Senior Investigator II
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 Biological Products Operations (OBPO)
Division of Biological Product Operations I & II (DBPOI & DBPOII)
Biological Products Inspection Staff

Summary:
The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA) 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 Medical Products and Tobacco Operations (OMPTO) oversees four program directors in the coordination, interpretation, and evaluation of the Agency's overall field inspections and compliance efforts in the areas of medical products and tobacco. OMPTO is led by an Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) who reports directly to the Associate Commissioner for Regulatory Affairs.

The Office of Biological Products Operations (OBPO) provides advice and counsel to the ACMPTO and other Agency leaders relative to biological products field operations and emergency response activities, including all biological products regulated by the Center for Biologics Evaluation and Research (CBER). Responsibilities include biological product investigative activities; policy development; monitoring emerging technology advancements; evaluating program activities and recommending improvements. The office also oversees the agency's special medical programs, interprets and evaluates FDA's field inspections and compliance efforts in the areas of emerging technologies, and initiates action to improve the management of global biological drug product field activities.

Title 21, Band C, Pay Table 1

Minimum – **$117,962**
Maximum – **$164,260**

Overview:

Open & Closing Date: August 27, 2024 through February 27, 2025
Salary Range: $117,962 - $164,260
Band: AD-C (GS-13 equivalent)
Occupational Series: 0696
Duty Location: Various Locations
Remote Job: No
Telework Eligible: Yes
Travel Required: Yes, up to 50%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band C
Supervisory Status: No
Security Clearance: N/A
Drug Test: No
Position Designation: Non-Sensitive / Moderate Risk / Tier 2 / Moderate Tier
Trust Determination Process: Suitability/Fitness

This job is open to: The public.

Hiring Path Clarification:
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 incumbent of this position is responsible for conducting investigations and inspections of domestic and foreign manufacturers of licensed biological drugs and devices and represents a specialty level responsible for providing technical assistance and expert investigational guidance to the biologics program in areas of biotechnological principles and techniques used in manufacturing biological products and enforcement.

Inspections and Investigations
• Serves as an expert and independently conducts complex, technical investigations and inspections of establishments in the assigned area of responsibility (e.g., domestic and international biological drug and device establishments) requiring special abilities and skills to effectively deal with people and to negotiate in sensitive situations arising in highly complicated assignments.
• Assignments cover the most complex and high-profile inspections where new or unusual features are present. The inspection or investigation may result in considerable attention and review in the media, Congress, or other forces inside or outside the Agency.
• Inspections cover all the types of products and problems within the area of assigned responsibility. Investigates and evaluates the adequacy of complex manufacturing practices to determine compliance with GMP regulations. Interacts and engages with a wide range of biologics stakeholders to advance mutual understanding of biotechnology operations, regulatory compliance, guidance applications, and other related initiatives.
• Provides policy and program advice to the Center and the greater FDA in response to evolving policy, emergencies, regulatory follow-up investigations, education/outreach programs, and risk-based research needs for biotechnological products. Provides advanced technical advice to management on the risk and prioritization for inspection of biologic facilities.
• Prepares memoranda, briefings, and other background material concerning substantive issues, findings, conclusions, and proposed solutions to keep the Director and appropriate staff involved at key decision points. Research involves reviewing reports and publications for relevant information; and organizing, analyzing, and summarizing information.

Reporting and Analysis
• Independently performs investigations involving complaints of injury or death attributable to products regulated by the FDA.
• Plans and decides how investigations should proceed, when the investigation is complete, and what reporting is required. May be assigned to long term investigations and grand juries with only limited oversight from the supervisor; may serve as an expert witness in court on circumstances relative to the way evidence was collected during inspections and/or investigations; may be designated as the lead Agency representative of multi-agency/multi-organization investigations; and is assigned to either assist or directly monitor or manage compliance programs for inspection programs.
• Provides timely and accurate feedback to Division and Office management as well as effective guidance to other division staff assisting in the investigations. The incumbent is often consulted on and participates in the formulation and development of inspectional and investigational procedures and techniques to problems within his/her area(s) of expertise.

Leadership and Guidance
• Provides guidance to less experienced staff on the tasks and responsibilities regarding technical and scientific matters, inspectional/investigational issues, policies, and laws affecting the biologics program area.
• Serves as a principal advisor of regulatory and compliance matters, responsible for planning, coordinating, and evaluating programs and activities for a professional regulatory field. Prepares and presents informal remarks at briefings, training sessions, consumer, and industry workshops, etc. In collaboration with local biologics partners, develops, plans, and executes appropriate outreach sessions and/or trainings for local stakeholders in consultation with national experts.
• Conducts on-the-job training in complex inspections of foreign and domestic firms falling within their area of expertise(s) and is frequently accompanied by another investigator of lesser experience to provide a training opportunity to that investigator to broaden their expertise. Serves on task forces and study groups charged with considering problems or directions in the area of biologics; consults with staff members at all levels of the organization to achieve consensus on issues and resolve any disagreements on standards.
• Represents the Agency on inter-agency review committees charged with reviewing Federal policies and making recommendations for consistency across agency lines and is a member of the international inspection cadre and conducts inspections of both domestic and international biologics operations.
• Represents the Agency with industry representatives, to exchange information and to provide advice and guidance regarding those aspects of the application, notice, amendment, supplement, or report which fall within area of review with emphasis on deficiencies.

Supervisory Responsibilities: This is a non-supervisory role.

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.
- 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 later.

- This position requires the incumbent to have the following current License and/or Certification: Driver's License required.
- This position requires up to 50% travel.
- 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.

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.

In order to qualify for the **Senior Investigator II** position which falls under the **0696 series**, you must meet the following requirements by 11:59pm EST on **February 27, 2025.**

In order to qualify for a **Senior Investigator II** position, **AD-0696,** you must meet the following requirements:

Basic Qualification Requirements:
This 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: 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.

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 the Band C, candidate must have:

- A bachelor's degree and (4) years of comparable experience; or
- A master's degree and (3) years of comparable experience; or
- A Doctorate and/or J.D. and (1) year of comparable experience; or
- An MD, DO, DDS, DPM or DVM and no additional comparable experience.

OR

Experience: To qualify for Band C without a bachelor's degree, you must have at least six (6) 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.

Desired Education: An advanced degree.

Desired Professional Experience:

- Mastery of various scientific and technical disciplines to carry out tasks related to the regulation of 1) the biologic industry including production of plasma fractionation products, cellular and gene therapies, recombinant proteins, vaccines, and in-vitro products; and 2) the related laboratory test instrumentation, computer systems, and software development and maintenance.
- Advanced and detailed knowledge of biotechnology facilities and the biotechnical industry combined with comprehensive knowledge of biotechnology, aseptic technique processes, sterilization processes, CGMP, advanced manufacturing, lyophilization processes and biotechnology products and medical devices manufacturing.
- Advanced scientific knowledge of biological technologies, products, new programs, laws, and regulations, significant court decisions, new trends or scientific findings involving biological products coupled with in-depth knowledge of related Inspection and Investigation techniques and approaches and expertise in developing evidence when situations are encountered that may result in regulatory action.
- Leadership skills sufficient to coordinate a team project by providing technical oversight and direction for a variety of principal team members representing related professional disciplines, and evaluate and present plans, designs, reports, and correspondence concerning projects and product issues.

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:** No.
- **Drug testing required:** No.
- **License Required:** Yes. Valid U.S. driver's license.
- **Mobility agreement required:** No.
- **Immunization required:** No.
- **Bargaining Unit:** This is a bargaining unit position.
- **Telework eligible position**: Telework is at the discretion of the supervisor.
- **Remote eligible position for highly qualified candidates at the discretion of the supervisor.**
- **Incentives:** Incentives may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 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.

- 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.*

- Applicants selected for this position will be subject to reasonable suspicion and post-accident drug testing upon hiring. To demonstrate commitment to the HHS goal of a drug-free workplace and to set an example for other Federal employees, employees not in a testing designated position may volunteer for unannounced random testing by notifying their Drug-free Federal Workplace Program Point of Contact upon hiring.

All requirements must be met by the closing date of this announcement February 27, 2025; 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 **February 27, 2025**, or until all positions have been filled.

Applicants must reference: **5-OBPO-Sr.Inv.III** in the email subject line.

NOTE: It is your responsibility to ensure the job ID is noted in the subject line and the appropriate documentation is submitted prior to the closing date for your application to be considered.

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: **5-OBPO-Sr.Inv.III.**

The Department of Health and Human Services is an equal opportunity employer with a smoke-free environment.

FDA is an equal opportunity employer.