**Title 21 Vacancy Announcement**
**Department of Health and Human Services (HHS)**
**Food and Drug Administration (FDA)**
**Office of the Commissioner (OC)**
**Office of Policy, Legislation and International Affairs (OPLIA)**
**Office of Global Policy and Strategy (OGPS)**
**Office of Global Operations (OGO)**
**China and India Office**

**Application Period:** December 21, 2023 to January 19, 2024

**Area of Consideration:** United States Citizenship is required. You must be a U.S. Citizen or U.S.

**Position:** Regulatory Specialist

**Series:** 0696

**Location:** Beijing, China and New Delhi, India

**Salary:** Starting at $112,015

**Work Schedule:** Full Time, Temporary/Term NTE 2 or 3 years, with a possible extension to 6 years.

**Cures Band:** Band C

**Full Performance Band Level:** Band C

**Travel Requirements:** 25%

**Bargaining Unit:** 8888

**Relocation Expenses Reimbursement:** You may qualify for reimbursement of relocation expenses in accordance with agency policy.

**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 Office of Policy, Legislation, and International Affairs (OPLIA), Office of Global Policy and Strategy (OGPS) plans, directs, manages, and coordinates a comprehensive international program for the Food and Drug Administration (FDA). This position is located within OGPS' foreign post and is a field resource in conducting foreign inspection/investigations of the commodities regulated by the FDA. The Regulatory Specialist serves as an expert in the Foreign Field Office in the specialty area of Human and Veterinary Drugs and Bioresearch Monitoring.

## Duties/Responsibilities

- Plans, coordinates, and conducts inspections and investigations with numerous complications, where timeliness, skill, and tact are critical.
- Makes recommendations on new inspectional approaches and methodologies; the extent and seriousness of violations; and the acceptability of voluntary corrective

actions.

- Provides information and guidance to foreign government counterparts or entities, U.S. Federal Agencies, private industry, and universities on unique and complex regulatory issues.
- Inspects new or unusual commodities and manufacturing practices, and devises needed innovations, approaches, methodologies, and modifications.
- Prepares correspondence, technical reports, estimates, fact sheets, status reports, and schedules to complete project assignments.
- Independently acts upon a full range of violations, including those involving emergency situations, lack of precedents or guidelines, ambiguous or dubious evidence, and/or uncooperative industry officials.
- Develops formal training programs that provide training and instruction to agency employees and State and local government personnel regarding inspection and investigative techniques; regulatory policies, standards, and requirements; and other compliance and enforcement matters.
- Serves as a foreign post focal point in conducting investigations of the most complex, controversial, and precedent setting scientific and regulatory problems involving industry practices and products within the specialty area.
- Provides expert technical guidance to management for strategic planning and program development.
- Serves on working groups to develop critical guidance for industry pertaining to the manufacture of FDA regulated products.

Supervisory Responsibilities: None

## 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 b2e registered with the Selective Service.
- One-year probationary period may be required.
- Position subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.
- 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.
- A Top-Secret Clearance is required for China.

- A Secret Clearance is required for India.
- This position is temporary and does not provide permanent placement upon completion or termination of the overseas assignment.
- Selectees for temporary/term assignments may begin and remain stateside until all required clearances and trainings (security, medical and applicable trainings) are completed before being deployed to an overseas location.
- A Statement of Understanding is required to be signed by the selected candidate indicating they understand the terms and conditions of this temporary appointment.

## 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 /Experience Requirement:** Applicants must meet one of the following requirements:

**Education:** A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

**OR**

**Experience:** Comparable regulatory experience or FDA regulated product lifecycle experience focused on enforcing and/or ensuring compliance with FDA laws and regulations or experience in one or more of the following:

- Knowledge of the FD&C Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates.
- Interpreting the statute, regulations, guidance, and other quality policies to assess compliance, quality, manufacturing performance, or quality management maturity.
- Product development, process development, scaleup, or commercial manufacturing.
- Sterility assurance and microbiological controls.

**Desired Education:** There is no desired education for this position. The education requirement above must be met for consideration.

**Professional Experience:** Experience performing, evaluating, and assessing analyses and results from inspections, and determining the nature of compliance violations; Initiating appropriate regulatory action and using various scientific and technical disciplines to carry out tasks related with compliance in one of the FDA's regulated-commodities.

**Desired Professional Experience:**

- Familiarity with the host country's products and services that fall under assigned areas of responsibility and ability to develop and maintain professional working relationships with key U.S., national, and international stakeholders.
- Experience conducting inspections investigations, and sample collection for violations.
- Representing the organization before large public and private organized groups and meetings as a technical expert in area of specialization.
- Providing information and guidance to foreign government counterparts or entities, U.S. Federal Agencies, private industry, and universities on unique and complex regulatory issues and matters.
- Experience serving as an instructor with responsibility for providing training and instruction to acquaint lower-level trainees, agency employees, foreign regulatory counterparts and regulated industry.

**NOTE:** For FDA employees under Title 21, Cures appointment, the Center/Office has the responsibility of determining a "comparable" position for the employee upon return if the position of record is backfilled during deployment. If there is no comparable Title 21 Cures position, it is likely that the employee will not be able to return to a Title 21 Cures appointment and will be returned under Title 5 at the appropriate grade, step and pay, if there is a comparable position under Title 5. The temporary assignments not-to-exceed 2 or 3 years but may be extended up to a total of 6 years.

## 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. 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.

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:

**Beijing, China: Top Secret Clearance** **New Delhi, India: Secret Clearance**

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 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 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

**Submit complete application package to Wahkeela.Hines@fda.hhs.gov by January 19,2024.**
**Applicants must show Job Reference ID: 24-T21OGPS-C and the location(s) in subject line.**

**Applicants must submit the following:**

**1.) Detailed Resume or Curriculum Vitae**

**2.) Must verify U.S. Citizenship in application email. Self-Declaration is acceptable.**

**3.) College Transcripts (if applicable)**

Candidate resumes may be shared with hiring official within the OGPS with a similar job vacancies. Candidates can opt out of this process by annotating resume with “do not share”.

## Announcement Contact

For questions regarding this position, please contact Wahkeela Hines, 301-796-7430, Wahkeela.Hines@fda.hhs.gov.

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