Job Title: Regulatory Specialist
Department of Health and Human Services (DHHS)
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

Summary:

The position is located in the Department of Health and Human Services (DHHS), 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) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.
At the Department of Health and Human Services (HHS) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

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 U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Office of Global Policy and Strategy (OGPS) is to protect and promote the public health of Americans by effectively advancing FDA's public health mission globally. OGPS performs foreign inspections, and provides executive oversight, strategic leadership, and policy direction on FDA's global engagements including information sharing, international standards development, trade relations, and collaboration activities with partner regulatory authorities or multilateral institutions. As evidenced in previous OIG, GAO, and media reports, OGPS has historically had difficulty recruiting and retaining candidates with appropriate skill sets, especially in foreign offices. Candidates who are

successful in positions with OGPS must possess not just a thorough understanding of FDA's regulatory system, processes, and procedures but also a comprehensive understanding of how partner regulatory agencies or multilateral institutions regulate medical products. To learn more about OGPS, please visit: https://www.fda.gov/about-fda/office-policy-legislation-and-international-affairs/office-global-policy-and- strategy.

Title 21 Band C
Minimum – **$117,962**
Maximum – **$164,260**

Open & Closing Date: September 19 – October 18, 2024
Salary Range: $117,962 - $164,260
Band: C
Occupational Series: 0696
Duty Location: Beijing, China and New Delhi, India
Remote Job: No
Telework Eligible: No
Travel Required: Up to 75%
Relocation Expenses Reimbursed: Maybe Authorized
Appointment Type: Temporary NTE 1 year and may be extended to 2 years; Term NTE 4 years and may be extended to 6 years
Work Schedule: Full Time
Competitive Service: *DO NOT CHANGE
Promotion Potential: No
Supervisory Status: None
Security Clearance: Beijing, China: **Top Secret** -- New Delhi, India: **Secret**
Drug Test: Yes
Position Designation: **Beijing, China:** Tier 5 Sensitivity/Risk: 3 - Critical-Sensitive / High Risk **New Delhi, India:** Tier 3 Sensitivity/Risk: 2 - Non-Critical Sensitive / Moderate Risk
Trust Determination Process: Yes

This job is open to: Open to the Public

Hiring Path Clarification Text: You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

- Plans, coordinates, and conducts inspections and in-depth investigations to ensure compliance with FDA laws, policies, and regulations.
- Makes recommendations on new inspectional approaches and methodologies.
- Provides supporting information and evidence regarding 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 academia on unique and complex regulatory issues.
- Conducts inspections of new or unusual commodities and manufacturing practices, and devises needed innovations, methodologies, and modifications to the inspectional approach.
- 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

Requirements

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.
- 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 Beijing, China.
- A Secret Clearance is required for New Delhi, India.
- Must verify U.S. Citizenship in application email. Self-Declaration is acceptable.
- 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.

  NOTE: For FDA employee 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 returned under Title 5 at the appropriate grade, step and pay, if there is a comparable position under Title 5. Temporary appointments are no more than 1 year and may be extended for an additional year. Term appointments are from 1 to 4 years may be extended to 6 years.

Qualifications

Basic Qualification Requirements: Applicants must meet one of the following requirements:

Minimum Years of Experience is the new standard, rather than specialized experience, for determining and validating a Title 21 candidate's band. This standard applies across all Title 21 positions.

Minimum Years of Experience required for Band C:

- Bachelor's – 4 Years
- Master's – 3 Years
- Doctorate and/or JD – 1 Year
- No Qualifying Degree – 6 Years

In order to qualify for the Regulatory Specialist which falls under the 0696 Series, you must meet the following requirements by 11:59pm EST on October 18, 2024.

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.

Desired Professional Experience:

- Proving 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.
- 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 and providing technical assistance and guidance to carry out tasks related to the compliance in one of the FDA's regulated commodities.
- Representing the organization before large public and private organized groups and meetings as a technical expert in area of specialization.
- 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.

Education

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 employee, you are not exempt from transcript requirements.

TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. You must submit an official transcript, unofficial transcript, or a list including courses, grades earned, completion dates, and quarter and semester hours earned. Transcripts must identify a degree type, date degree conferred, and identify the major if using education to meet basic degree requirements.

Education must be accredited by an accrediting institution recognized by the U.S. Department of Education in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Electronic Transcript Caution: If you have obtained your transcripts electronically, the file might contain security measures that could prevent our application system from reading the file. Therefore, you should consider asking the institution to provide the file in a non-secured electronic format. Alternatively, you could scan or take a photo of the printed copy of the transcript. If your uploaded transcript cannot be read by our system, you may receive consideration and credit for the information we can access.

See the Application Manager Documentation for tips on submitting your paper-based documents.

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 further information, visit the U.S. Department of Education website for Foreign Education Evaluation.***

To be acceptable, the foreign credential evaluation must include/describe at a minimum, the following information: (1) The type of education received by the applicant; (2) The level of education in relation to the U.S. education system, and state that its comparability recommendations follow the general guidelines of the International Evaluation Standards Council; (3) The content of the applicant's educational program earned abroad, and the standard obtained; (4) The status of the awarding foreign school's recognition and legitimacy in its home country's education system; and (5) Any other information of interest such as what the evaluation service did to obtain this information, the qualifications of the evaluator, and any indications as to other problems such as forgery.

Note: *Some positions require the completion of specific courses or a specified number of credit hours. Therefore, the foreign credential evaluation should provide information similar to that of an official transcript, to include a list of the courses taken, quarter and/or semester hours awarded, the cumulative grade point average (GPA), honors received, if any, date degree awarded.*

Applicants can request an evaluation from a member organization of one of the two national associations of credential evaluation services listed below:

1. National Association of Credential Evaluation Services (NACES)
2. Association of International Credentials Evaluators (AICE)

Credential evaluations are not free, and applicants are responsible for the cost of the selected service.

For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Additional Conditions of Employment:

- **Pre-employment physical required:** Yes
- **Drug testing required:** Yes
- **License Required:** No
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** 8888
- **Telework eligible position**: No
- **Incentives may be authorized;** however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.
- **Financial disclosure statement, OGE-450, required:** Please be advised that this position may be subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. Applicants are advised to seek additional information on this requirement from the hiring official before accepting this position.

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.

Additional Information:

- **Additional selections may be made for similar positions within the commuting area(s) of the locations listed through this vacancy announcement.**
- **If you are serving, or have served in the last 5 years (from** 12/01/2023**) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*

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 applicnats

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.

All requirements must be met by the closing date of this announcement October 18, 2024; only education and experience gained by this date will be considered. You must continue to meet all requirements throughout the entire hiring process.

How you will be Evaluated:

You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview; review of requested work samples, writing samples, most recent performance evaluation(s), or professional references; or results of an oral presentation or work-related test.
Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Please follow all instructions carefully. Errors or omissions may affect your eligibility.

How to Apply

Submit complete application package to Kimberly.Jones2@fda.hhs.gov by **October 18, 2024**.

Application must show Job Reference ID: **24-002T21OGPS-C** and the location(s) **China and/or India** 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 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 Kimberly Jones, 301-348-3922, Kimberly.Jones2@fda.hhs.gov.