Title 21 Vacancy
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner

Application Period: 5/3/2024- 6/3/2024

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: Chief Scientist

Series: 0601

Location(s): Silver Spring, MD

Salary: $259,391 - $373,165

Work Schedule: Full-time

Pay Band(s): Band H

Full Performance Band Level: Band H

Travel Requirements: 25%

Relocation Expenses Reimbursement: N/A

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 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.

FDA's Chief Scientist provides strategic leadership, coordination, and expertise on scientific matters in order to support scientific excellence, innovation and capacity to achieve FDA's public health mission. Incumbent serves as the Chief Scientist and is responsible for facilitating coordination between multiple, smaller program offices; oversight of research; approval and disapproval of subject matter expert (SME) designation; and oversight for the activities related to policy, guidance, and process improvement development within the super office to enhance

efficiency and ensure expeditious communication of decisions/actions across the Office, Agency and other external stakeholders, as appropriate. This position is located in the Office of the Office of the Commissioner, Office of the Chief Scientist.

Duties/Responsibilities:

- Provides executive and scientific leadership for FDA's cross-cutting scientific research and related policies, programs, and initiatives;
- Participates a senior science advisor to the Commissioner on FDA science, innovation, and capacity in research to meet FDA's regulatory mission and public health needs;
- As designated by the Commissioner, represents the Agency in meetings and conferences with officials/representatives of higher departmental echelons, counterpart government departments and agencies, national and international organizations and groups, the scientific and academic communities, and other stakeholders concerning the Agency scientific programs and activities. The incumbent is authorized to speak for the Commissioner and advocate for his/her and the Administration's priorities and initiatives.
- Facilitates scientific communication and cooperation at all levels, including among Centers and Offices, and nurtures interaction with the external scientific community to ensure the optimal use of available resources and tools to advance FDA's mission;
- Supports the Centers in creating nimble, responsive, high quality scientific research organizations that consistently bring the best science to bear on FDA decision- making;
- Provides oversight of the development and implementation of strategies, plans, policies, and budgets to build and improve FDA's regulatory and scientific capacities, systems, and programs, including:
- Developing the FDA Science and Research Plan for determining, prioritizing, and accomplishing the research needs of FDA;
- Developing and advocating for a budget to support intramural research;
- Tracking and, as appropriate, coordinating intramural research awards made by each center or science- based office within the Office of the Commissioner;
- Providing executive and scientific leadership in the development of agency fellowship programs;
- Facilitating and supporting training and skills improvement of the existing scientific workforce at FDA;
- Building capacity and expertise in the quantitative disciplines (e.g., data science, biostatistics, informatics) and other scientific disciplines across FDA;
- Developing and managing cross-cutting workgroups and develops cross-cutting extramural programs to advance FDA's science agenda and knowledge base; and
- Facilitating and supporting efforts for the modernization of cosmetics implementation
- Ensuring that there is no duplication of research efforts supported by the Reagan- Udall Foundation for the FDA;

Supervisory Responsibilities:

- Manages one or more portfolios and provides leadership and direction for multiple,

smaller program offices.

- The incumbent Acts on behalf of the Commissioner to provide executive leadership, guidance, and oversight of assigned programs, including direct line authority over the National Center for Toxicological Research (NCTR); the Office of Counterterrorism and Emerging Threats; the Office of Regulatory Science and Innovation; the Office of Scientific Integrity; the Office of Scientific Professional Development; and the Office of Laboratory Safety;
- Provides management and support services to the Science Board to the FDA, including convening the Science Board to provide advice to the Commissioner and other appropriate officials as circumstances warrant; and
- Implements initiatives, management and operational systems, concepts, techniques, and policies for improving and increasing contact, communication, and responsiveness on FDA, Departmental, Administration, and Presidential initiatives.

EEO responsibilities:

Exercises leadership to ensure that all programs under his/her direction reflect the principles of equal employment opportunity and workforce diversity in their management and operation in such areas as recruitment and staffing by inclusion of minority groups, women, and people with disabilities; employee development; staff assignments; and communications. In addition to demonstrating personal commitment to the objectives of equal employment opportunity and workforce diversity, the incumbent ensures that subordinate supervisors and managers recognize the importance of their EEO and diversity enhancement responsibilities. Provides reasonable accommodations needed to best utilize qualified people with disabilities. The incumbent is responsible for furthering 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, national origin, age, or disability.

Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Agency in the following:
(1) merit promotion of employees and recruitment and hiring of applicants;
(2) fair treatment of all employees;
(3) encouragement and recognition of employee achievements;
(4) career development of employees; and
(5) full utilization of their skills.

Position requires eligibility for access to Sensitive Compartmented Information (SCI), other intelligence-related Special Sensitive information, or involvement in Top Secret Special Access Programs (SAP).

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 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.
- This position is designated as an SES Equivalent position.

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

1. Qualified and Outstanding Candidates
   a. ***Qualified*** applies to all candidates for Title 21 appointments. The FDA Office of Talent Solutions (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 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:

General Medical and Healthcare Series, 0601

Candidates must have the following:

Degree - a doctoral-level degree from an accredited institution of higher learning, such as: Ph.D., M.D., D.V.M., D.D.S., D.N.D., Sc.D., or degree with major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position equivalent to a Ph.D.;

AND

Professional Experience:

- A minimum of **five years related experience** in the scientific, clinical, and/or public health research fields.
- A strong record of peer-reviewed original and applied research.
- Strong interest in the breadth of science applicable to FDA regulatory programs.
- In-depth knowledge of the Agency's policies, and scientific and regulatory programs as they relate to medical products.
- Talent for building partnerships and coalitions with stakeholders in public and private arenas.

Mandatory Managerial/Executive Qualifications:

Candidates must have the ability to bring about strategic change, both within and outside the organization, to meet organizational goals; the ability to lead people toward meeting the organization's vision, mission, and goals:

- Ability to meet customer expectations;
- Ability to manage human, financial, and information resources strategically;
- Ability to build coalitions internally and with other Federal agencies, State and local governments, nonprofit and private sector organizations, foreign governments, or international organizations to achieve common goals.

Desired Qualifications:

Candidates should have:

- Executive level administrative or managerial experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment;
- Demonstrate leadership competence and abilities to:
- develop complex and basic program goals, and assure that agency goals and priorities are considered in carrying out and completing responsibilities;
- direct and guide projects, including long-term and short-range planning;
- establish objectives and priorities;
- conduct periodic program assessments;
- plan and direct the work of a large scientific research staff;
- Experience indicating the ability to communicate and effectively interact with the scientific/academic and public health communities; medical and other health-related organizations; high level government officials, including members of Congress, principal representatives of counterpart Federal agencies, foreign government officials; CEO-level and other senior representatives from regulated industry; and other research stakeholders.
- Experience leading a significant scientific organization within government, industry, or academia;
- Extensive knowledge in the development and manufacturing of drugs, devices, biologics, food, veterinary products, cosmetics, and/or tobacco products;

- Familiarity with the application of FDA laws and regulations;
- Training, professional development, and outside activities that provide evidence of initiative, resourcefulness, and potential for effective job performance, such as invitations, presentations, and international activities;
- Receipt of honors, awards, or other recognition for performance or contributions based on managerial
- excellence.
- Receipt of honors, awards, or other recognition for performance or contributions based on scientific excellence.
- Broad familiarity with diverse, cutting-edge scientific technologies used in FDA regulatory science labs.

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:
This position requires a Top-Secret security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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.

Drug Impact Statement for Top Secret Clearance

The incumbent serves under the executive direction of the ACIO, OIO and the ACRA in the FDA and is a lead for national security intelligence matters involving ORA-regulated products. As such, the incumbent will have access to classified data, documents, facilities and/or materials related to national security, thus demanding a high degree of public trust and requiring the incumbent to possess and maintain a Top-Secret Security clearance.

The position requires a Top-Secret/Sensitive Compartmented Information (TS/SCI) security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top-secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage.

Testing Designated Position (TDP)

This is a Testing Designated Position. Incumbent must submit to and successfully pass a urinalysis drug screening prior to appointment. The Incumbent will also be subject to unannounced random drug testing for the duration of their time in this position, in accordance with the HHS plan for a Drug Free Workplace.

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 **11:59pm on 6/3/2024** to: CuresExecutives@fda.hhs.gov.

For questions, please contact CuresExecutives@fda.hhs.gov. Please reference Job Reference ID in subject line of email: OC-OCS-2024-02

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