Investigator II (Band A) / Senior Investigator I (Band B)
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 Bioresearch Monitoring Operations (OBIMO)

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 Bioresearch Monitoring Operations (OBIMO) 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 FDA's Office of Bioresearch Monitoring Operations (OBIMO) is the lead office for conducting inspections and investigations of clinical and nonclinical research performed in support of marketing applications for regulated products, as well as post marketing adverse drug experience reporting and risk evaluation and mitigation strategies for approved products. OBIMO works with all six product centers to develop policies on compliance and enforcement and is responsible for the following: Inspecting foreign and domestic bioresearch monitoring establishments for which FDA has regulatory responsibility, collecting samples for analysis, and preparing reports. These establishments include sponsors, clinical investigators, institutional review boards, and nonclinical laboratories. OBIMO evaluates inspectional and/or analytical findings relative to compliance and recommends appropriate follow-up. OBIMO is responsible for preparing and providing evidence of investigational findings. OBIMO provides dedicated inspectional and investigational support to Headquarters and other divisions, as needed. OBIMO advises ORA and other centers on emerging inspectional, scientific, and regulatory issues related to FDA regulated products. Additionally, OBIMO provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

Title 21 Pay Table 1, Band A/GS-11 equivalent & Band B/GS-12 equivalent
Minimum – Band A: $82,764; Band B: $99,200
Maximum – Band A: $109,506; Band B: $133,845

Overview

Open & Closing Date: August 14 – September 4, 2024, or until all positions have been filled.
Salary Range: $82,764–$109,506 (Band A) or $99,200–$133,845 (Band B)
Band: AD-A (GS-11 equivalent) or AD-B (GS-12 equivalent)
Occupational Series: 0696
Duty Location: Little Rock, AR; Columbus, OH; Oklahoma City, OK; Pittsburgh, PA, Dallas, TX; Falls Church, VA
Remote Job: No
Telework Eligible: Determined upon selection
Travel Required: Up to 50%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent

Work Schedule: Full Time
Competitive Service: *DO NOT CHANGE
Promotion Potential: Yes, Band B
Supervisory Status: No
Security Clearance: No
Drug Test: No
Position Designation: Non-Sensitive/High Risk/Tier 4/High Tier/SF 85P
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 Investigator II (Band A) / Senior Investigator I (Band B) has demonstrated and is recognized for a high level of competence in the full range of establishments regulated within the OBIMO program such as: clinical investigators, nonclinical laboratory facilities, sponsors, contract research organizations, institutional review boards, post marketing adverse drug experience reporting, and risk evaluation and mitigation strategies.

Assignments involve a combination of scientific and regulatory responsibilities which usually call for several atypical inspectional or intensive investigative approaches to be applied to a wide variety of regulatory functions or scientific evaluations; and include the most difficult and complex sample collections, establishment inspections, unusual or novel special investigations and conducting objective surveys and emergency activities within the assigned area of responsibility. The Investigator II will also perform international inspections.

Inspections and Investigations

- Assignments cover large, medium, and small firms, complex investigations and inspections of various industry establishments covered by the program such as: clinical investigators, sponsors, contract research organizations, institutional review boards, nonclinical laboratories, post marketing adverse drug experience reporting, and risk evaluation and mitigation strategies. The Investigator II independently conducts inspections, investigations, and sampling where new or unusual features are present, only limited guidance documents are available; proposed or new regulations must be used to evaluate the industry; or the inspection or investigation may result in considerable attention and review in the media, the Department, Congress, or other forces inside or outside the Agency. Inspections cover all types of products and problems within the area of assigned responsibility.

- Investigates and evaluates the adequacy of complex practices to determine compliance with the regulations.
- Incumbent interacts with and advises various levels of officials representing the establishments subject to regulatory review. The incumbent initiates contact with industry officials to obtain information on regulatory and scientific documents and to discuss the status of investigations.
- Assists the immediate supervisor in planning inspections, investigations, sample collections, and related activities in the area of assigned responsibility; training new personnel and higher graded personnel, as appropriate; training foreign government personnel. Developmental assignments include assisting higher level employees in inspections or other field activities, meetings, and conference calls with regulated industry.
- Incumbent conducts re-inspections to follow up with non-compliant industry establishments on previously noted violations. In situations where compliance is not offered, it is enforced through other methods, including administrative action, informational agency meetings, and legal court actions.

Analysis and Reporting

- The Incumbent will perform analyses and evaluation on data samples and documented information gathered during inspections and investigations to ensure that documentation and practices are in compliance with Federal laws, rules, and regulations. Documents and organizes required evidence, data, and other information to support violations noted during inspections, investigations, and sample collections.
- Incumbent gathers scientific and technical comments from team members, assists with the preparation of reports relevant to the inspection, and contributes to status reports for inspections and investigations under review.
- Prepares final reports, position papers and other written documentation that support investigative findings and recommendations. Reports are developed and well-written in accordance with quality elements.

Supervisory Responsibilities: This is not a 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 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.
- Candidates for this position must complete a statement regarding their physical ability and may be required to undergo physical examination because the position requires:
    - the need to work long and unscheduled hours.
    - exposure to all kinds and extremes of weather and noise.
    - the need to lift heavy objectives up to 50 pounds; walk, bend, stand, stoop, kneel, and climb.
    - the need to meet the vision, hearing, and olfactory requirements necessary to perform the work of this position.
- Travel approximately 50 percent of the time, which will often require the incumbent to be away (e.g., travel) from the duty station for up to two to three weeks at a time.
- The work involves regular and reoccurring exposure to moderate risks, discomforts, and unpleasantness such as:
    - contagious diseases
    - infectious materials, or toxic or irritating chemicals
    - carcinogenic materials
    - noxious fumes
    - flammable liquids
    - radiation, and/or
    - potentially pathogenic bacteria.
- Special safety precautions such as protective clothing and equipment may be necessary.
- While some work is performed in an adequately lighted and climate-controlled office, onsite investigations and inspections may involve exposure to moderate risks or discomforts such as high levels of noise, dust, moving parts of machinery, irritant fumes, etc. Protective clothing and gear, and observance of safety precautions are required.
- Inspection and sample collection duties are performed either inside buildings and other structures, outdoors, or both depending on the type and location of the facility. Consequently, employees are exposed to a variety of environmental conditions including extremes of heat, cold or humidity; excessive noise; excessive dust; uneven surfaces and slippery floors; and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, etc. During these periods, employees must eat

and sleep in primitive conditions with little or no privacy. The incumbent must travel into and work in areas that have been the subject of violence and that are otherwise considered unsafe.
- This position requires the incumbent to possess a valid Driver's License to drive a government/privately owned motor vehicle.

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 **Investigator II** or **Senior Investigator I** positions which fall under the **0696 Series**, you must meet the following requirements by 11:59pm EST on **September 4, 2024.**

In order to qualify for an **Investigator II** or **Senior Investigator I**, 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 A, candidate must have:

- A bachelor's degree and (2) years of comparable experience; or
- A master's degree and (1) year of comparable experience; or
- A Doctorate and/or J.D. or higher with no experience.

To qualify for the Band B, candidate must have:

- A bachelor's degree and (3) years of comparable experience; or
- A master's degree and (2) years of comparable experience; or
- A Doctorate and/or J.D. or higher and (1) year of comparable experience.

OR

Experience: To qualify for Band A without a bachelor's degree, the candidate must have at least 4 years of comparable experience. To qualify for Band B without a bachelor's degree, the candidate must have at least 5 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: Advanced Degree.

Desired Professional Experience:

- Knowledge and skill in applying a wide range of complex professional theories, concepts, principles, standards, and methods to determine, execute, and explain actions that modify standard practices, equipment, devices, processes, and well-known techniques and resolve a wide variety of complications and constraints contained in traditional projects.
- Skill to adapt precedents and existing strategies which allow occupational projects to meet unusual needs or demands and serves as a principal contributor for the assigned specialty areas on team-based projects.

- Ability to coordinate a team project by providing technical oversight and direction for a variety of principal team members representing related professional disciplines, and evaluates and presents plans, designs, reports, and correspondence concerning projects and product issues.
- Knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques to conduct complete and professional inspections and investigations, persuade reluctant persons and officials to provide information or access to information, and persuade industry representatives to agree to terms needed to achieve compliance.
- Skill in planning and carrying out assignments, resolving most conflicts that arise, coordinating the work with others as necessary, and interpreting policy on own initiative in terms of established objectives. In some assignments, the employee also determines the approach to be taken and the methodology to be used. The employee keeps the supervisor informed of progress and potentially controversial matters.
- Ability to apply judgment in interpreting and adapting guidelines, such as agency policies, regulations, precedents, and work directions for application to specific cases or problems. The employee analyzes results and recommends changes. Skilled in making decisions to assess unusual circumstances, variations in approach, and incomplete or conflicting data.

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; valid driver's license**
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** National Treasury Employees Union (NTEU), 3591
- **Telework eligible position**: Telework is at the discretion of the supervisor.
- **Remote eligible position:** No
- **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.*

- 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: September 4, 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: ORAInvestigatorHiring@fda.hhs.gov. Applications will be accepted through September 4, 2024, or until all positions have been filled.

IMPORTANT: Applicants must reference: **8-INV-OBIMO-A/B-name of preferred location(s)** in the email subject line.

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

Announcement Contact

For questions regarding this T21 position, please contact ORAInvestigatorHiring@fda.hhs.gov. and include the following job reference ID in the subject line: **8-INV-OBIMO-A/B-Q**.