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 Pharmaceutical Quality Operations (OPQO)
Division of Foreign Pharmaceutical Quality Inspections (DFPQI)
Foreign Pharmaceutical Quality Inspection Branch I and II (FPQIBI & FPQIBII)
Consumer Safety Officer – International (CSOI)

Application Period: June 21, 2022 to July 5, 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: Consumer Safety Officer – International (CSOI)

Series: AD-0696

Location(s): US, Determined upon selection

Salary: Starting at $126,233

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: Up to 50-75% travel

Bargaining Unit: 3591

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 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 Pharmaceutical Quality Operations (OPQO) is specialized to help protect and promote the safety and quality of human and animal products. This program, within the Office of Medical Products and Tobacco Operations (OMPTO) in the ORA, provides advice and counsel to ORA and FDA leaders regarding pharmaceutical products, field operations, and emergency response activities. OPQO collaborates with the agency's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM) on all FDA-regulated pharmaceutical and biopharmaceutical products. The Division of Foreign Pharmaceutical Quality Inspections (DFPQI) oversees the Foreign Drug Cadres. DFPQI serves as subject matter experts on foreign operations relative to the pharmaceutical quality program on internal cross-Agency committees, workgroups, and task forces. The Foreign Pharmaceutical Quality Inspections Branch (FPQIB) is responsible for inspecting and conducting remote regulatory assessments of foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collecting samples for analysis, performing field examinations, and preparing reports.

Duties/Responsibilities

The Consumer Safety Officer – International (CSOI) serves as a foreign and national authority in inspectional and investigative techniques within multiple functional areas, with an intensive awareness of current and emerging technologies. The CSOI provides guidance on FDA regulations and procedures to foreign competent authorities, foreign government inspectors/investigators and presents the most authoritative recommendations, assures consistent and coordinated policy development and implementation, ensures consistency, uniformity, and fairness in the application of law and regulation, and develops innovative ways of conducting business. Additionally, the CSOI is responsible for the following:

- Provides inspectional, investigational/technical advice, guidance, training and assistance to foreign competent authorities, foreign government inspectors and investigators, ORA HQ, CDER, CVM, foreign regulatory industry, and entities when requested.
- Gathers information on the foreign regulated industry preventive controls and industry practice to better inform DFPQI and domestic CSOs involved in foreign inspection activities.
- Serves as a Senior Level CSOI and is a field resource in conducting foreign inspections/investigations and remote regulatory assessments of the commodities regulated by the FDA.
- Identifies the need for a policy draft, and provides technical advice, counsel, leadership, and comment in the drafting of ORA policies and practices impacting pharmaceutical facilities and any related compliance activities.
- Participates in inter-Agency meetings or conferences as a specialist in specialty area involving broad policies and issues.
- Develops and recommends new and revised guidelines for investigative techniques and proposes areas of study for new and revised policy and guidelines as related to ORA investigations.

Supervisory Responsibilities:

This position is not supervisory. The CSOI serves as a senior level CSO and is a field resource in

conducting foreign inspections/investigations and remote regulatory assessments of the commodities regulated by the FDA. The CSOI serves as an advisor for DFPQI and ORA management in the areas of assigned responsibility.

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.

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.

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:
Individual Occupational Requirements
Basic Requirements:

Applicants must meet one of the following requirements.

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

   The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

or

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience 6 or additional education.

Specialized Experience:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. Examples of specialized experience include independently carrying out routine investigations, inspections, sampling, documenting, and organizing evidence, data, and other information to support violations, and assisting higher level employees in the review and evaluation of inspection reports of products or establishments.

- Expert knowledge of ORA's portfolio of services, internal policies, and procedures.
- Knowledge of ORA administrative concepts, principles, and practices.
- Skill in identifying problems, analyzing data, making recommendations, and implementing corrective actions.
- Expert in evaluating data and evidence; assessing policy and regulatory issues; interpreting and implementing existing laws, regulations, and guidance; and conducting and directing highly technical, complex, and multi-faceted inspections.
- Knowledge and skill in applying the consumer safety concepts, principles, theories, practices and procedures in a scientific field, such as chemistry, biology, pharmacology, or food technology to serve as an agency authority and Foreign Investigational Expert.
- Ability to communicate effectively orally and in writing.

Desired Education: Advanced degree

Desired Professional Experience:

- The incumbent Is capable of leading teams of specialists, Consumer Safety Officers, analysts and/or Center personnel to accomplish highly complex projects and assignments.

- The incumbent has the expertise to conduct inspections, remote regulatory assessments and investigations related to the most complex, controversial, and precedent setting scientific and regulatory problems involving foreign industry practices and products within the specialty areas.
- Expert knowledge of inspectional and investigative techniques with the regulation of the international industries 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.

Position requirements:

- This position requires the incumbent have the following current License and/or Certification: Valid U.S. driver's license.
- This position requires 50% to 75% travel. It is expected that 75% to 100% of the incumbent's operational time is spent conducting inspections in the international arena.

Physical demands:

- The work is both sedentary and, physical as the incumbent conducts inspections and investigations. Foreign and domestic travel requires the ability to carry equipment, i.e., laptop computers, portable printers, camera, and reference materials through airports, bus, ferry, and train stations. The work may require specific, but common, physical characteristics and abilities, such as above average agility and dexterity. Incumbent will be exposed to working long working hours greater than 8-hour days and unscheduled hours; exposure to all kinds of extreme weather and noise, lifting heavy objects such as luggage up flights of stairs, train platforms, airport, and ferry ramps; frequent walking, standing, and bending; and adjusting to unforeseeable scheduling demands, flight, bus, ferry, and train delays, cancelled flights, and agency priorities. International travel during a single trip will include multiple hotels, international time zones, and may exceed 21 days.

Work environment:

- The position involves working in foreign countries where living, working, and travel conditions and public health practices and procedures may be inadequate. International and in-country travel may expose the incumbent to additional hazards. The incumbent may be required to perform assigned inspections in remote areas. The incumbent may be exposed to extremes in climate and hazardous work environments, i.e., exposure to extreme hot and cold as well as humid climates, air pollution with certain countries and diseases. The incumbent will generally reside at a hotel and work in a pharma manufacturing facility during the day. The work involves moderate risks and discomforts that require special safety precautions, i.e., working around moving parts of machinery, carts and tracks; exposure to contagious diseases, irritating chemicals, and working at great heights under extreme outdoor weather conditions. During inspections there is potential for exposure to hazards involved in a manufacturing setting. The use of safety equipment is required including personal protective equipment (PPE) that includes lab coats, safety shoes, and head protection.

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 or curriculum vitae and bibliography, 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 **July 5, 2022**. 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”. For questions, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov. Please reference **CSOI Band D** in the email subject line.

Announcement Contact

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

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