Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Information Systems Management (OISM)
Director

Application Period: August 22, 2022 – September 4, 2022

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: Director, OISM

Series: AD-0301

Location(s): Location determined upon selection

Salary: Starting at $203,596

Work Schedule: Full Time

Cures Band(s): Band G

Full Performance Band Level: Band G

Travel Requirements: Up to 25% travel

Bargaining Unit: This is a non-bargaining unit position.

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

Join the Food and Drug Administration (FDA) and serve on the frontlines protecting our nation's public health and safety within the Office of Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 16 laboratories throughout the nation or around the world. Our employees inspect product facilities; investigate criminal violations; analyze lab samples; provide administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

To view our ORA Vision, Mission, and Values please visit:
https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. ORA supports the six FDA product centers by inspecting regulated products and manufacturers,

conducting sample analyses on regulated products, and reviewing imported products offered for entry into the United States. In addition to executing its mission through its federal workforce, ORA also works with the FDA Centers, who develop FDA wide policy on compliance and enforcement and ORA executes the annual commodity work plans. Over 5,000 ORA employees located in district offices, resident posts, and laboratories, strategically located throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education, and outreach directly to consumers, industry representatives, importers, and shippers as well as other stakeholders across the nation. ORA also works with its federal, state, local, tribal, territorial, and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

The Office of Information Systems Management (OISM) supports ORA's Information Technology (IT) and business priorities. OISM focuses work in three areas: Enforcement Systems Solutions, Imports Systems Solutions, and IT Management/Planning Services.

Duties/Responsibilities

The incumbent is responsible for assessing, identifying, and ensuring the technical needs for the ORA, the agency and the programs are met. As the Director OISM, the incumbent provides expert advice in matters as they relate to governance, policy, and technological investment. As subject matter expert, the Director OISM advises the ACRA, Deputy Associate Commissioner for Regulatory Affairs (DACRA) and other senior management officials on all matters related to ORA's information technology needs, information technology governance and acquisitions, infrastructure requirements, systems development, and related budgetary issues. The Director OISM oversees two divisions: the Division of Special Initiative and Coordination and the Division of Systems Solutions. The Director OISM represents ORA as a voting member on the FDA's CIO Council which provides governance oversight and approval for all major IT programs at the FDA. The Director OISM works with ORAs Center IT Liaison to ensure information and technology planning and management as delivered by the Office of Information Management and Technology (OIMT) is focused and delivered according to Service Level Agreements and other expectations.

- Serves as primary advisor for implementing regulatory informatics plans and identifying the information management needs of the ORA's regulatory review programs and activities, with an over-arching goal to promote the use of standardized regulatory data, electronic data submission, analysis, and storage by ORA staff.
- Remains current on information technology, disseminating this information to FDA offices and providing technical advice, guidance, and assistance throughout the agency on information technology matters.
- Performs outreach and directs studies and analyses to determine appropriate IT hardware, software, and infrastructure requirements. Formulates the vision and strategy, short and long-range program policies, and budget plans for IT services based on response to input from customers

- Oversees and coordinates ORA's IT Investment Review Board (ITIRB) and Change Control Boards (CCBs). Oversees ORA's IT Portfolio and provides Capital Planning and Investment Control (CPIC) functions to ensure that all IT initiatives are managed with sound life cycle management principles and practices consistent with the agency policies and procedures.
- Evaluates and recommends the prioritization of business needs in relation to current and planned information technology systems, data standards, reporting and visualization functions in partnership with internal clients in ORA offices, field offices and laboratories as well as partners external to ORA
- Facilitates the efforts of the business unit and information technology organization to translate business needs into information technology requirements. Works with ORA's Office of Management and OIMT on budget development and execution

Supervisory Responsibilities: The Director OISM supervises the division directors and acts as the second level supervisor for branch staff; counsels and rates immediate subordinates; manages the Office budget; develops strategic plans; sets and adjusts priorities. Additionally, the Director OISM furthers the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to 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. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Center in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills.

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.

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 Requirement: There are no Individual Occupational Requirements for this series.

Desired Education: Advanced degree in computer science, or a related discipline.

The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Desired Professional Experience: Demonstrated experience directing the development and implementation of business information systems solutions and providing strategies to improved IT infrastructure in a complex public health services environment including multiple types of services), including oversight of budget formulation, personnel management, and the implementation of policies to comply with applicable laws and regulations.

- Knowledge of business and management principles involved in strategic planning, resource allocation, human resources modeling, leadership technique, production methods, and coordination of people and resources.
- Identifying complex problems and reviewing related information to develop and evaluate options and implement solutions.
- Establishing long-range objectives and specifying the strategies and actions to achieve them.
- Ability to communicate effectively with stakeholders at all levels of the organization,

including presenting options and recommendations to senior stakeholders.
- Demonstrated substantial experience formulating policies, goals, objectives, and operational strategies, in decision making for business information systems programs and emerging technology.
- Experience in effectively coordinating and productively integrating the multidisciplinary efforts of a scientific/regulatory workforce.

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: 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.

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

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: Applications will be accepted from all qualified internal and external applicants. Please email letter of interest addressing your experience in the major duties and responsibilities of the position, resume, redacted SF-50 (for federal employees only), transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee: oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through **September 4, 2022**. Candidate resumes may be shared with hiring officials within the OISM with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov. Please reference **Director, OISM** in the email subject line.

Announcement Contact

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

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

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