Title 21 Vacancy Announcement
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 Product Operations I & II (DBPOI & DBPOII)
Biological Products Inspection Staff
Consumer Safety Officer (Biotechnology)

Application Period: July 21, 2023 through August 11, 2023

Area of Consideration: Open to all qualified applicants. 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: Consumer Safety Officer (Biotechnology)

Series: AD-0696

Location(s): All U.S. FDA Locations

Salary: Starting at $112,015

Work Schedule: Full Time

Full Performance Band Level: Band C

Title 21 Band(s): Band C, Pay Table 1

Travel Requirements: Up to 50%

Bargaining Unit: This is a bargaining unit position.

Hiring Incentives: Incentives may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 Policy.

This position is being filled under a stream-lined hiring authority, Title 21 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072, and the Consolidated Appropriations Act of 2023, Section 3624. 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 the 21st Century Cures Act can be found here:

21st Century Cures Act Information

Version: 11/2021

Introduction

The Food and Drug Administration (FDA) 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 and abroad.

The mission of the Office of Regulatory Affairs (ORA) is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs.

The Office of Regulatory Affairs (ORA) is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 12 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

The Office of Medical Products and Tobacco Operations (OMPTO) oversees four program directors in the coordination, interpretation, and evaluation of the Agency's overall field inspections and compliance efforts in the areas of medical products and tobacco. OMPTO is led by an Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) who reports directly to the Associate Commissioner for Regulatory Affairs.

The Office of Biological Products Operations (OBPO) provides advice and counsel to the ACMPTO and other Agency leaders relative to biological products field operations and emergency response activities, including all biological products regulated by the Center for Biologics Evaluation and Research (CBER). Responsibilities include biological product investigative activities; policy development; monitoring emerging technology advancements; evaluating program activities and recommending improvements. The office also oversees the agency's special medical programs, interprets and evaluates FDA's field inspections and compliance efforts in the areas of emerging technologies, and initiates action to improve the management of global biological drug product field activities.

Duties/Responsibilities

The incumbent of this position is responsible for conducting investigations and inspections of domestic and foreign manufacturers of licensed biological drugs and devices and represents a specialty level responsible for providing technical assistance and expert investigational guidance to

the biologics program in areas of biotechnological principles and techniques used in manufacturing biological products and enforcement.

Inspections and Investigations

- Serves as an expert and independently conducts complex, technical investigations and inspections of establishments in the assigned area of responsibility (e.g., domestic and international biological drug and device establishments) requiring special abilities and skills to effectively deal with people and to negotiate in sensitive situations arising in highly complicated assignments.
- Assignments cover the most complex and high-profile inspections where new or unusual features are present. The inspection or investigation may result in considerable attention and review in the media, Congress, or other forces inside or outside the Agency.
- Inspections cover all the types of products and problems within the area of assigned responsibility. Investigates and evaluates the adequacy of complex manufacturing practices to determine compliance with GMP regulations. Interacts and engages with a wide range of biologics stakeholders to advance mutual understanding of biotechnology operations, regulatory compliance, guidance applications, and other related initiatives.
- Provides policy and program advice to the Center and the greater FDA in response to evolving policy, emergencies, regulatory follow-up investigations, education/outreach programs, and risk-based research needs for biotechnological products. Provides advanced technical advice to management on the risk and prioritization for inspection of biologic facilities.
- Prepares memoranda, briefings, and other background material concerning substantive issues, findings, conclusions, and proposed solutions to keep the Director and appropriate staff involved at key decision points. Research involves reviewing reports and publications for relevant information; and organizing, analyzing, and summarizing information.

Reporting and Analysis

- Independently performs investigations involving complaints of injury or death attributable to products regulated by the FDA.
- Plans and decides how investigations should proceed, when the investigation is complete, and what reporting is required. May be assigned to long term investigations and grand juries with only limited oversight from the supervisor; may serve as an expert witness in court on circumstances relative to the way evidence was collected during inspections and/or investigations; may be designated as the lead Agency representative of multi-agency/multi-organization investigations; and is assigned to either assist or directly monitor or manage compliance programs for inspection programs.
- Provides timely and accurate feedback to Division and Office management as well as effective guidance to other division staff assisting in the investigations. The incumbent is often consulted on and participates in the formulation and development of inspectional and investigational procedures and techniques to problems within his/her area(s) of expertise.

Leadership and Guidance

- Provides guidance to less experienced staff on the tasks and responsibilities regarding technical and scientific matters, inspectional/investigational issues, policies, and laws affecting the biologics program area.

- Serves as a principal advisor of regulatory and compliance matters, responsible for planning, coordinating, and evaluating programs and activities for a professional regulatory field. Prepares and presents informal remarks at briefings, training sessions, consumer, and industry workshops, etc. In collaboration with local biologics partners, develops, plans, and executes appropriate outreach sessions and/or trainings for local stakeholders in consultation with national experts.
- Conducts on-the-job training in complex inspections of foreign and domestic firms falling within their area of expertise(s) and is frequently accompanied by another investigator of lesser experience to provide a training opportunity to that investigator to broaden their expertise. Serves on task forces and study groups charged with considering problems or directions in the area of biologics; consults with staff members at all levels of the organization to achieve consensus on issues and resolve any disagreements on standards.
- Represents the Agency on inter-agency review committees charged with reviewing Federal policies and making recommendations for consistency across agency lines and is a member of the international inspection cadre and conducts inspections of both domestic and international biologics operations.
- Represents the Agency with industry representatives, to exchange information and to provide advice and guidance regarding those aspects of the application, notice, amendment, supplement, or report which fall within area of review with emphasis on deficiencies.

Supervisory Responsibilities: This is a non-supervisory role.

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 requires the incumbent to have the following current License and/or Certification: Driver's License required.
- This position requires up to 50% travel.

Qualifications

To be placed into a Title 21 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 Title 21 appointments. The FDA Office of Talent Solutions 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: 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 the: OPM Qualification Requirements for the occupational series below.

Candidates must possess the required individual occupation requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine if you qualify for this series: Consumer Safety Series, 0696.

Desired Professional Experience:

- Mastery of various scientific and technical disciplines to carry out tasks related to the regulation of 1) the biologic industry including production of plasma fractionation products, cellular and gene therapies, recombinant proteins, vaccines, and in-vitro products; and 2) the related laboratory test instrumentation, computer systems, and software development and maintenance.
- Advanced and detailed knowledge of biotechnology facilities and the biotechnical industry combined with comprehensive knowledge of biotechnology, aseptic technique processes, sterilization processes, CGMP, advanced manufacturing, lyophilization processes and biotechnology products and medical devices manufacturing.
- Advanced scientific knowledge of biological technologies, products, new programs, laws, and regulations, significant court decisions, new trends or scientific findings involving biological products coupled with in-depth knowledge of related Inspection and Investigation techniques and approaches and expertise in developing evidence when situations are encountered that may result in regulatory action.
- Leadership skills sufficient to coordinate a team project by providing technical oversight and direction for a variety of principal team members representing related professional disciplines, and evaluate and present plans, designs, reports, and correspondence concerning projects and product issues.

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

The United States Government does not discriminate in employment based on 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

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request 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

Applications will be accepted by all qualified applicants. Please send (in PDF format) letter of interest addressing your experience in the major duties and responsibilities of the position, detailed resume, SF-50 (redacted for birth year and SSN; applies to current federal employees only), and college transcript(s) (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through August 11, 2023. Please reference Job ID: **5-CSO-Biotech-BPIS-OBPO-C** in the subject line of your email.

Announcement Contact

For questions regarding this Title 21 position, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov.

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

FDA is an equal opportunity employer.