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)
Biological Products Operations Staff (BPOS)

Application Period: June 20, 2023 – July 18, 2023

Area of Consideration: Open to current FDA employees. 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 (National Expert)

Series: AD-0696

Location(s): FDA – All U.S. Locations

Salary: Starting at $132,368

Work Schedule: Full Time

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

Full Performance Band Level: Band D

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

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 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 Consumer Safety Officer – National Expert (CSO-NE) serves as a program expert in inspectional and investigational techniques, providing authoritative advice and counsel both within and outside the OMPTO/OBPO. Additional duties include, but are not limited to:

- Identifying the need for and drafting and/or providing advice and comment on draft regulations that impact the domestic and import industries within the specialty area.
- Developing Agency policy relating to domestic and import program area issues through the preparation of option papers and the provision of advice and counsel to ORA and FDA Center management corresponding to biological drugs and developing new programs and initiatives that affect the domestic and imported industries of the specialty area.
- Leads teams of specialists and/or generalist consumer safety officers (CSOs/investigators) and analysts to accomplish highly complex projects or assignments. Defines and resolves major consumer safety problems encountered and as appropriate, develops and recommends alternatives to meet program objectives.
- Meets with hostile or uncooperative industry representatives to exchange information and to provide advice and guidance regarding those aspects of reviews/reports with emphasis on deficiencies. Advises field and ORA headquarters investigations and compliance management, FDA Center compliance management and specialists in the development and management of the most complex, controversial and precedent-setting regulatory cases involving specialty area program matters.
- Serves as an expert authority and provides expert advice and assistance particularly with regard to emerging and novel technologies and in state-of-the-art advances within the biological drug products area, including vaccines and cell and gene therapy.
- Provides technical consultation and guidance within and outside the Agency, to include enforcement officials, general counsel, regional and district offices, and State officials.
- Oversees and/or conducts technical inspections and investigations related to the most complex, controversial, and precedent-setting scientific and regulator problems involving industry practices and products within the area of biological drug products. Evaluates standards or criteria for adequacy in light of emerging technologies and changing needs and recommends new standards as appropriate.
- Maintains contacts with other federal, state, local and foreign regulatory agencies, trade and cooperative organizations, in an effort to achieve and maintain a uniform approach to the resolution of problems in the domestic, import and foreign industries and venues. Participates in inter-Agency meetings or conferences as an authority in biological drug products. Participates in meetings or conferences within the Agency to plan cooperative activities and devise concerted approaches to problems.
- Identifies training needs for federal, state, local and foreign regulatory agencies, and the biological products industry. Takes a leading role in development and presentation of training programs and materials within the biological drug specialty. Works with ORA's Division of Human Resource Development in the implementation of the investigator certification programs in the area of specialization.

Supervisory Responsibilities:

The CSO-NE position is not a supervisory role. The purpose of the work is to serve as an ORA/agency expert in a major functional regulatory OMPTO program area; specifically, within the biologics program area (e.g., biological drugs) of expertise, providing authoritative advice and assistance and resolution of critical or unusual problems. Using delegated authority, the incumbent independently develops regulatory strategies and proposes policy and policy changes and decides when to broaden

or narrow the scope of major activities, programs, initiatives, and projects, as the incumbent deems necessary. The incumbent provides administrative direction only and reports to a Supervisory Consumer Safety Officer.

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 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 (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: 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 each occupational series of interest 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:

- Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Advanced knowledge of Medical Products (biological drugs and devices) inspections and investigations.
- Expert knowledge of inspectional and investigative techniques within the functional program areas of expertise including evidence development, case preparation and report writing for a broad range of operational schemes, and the skill to recognize, apply and adapt the appropriate methods.
- Skill to conduct inspections, remote regulatory assessments and investigations related to the most complex, controversial, and precedent setting scientific and regulatory problems involving industry practices and products within the specialty areas.
- Demonstrated knowledge of written and verbal communication practices and principles to prepare and present reports, findings, and recommendations.

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.

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 on the basis of race, color, religion, gender identity and sexual orientation, 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 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

Applications will be accepted by all qualified applicants. Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, redacted SF-50 (for current federal employees), and college transcripts (with foreign credentials evaluation if applicable) to the ORA Executive Recruitment Team at:

ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through July 18, 2023. Please reference Job ID: **5-CSO-NE-BPOS-OBPO-D** in the email subject line.

Announcement Contact

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

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FDA is an equal opportunity employer.