and operations including budget planning and execution, acquisition management and staff development to ensure that the OBI functions are aligned with the emerging needs of the U.S. human drug review program.
- Leads the operational decision-making body to evaluate CDER cross-office and cross-functional technology needs.
- Provides leadership and direction of the objectives of the CDER Technical Operation Committee (TOC) are based on the need to operationalize CDER's transition plan for the workflows, tools, and systems.

Supervisory Responsibilities:

The incumbent is under the general administrative supervision of the Director, Office of Strategic Programs, and is delegated authority to plan, conduct, and direct the programs of OBI.

Supervision is in the form of general policy approval of plans and policies developed by the incumbent, OSP Director and CDER BIG Board. Other guidelines are legislation, Center and Agency policies, and technical and scientific developments reported by other government groups, private research laboratories, and industry laboratories.

The incumbent runs a multi-disciplinary program in OBI and identifies specific activities needed to achieve desired outcomes. The incumbent will provide the framework for the Division Directors in the form of broad functional responsibilities and overall performance expectations. The incumbent plans, organizes and directs work independently with full responsibility for setting operational priorities, tracking the progress of the work, and evaluating the performance of programs.

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.

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:
A bachelor's degree or higher in business administration or business analytics, computer science, systems engineering, information systems, operations management. The degree must be from an accredited program or institution.

Desired Skills, Experience, or Education:
Our ideal candidate will possess experience that equipped the applicant with the knowledge, skills, and abilities to perform successfully the duties of the position, and that is typically in or related to the work of the position to be filled.

- Ability to lead and organization, end-to-end tasks for major projects, and facilities.
- Ability to constructively interact with a wide variety of stakeholders within and outside the organization, including senior leadership and external contractors; able to balance competing priorities.
- Demonstrated skill in business analysis and in leading business analysts.
- Strong verbal and written communication skills; ability to modulate communication approach depending on audience.
- Ability to derive and communicate underlying insights, risks and root causes from diverse program data sources in a fashion understandable by audiences of all types with interest in the program(s).
- Demonstrated successful experience and skill with agile development methods; scrum experience desirable.
- Ability and willingness to adjust to organizational and program-specific context.
- Ability to develop an intimate understanding of one or several complex technology programs.
- Demonstrated skill in organization strategy, business process, and technology.
- Experience and skill in systems architecture.

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: Non-Sensitive/High Risk

A background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

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.

How to Apply

How to Apply: Submit resume or curriculum vitae with cover letter by June 25, 2004, to: Whitney Flickinger, Whitney.Flickinger@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

For questions please contact Whitney Flickinger – Whitney.Flickinger@fda.hhs.gov. Please reference Job Reference ID: OBI Director

Announcement Contact

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

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