Deputy Office Director
Supervisory Investigator
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Pharmaceutical Quality Operations (OPQO)

Summary:
The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA) Office of Medical Products and Tobacco Operations (OMPTO), Office of Pharmaceutical Quality Operations (OPQO) 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 Regulatory Affairs (ORA) 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 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), 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.

Title 21 Pay Table 1, Band F/>GS-15 equivalent
Minimum – $181,551
Maximum – $260,823

Overview

Open & Closing Date: August 28, 2024 – September 11, 2024
Salary Range: $181,551 - $260,823
Band: AD-F (>GS-15 equivalent)
Occupational Series: 0696
Duty Location: Various locations
Remote Job: No
Telework Eligible: Determined upon selection
Travel Required: Up to 25%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band F
Supervisory Status: This is a supervisory role
Security Clearance: Secret
Drug Test: Yes
Position Designation: Non-Critical Sensitive/High Risk /Tier 5/High Tier/SF 86
Trust Determination Process: Suitability/Fitness

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

The Deputy Office Director for Field Operations (DOD-FO or Deputy) assists the Office Director, OPQO and is empowered to exercise full authority in the absence of the Director. This involves the advancing of regulatory programs, promoting an understanding of FDA's responsibilities for enforcing regulatory standards to protect and promote public health, actions and activities related to FDA pharmaceutical inspection operations, and resolving complex technical and/or scientific questions and issues that arise. The Deputy, along with the Director, is directly responsible for providing leadership to employees who are engaged in inspectional and compliance activities related to the program area. The Deputy shares fully with the Director and Deputy Office Director (Strategic Oversight), in the facilitation of office staff coordination between multiple, smaller field divisions. As an advisor to the Director, the incumbent is expected to assist with development of inspectional and compliance related guidance; provide scientific and technical direction; advise and represent the Director; provide leadership to subordinates and oversight of operations; coordinate advanced training opportunities; serve as liaison/coordinator with field offices; and develop short/long term goals for the Center.

The DOD-FO participates fully with the Director in planning, managing, organizing, and directing all the field activities of the organization through subordinate supervisors and/or team leaders and a highly trained and skilled staff of professional supervisors and subject matter experts in a variety of professional, administrative, and support staff occupations organized into subordinate organizations. The incumbent shares the Director’s responsibility for assuring the efficient operation of the Office, including adequacy of on-the- job training, assignments, and performance of personnel. The Deputy provides oversight and technical guidance to programs and activities related to pharmaceutical field operations and inspections. In conjunction with the Director, the DOD-FO serves as the agency’s authoritative consultant and focal point for ORA and personnel of state, local, tribal, and international regulatory agencies in planning and implementing necessary efforts related to the pharmaceutical program. As delegated, the Deputy represents and speaks for the Director in meetings with agency and state officials in matters related to operations administered by ORA.

The Deputy Office Director represents ORA in joint development, monitoring, and the execution of the program work plan and, in consultation with the Director, negotiates on behalf of ORA any necessary adjustments required throughout the year. The Deputy monitors performance for adherence to plans and negotiates modifications to plans and agreements for ORA as needed and assures all impacted ORA parties are informed of changes in a timely manner. In consultation with the Director and other ORA leadership, the Deputy develops long-range

strategic, scientific, and tactical plans for specialization of ORA resources including inspectional staff and compliance staff to meet ORA's current and future needs.

Supervisory Responsibilities: Manages a functional discipline. The incumbent is required to: exercise delegated managerial authority to set a series of annual, multiyear, or similar types of long-range work plans and schedules for in-service or contracted work. The DOD-FO assures implementation (by lower and subordinate organizational units or others) of the goals and objectives for the program segment(s) or function(s) they oversee. The Deputy determines goals and objectives that need additional emphasis; determines the best approach or solution for resolving budget shortages; and plans for long-range staffing needs, including such matters as whether to contract out work. Additionally, the Deputy works closely with high level program officials (or comparable agency level staff personnel) in the development of overall goals and objectives for assigned staff function(s), program(s), or program segment(s).

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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. Please go to http://www.sss.gov for more information.
- One-year probationary period may be required.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- All applicants tentatively selected for this position will be required to submit to urinalysis to screen for illegal drug use prior to appointment and be subject to random, reasonable suspicion, and post-accident drug testing upon hiring. Appointment to the position will be contingent upon a negative applicant drug test result.

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. (Please use this Link for reference).

In order to qualify for the **Deputy Office Director** position which fall under the **0696 Series**, you must meet the following requirements by 11:59pm EST on **September 11, 2024.**

In order to qualify for **Deputy Office Director**, AD-0696, you must meet the following requirements:

Basic Qualification Requirements:

This Investigator job family covers professional positions that conduct inspections in FDA regulated industries and prepare and submit reports accompanied by supporting evidence documenting violations of the FD&C Act and other laws, regulations, and requirements administered by FDA. The position investigates and/or inspects FDA-regulated industry globally and evaluates compliance with U.S. laws and regulations in order to promote a culture of safety and quality with the objective of preventing unsafe, ineffective and/or defective products from becoming available to patients and consumers or used in clinical trials while facilitating appropriate development of novel products. FDA's enforcement of the laws and regulations protects patients and consumers from products that are impure, unsafe, ineffective, improperly, or deceptively labeled or packaged, or in some other way dangerous or defective. Investigators routinely examine products; collect samples; conduct inspections of establishments that design, make, process, hold, or distribute FDA-regulated products; and otherwise gather information and evidence to document objectionable conditions and assess compliance with U.S. law and regulations. Investigators apply critical thinking to evaluate manufacturing processes, design practices, facility and material controls, supply chains, quality management systems, laboratory analyses, and clinical investigation programs to assess compliance with U.S. laws and regulations and to support advancements and innovations. Investigators continuously maintain required certification and credentials; provide internal and external stakeholder outreach, assistance, and education; and may mentor less experienced personnel. These positions require knowledge of various scientific fields such as biochemistry, biology, biotechnology, chemistry, data science, digital health, engineering, epidemiology, food engineering, food processing technologies, food safety, healthcare, medical technology, microbiology, nutrition, pharmaceutical science, pharmacology, public health, quality assurance, and quality management.

Education/Experience Requirement: Candidates must meet the following:

> **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.

To qualify for Band F, candidate must have:

- A bachelor's degree and (7) years of comparable experience; or
- A master's degree and (6) years of comparable experience; or
- A Doctorate and/or J.D. or higher (MD, DO, DDS, DPM, DVM) and (4) years of comparable experience.

OR

Experience: To qualify for Band F without a bachelor's degree, the candidate must have at least 11 years of comparable experience.

Comparable experience is defined as experience with FDA, a state or federal partner agency, or in an FDA-regulated industry or organization providing investigative or compliance services to an FDA-regulated industry, focused on evaluating or ensuring compliance with FDA or related public health laws and regulations.

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-secure 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:** No
- **Drug testing required:** No
- **License Required:** Yes, driver's license.
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** 8888
- **Telework eligible position**: Telework is at the discretion of the supervisor.
- **Remote 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 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.**
- **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.

- **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.*

All requirements must be met by the closing date of this announcement: September 11, 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

Applications will be accepted by all qualified applicants. United States Citizenship is required. Applicants must submit a detailed current resume, and college transcript(s) showing degree was awarded (with foreign credentials evaluation if applicable). A diploma will not be accepted as part of your application. All required materials should be sent to:

ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through September 11, 2024.

IMPORTANT: Applicants must reference: **4-OPQO-DOD-FO-F** in the email subject line.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAExecutiveandScientificRecruitment@fda.hhs.gov and include the following job reference ID in the subject line: **4-OPQO-DOD-FO-F-Q**