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: Aug 9, 2024 – Aug 19, 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: Business Informaticist

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at $139,395

Work Schedule: Full-time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 **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. The Business Informatics Specialist supports the mission of the office by performing the following duties:

- Serves as subject matter expert among business and technical stakeholders to manage projects involving elicitation of business processes (business analysis), project management, product management and/or technical requirements to centralize workflow management, reporting, and other information systems.
- Leverages experience in deploying high quality enterprise-wide platforms and services to lead major initiatives, provide consultation on systems and policy proposals, and provide technical and programmatic guidance and recommended solutions. May manage funding and resource planning to ensure the successful delivery of approved projects.
- Assesses end user requests and makes recommendations for CDER informatics applications on timing, scope, funding, and required resources. Recommendations to end users, developers, supervisors. Recommends projects to be added to the

Informatics Action Plan to support the CDER Business Informatics Governance board and FDA modernization activities and assigns resources as necessary to work on projects.

- Ensuring successful on-time delivery of informatics projects and effective planning for lifecycle maintenance to support Prescription Drug User Fee Amendments (PDUFA), Generic Drug User Fee Amendments (GDUFA), and Over-the-Counter Monograph User Fee Amendments (OMUFA) regulatory activities.
- Coordinates efforts for assigned CDER Informatics Platform applications (to include data analytics, workflow management, help desk, training, testing, data management, and electronic submissions) to determine appropriate requirements elicitation (such as, but not limited to brainstorming, interviews, and requirements gathering) and documentation techniques.
- Determines appropriate requirements management processes and assesses progress of project efforts. Facilitates and prepares issue-based agendas and ensures stakeholder needs are defined and solutions meet the needs.
- Recommends new policies, procedures, and/or systems to improve, streamline and/or standardize agency operations. Leads the project team in effective and efficient execution of agile projects for software development. Makes recommendations supervisor or OBI leadership on IT modernization efforts that support long-term strategic goals.
- Serves as a subject matter expert to ensure that stakeholders' actual underlying needs are understood, rather than stated or superficial needs; leads the prioritization of user requirements to enable the project team to implement an informatics solution that meets the stakeholder needs; and provides advice and proposes solutions for information technology system modernization and enhancements.
- Provides subject matter expertise to execute project management and agile methodologies (i.e., Federal Acquisition Certification for Program and Project Managers or Project management Professional certification) for complex technical projects; leads project teams in effective and efficient execution of agile projects for software development.
- Negotiates and builds consensus among stakeholders. Manages changes and conflicts during requirements gathering sessions and user acceptance testing in order to ensure stakeholders and the project team remain in agreement on the solution scope. Discusses tentative solutions or alternatives means of achieving prescribed objectives.
- Subject matter expert initiating continuous quality improvement activities by gathering lessons learned, assessing project management effectiveness, identifying gaps, and implementing corrective measures to improve project management execution
- Articulates positions/policy of vast technical complexity and obtains compliance with policies and procedures.
- Manages and effectively communicates requirements scope and risks. Assesses scope and risks, solves problems of many complexities. Prioritizes and communicates business and stakeholder/user requirements to enable the project team to implement an informatics solution that will meet the business needs of the stakeholders.

- Leads the teams benchmarking activities to improve requirements, strategies, operations, and processes. Reviews and approves standard templates for deliverables across projects.
- Communicates and collaborates with CDER Stakeholders, scientific reviewers, regulatory project managers, technical personnel, consultants, and industry supporting CDER's mission related to the modernization of data analytics, electronic submissions, and regulatory related information technology systems.
- Drafts and delivers detailed and informative written as well as oral reports and presentations based on sensitive or complex analyses from complex analysis pertaining to feasibility and usability of systems and other critical data and sensitive information to senior center management. Information is analyzed, coordinated, and synthesized to support IT modernization initiatives.
- Works with little to no supervision, collaborates with external and internal stakeholders to identify and understand their business informatics, concerns, and training needs in context to their current and future business processes.

Supervisory Responsibilities: None

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.
OR
Comparable work in technical analysis, data analysis, analyzing and interpreting data, developing information systems that support the collection, sharing, standardization, or integration of program related data.

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

- Experience serving as a subject matter expert with the delivery of agile applications and coordinating requirements gathering activities.

- Experience applying knowledge of IT modernization activities, including elicitation techniques to gather and understand business requirements (business analysis), product management, and continuous quality improvement.

- Demonstrate experience utilizing agile project management methodologies, (i.e., Federal Acquisition Certification for Program and Project Managers or Project management Professional certification).

- Experience analyzing and solving problems pertaining to systems analysis.

- Ability to communicate orally and in writing to prepare and deliver reports and presentations on study results and other critical data and information.

- Experience in working with staff at all levels of the organization and varying levels of domain expertise.

- Demonstrated experience applying knowledge of business processes, to determine appropriate IT solutions.

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/Moderate 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

Submit resume or curriculum vitae with cover letter by **August 19, 2024**, to: cderosprecruitment@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”.

Announcement Contact

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

Please reference Job Reference ID: **OBI IO Business Informaticist.**

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