



Job Title: International Science Policy Analyst
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)
Europe 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 E

Minimum – **\$163,964**

Maximum – **\$225,011**

Open & Closing Date: September 13, 2024 – September 27, 2024
Salary Range: \$163,964 - \$225,011
Band: E
Occupational Series: 0601
Duty Location: Amsterdam, Netherlands
Remote Job: No
Telework Eligible: No
Travel Required: Up to 25%
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: Secret
Drug Test: Yes
Position Designation: Tier 5 Sensitivity/Risk: 2 - Non-Critical Sensitive /High 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

- Serves as an agency representative and focal point at the European Medicines Agency (EMA) in support of FDA Directorates, Centers, and Offices, as well as with USG Agencies, and with regulatory counterparts, governments, multilateral and academic institutions and other relevant entities within the Europe Region. Represents the Agency with high-level EMA and European government representatives. Designs and conducts a wide variety of comprehensive studies and detailed analyses of complex functions and processes related to program planning and management. Identifies and proposes solutions to management problems that are of major importance to planning program direction.

- Represents the Agency with high-level EMA and European government representatives. When representing FDA or the Department, the incumbent speaks on behalf of the Commissioner, Deputy Commissioners, Associate and Assistant Commissioners, Center Directors, or other agency senior leadership.
- Leads, maintains, and strengthens strategic working relationships and knowledge networks with high-level foreign government officials and institutional leadership within EMA and the Europe region. He/she provides leadership and guidance to FDA officials in their engagement with foreign officials.
- Serves as an Agency expert who works proactively and strategically with senior policy-level officials and technical specialists at other U.S. agencies who work in medical product areas that impact FDA.
- Stays abreast of new developments at the EMA and in the Europe region by analyzing proposed legislation, new policies, and other materials, and preparing appropriate reports for use both locally in making determinations and in specific cases for transmittal to Headquarters.
- Works with the FDA Europe Office Director and Deputy Director in providing technical assistance and scientific leadership in directing the FDA presence and responsibilities in the Europe region. This includes, but is not limited to: (1) ensuring relevant and timely information exchange and analyses on medical product policy issues, regulatory science, and inspections between the FDA and EMA, as well as regulatory counterparts in the Europe region; (2) developing the necessary policy drafts, briefing materials for high level meetings, white papers, policy monographs, and creative strategies as key inputs for FDA regulatory decisions and actions; (3) landscaping trends in EMA regulatory science, EU regulatory policy, and more broadly European regulatory policy, clinical and scientific development, and industry manufacturing; (4) providing strategic advice to FDA at various levels on the EMA and European perspective and policies and the potential impact on or consideration toward FDA's work.
- Works strategically within EMA and, as needed, the Europe Region to contribute to, better align, strengthen, and maximize FDA efforts in sustainable ways.
- Stays abreast of new developments at the EMA and in the Europe region by analyzing proposed legislation, new policies, and other materials, and preparing appropriate reports for use both locally in making determinations and in specific cases for transmittal to Headquarters.

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 Secret Clearance is required for Amsterdam, Netherlands.
- 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 be 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

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 E:

- Bachelor’s – 6 Years
- Master’s – 5 Years
- Doctorate and/or JD – 3 Years
- MM/DO/DDS/DPM/DVM – 3 Years
- No Qualifying degree/HS or equivalent diploma/Associate’s Degree – 9 Years

In order to qualify for the International Science Policy Analyst which falls under the 0601 Series, you must meet the following requirements by 11:59pm EST on September 27, 2024.

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

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 Requirement: Bachelor’s or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

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

Professional Experience: Priority will be placed on candidates with relevant, experience involving the regulatory cycle and the review and evaluation of processes necessary for effective delivery of product approval/disapproval.

Desired Professional Experience:

- A strong candidate can readily provide authoritative medical information, conduct extensive studies analyses, manage cross-Agency coordination, and develop strategies for responding to and resolving complex issues of national and international interest and impact.
- Expert skill in planning and organizing the work of the regulatory review teams to accomplish a variety of concurrent activities performed among a variety of medical and scientific disciplines and across several organizations and to anticipate issues of mutual concern to FDA and regulatory authorities.

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:

Amsterdam, Netherlands: 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, 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.

All requirements must be met by the closing date of this announcement September 27, 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 Daren.Miles@fda.hhs.gov by **September 27, 2024**.

Application must show Job Reference ID: **24-T21OGPS-A** and the location **Netherlands** 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 Daren Miles, Daren.Miles@fda.hhs.gov.