Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Biological Products Operations (OBPO)
Division of Biological Products Operations II (DBPOII)

Application Period: December 19, 2022 – January 11, 2023

Area of Consideration: Open to current FDA employees only. 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: Staff Director – Biological Products Operations II

Series: AD-0696

Location(s): All FDA District Offices and Resident Posts in the following FDA Districts - Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Francisco, San Juan, Seattle

Salary: Starting at $126,233

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): D, Pay Table 1

Travel Requirements: Up to 25% travel

Bargaining Unit: This is a non-bargaining unit position

PCS Funding: May be authorized

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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured, packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The mission of the Office of Regulatory Affairs (ORA) is to protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

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

The Office of Medical Products and Tobacco Operations (OMPTO) has responsibility for inspections, investigations, compliance and enforcement of medical products and tobacco facilities regulated by the Medical Product and Tobacco Centers. The incumbent is expected to have knowledge of ORA inspections of regulated products and manufacturers, provides expert advice and counsel to the Assistant Commissioner for Medical Products and compliance operations, training needs and emergency response activities related to advanced manufacturing and medical countermeasure regulated products.

Office of Biological Products Operations (OBPO) covers a wide range of products such as vaccines, blood and blood components, allergenics, gene therapies, human and animal cells, tissues, and cell- and tissue-based products, and recombinant therapeutic proteins. OBPO protects public health by assuring the safety, efficacy and quality of biological products and ensures that consumers have access to safe, high quality biological products by striving to be the world's pre-eminent biologics inspectorate.

Duties/Responsibilities

- Provides technical and administrative direction to subordinate employees performing medical product (biological drugs and devices) inspectional and investigational activities. Reviews domestic and foreign medical product (biological drugs and devices) inspectional and investigative reports for conformance to the Agency's policies and management expectations, provides constructive feedback to subordinates on these work products, and as appropriate determines the initial and final Agency classification.
- Evaluates the adequacy of evidence documented in medical product (biological drug and devices) inspectional and investigative reports and other pertinent records relative to

applicable laws, regulations, policies, procedures, programs and instructions, established precedents, and current science.

- Recommends regulatory action and/or compliance follow-up when appropriate. Tracks recommended regulatory actions to monitor timely follow-up or to determine if additional information should be provided to support the recommended action.
- Plans, sets priorities, and schedules high priority and/or complex medical product (biological drugs and devices) assignments having national and international significance. Monitors work plan performance and goal accomplishments.
- Represents the FDA/OBPO at interagency, national, and international committees and forums; at professional meetings with regulated industry; and with Federal and State regulatory counterparts and agencies. Collaborates and engages with representatives from within ORA, and across Centers and other intra-Agency organizations to develop innovative investigative and compliance strategies for reducing risk to the public health resulting from or potentially resulting from regulated industry practices, processes, products, and emerging problems.
- Represents FDA/OBPO by participating on internal and external working groups, task forces, symposia, and workshops.
- Ensures work performed adheres to the Agency's Quality Assurance Program.
- Advises the OBPO Program Director of emerging problems, trends, program needs, and any local or state issues.

This position requires the incumbent have a current Drivers License.

Supervisory Responsibilities:

As a first line supervisor (Staff Director) the incumbent directs and manages the operations of the investigators and support staff with primary responsibility for providing leadership and guidance to subordinate employees. The Staff Director 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 Staff Director will promote and facilitate: policy/procedural development and evaluation to ensure compliance with laws and regulations administered by the Agency; establishment of programmatic objectives and resource support; assessment of high priority/high risk assignments; internal/external relationships within the Agency and with industry, academia, and State/Federal agencies; and consultative support, mentorship, and classroom/on-the-job training to ORA and Center for Biologics Evaluation and Research (CBER) staff. The Staff Director reviews work for administrative coordination and program effectiveness and is a member of the OBPO's management, and reports to the Program Division Director.

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.
- This position requires the incumbent have the following: current Driver's License.
- This position requires up to 25% travel.

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: 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.

Consumer Safety Series 0696

Professional Experience:

- Knowledge of the principles, theories, and practices of related scientific or professional fields that enable the incumbent to direct the work operations of biological products inspection staff.
- Mastery of inspectional and investigative techniques associated with coordinating, directing, and assisting OBPO domestic and foreign operations related to biological products regulated by CBER.
- Experience serving as subject matter expert on operations relative to the biological products program on external and internal cross-Agency committees, workgroups and task forces; and reviewing, developing and evaluating policy, procedures, and guidance related to biological products.
- Thorough knowledge and understanding of the Agency's programs activities and regulations and assisting higher level employees in the review and evaluation of inspection reports of products or establishments.
- Skill in oral and written communications to make clear, convincing presentations; represent the Agency at meetings and conferences; interact with high level officials and representatives from public and private public health organizations.

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: 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.

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 applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the

position, resume/CV and bibliography, SF-50, 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 January 11, 2023. Candidate resumes may be shared with hiring official within the OMPTO with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". Please reference Job Reference ID: **Staff Director – Biological Products Operations II**.

Announcement Contact

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

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FDA is an equal opportunity employer.