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)
Immediate Office

Position:	Supervisory General Health Scientist (Director OBI)
Series:	601
Location(s):	Silver Spring, MD
Travel Requirements:	Up to 25%
Application Period:	May 15, 2020 to June 5, 2020
Salary:	Starting at $162,339
Area of Consideration:	United States Citizens or Nationals

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

Special Notes**:** This position is being filled under an excepted 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 the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:

The Food and Drug Administration (FDA or Agency) 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 and prescription drugs, including biological therapeutics and generic drugs.

This position is located in the Office of Business Informatics, Office of Strategic Programs (OSP) within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). The Office of Business Informatics 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 Governance Board and the CDER Informatics Program Management Office (iPMO) 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.

Position Summary:

The Director for CDER's Office of Business Informatics (OBI), 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. These changes depend on a parallel transformation of drug regulatory data, advances in data analysis, and modernization of the scientific computational and communications infrastructure that underpin operations. The modernization is informed by an enterprise-level IT strategy developed and overseen by the Center's Business Informatics Governance Board. The incumbent of this position will provide scientific and operational sophistication to the demand for world-class technical and operations management to ensure success in the critical IT transformation within the Center.

Supervisory responsibilities: Manages one or more portfolios and provides leadership and direction to four subordinate Division Directors. Provides occupational-specific technical and administrative direction 25 percent or more of the time to subordinate employees performing the work and functions of the organization.

The incumbent runs a multi-disciplinary program in OBI and identifies specific activities needed to achieve desired outcomes. Organizational staffing patterns are primarily homogeneous, but may also have staff in various scientific, professional, technical, or administrative occupational series.

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. Recommendations regarding resource management are normally accepted without significant change. The incumbent's work is reviewed for ongoing effectiveness in meeting the policy and operational needs of the Center.

Duties/Responsibilities:

- Provides leadership and direction for CDER's informatics delivery and operations to ensure 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, partnering with FDA's Office of Information Management and Technology (OIMT) to drive overall effective and efficient operations of the FDA enterprise. The incumbent will provide the leadership needed 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.
- 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 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. The incumbent establishes effective client relationships and strategic engagement with senior leadership and key stakeholders; anticipates the client's needs; and makes recommendations that support long-term strategic goals and the Center's regulatory and scientific mission.

- Provides leadership and direction in support of the implementation scientific and regulatory modernization initiatives sponsored by CDER and FDA. He/she 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.
- Works with the CDER Informatics PMO 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 reports on scientific findings to the Business Informatics Governance (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 counsel, either written or verbal, that 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, if necessary, engages in aspects of problem-solving methods and/or processes using conventional ideas, insights, programs, and/or technologies to execute the work requested while maximizing resources.
- Leads cross-functional teams responsible for planning, designing, and developing unprecedented approaches to addressing business needs, provides expert input to the Architecture Review Board on architectural issues and opportunities. The incumbent 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.

EEO Responsibility: 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.

The incumbent, in conjunction with his/her supervisor, develops an affirmative employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities. Incumbent will be appraised on the effectiveness of his/her performance.

Professional Experience/Desirable Qualifications:

- Exceptional organizational skills
- Proven track record of successful end-to-end ownership for major tasks and projects
- Strong demonstrated leadership, organizational and facilitation skills
- Ability to constructively interact with a wide variety of stakeholders within and outside the Center, including senior leadership and external contractors; able to balance competing priorities
- Demonstrated successful experience 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 with agile development methods; scrum experience desirable

Key requirements will include:

Meets Office of Personnel Management Individual Occupational Requirements for General Health Scientist, 0601. At a minimum candidate must have successful completion of a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree that included a major field of study or specific course requirements generally as stated in paragraph A in the individual occupational requirements. Where specific course requirements are not indicated in paragraph A, the number of semester hours required to constitute a major field of study is the amount specified by the college or university attended. If this number cannot be obtained, 24 semester hours will be considered as equivalent to a major field of study. The nature and quality of this required course work must have been such that it would serve as a prerequisite for more advanced study in the field or subject-matter area. Related course work generally refers to courses that may be accepted as part of the program major. Please review the entire IOR to confirm the minimum education requirements in the following link General Medical and Healthcare Series, 601.

Conditions of Employment:

Security Clearance: If not previously completed, 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 these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Requirements: This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report OGE 450 and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: All qualified candidates must submit curriculum vitae and cover letter in which you describe why you feel you are uniquely qualified for this position electronically to Normica Izzard at Normica.Izzard@fda.hhs.gov. by closing date of **June 5, 2020.**

First round cutoff date for applications is **May 22, 2020. Applications received after May 4th will be reviewed in a second round. To ensure consideration, submit application prior to cutoff date.**

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