Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Regulatory Science (ORS)
Office of Human and Animal Food Laboratory Operations (OHAFLO)
Irvine Human & Animal Food Laboratory (IRVLHAF)
Chemist (Advanced Analyst)

Application Period: December 8, 2023 – March 18, 2024

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Chemist (Advanced Analyst)

Series: AD-1320

Location(s): Irvine, CA

Salary: Starting at $117,962

Work Schedule: Full Time

Title 21 Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: Up to 25% travel is required.

Bargaining Unit: This is a bargaining unit position.

Hiring Incentives: 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 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with the FDA, Title 21 Policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

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 United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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 Regulatory Science (ORS) provides strategic leadership, coordination, and expertise to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy Associate Commissioner for Regulatory Affairs (DACRA) and other ORA senior leaders on scientific issues related to policy and regulations.

The Office of Human & Animal Food Laboratory Operations (OHAFLO) advises the ORS on scientific issues related to human and animal food laboratory operations and provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning the Food and Drug Administration (FDA) regulated products, including their evaluation, quality, safety, and effectiveness.

Duties/Responsibilities

The Chemist (Advanced Analyst) serves as an analytical instrumentation specialist within the Irvine Human and Animal Food Laboratory (IRVLHAF) where they are recognized as the expert, technical authority, and resource person in this specialization. Examples of highly technical chemistry instrumentation include—but are not limited to: Liquid or Gas Chromatography with Tandem Mass Spectrometry (LC-MS/MS)/ triple quadrupole mass spectrometer (QQQ), High-performance liquid chromatography (HPLC, Mass Spectrometry (MS), and Electron Microscopy

(EM).

Conducts sample analysis using approved analytical procedures in various areas of agency concern to identify and quantify contaminants and adulterants in FDA-regulated products. Formulates and conducts research that evaluates new chemistry instrumentation and its applicability to the required analyses. Plans and performs the development of analytical methods in accordance with FDA needs and priorities, which requires a strong understanding of the ISO 17025 accreditation, Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics and Veterinary Products and per local Standard Operating Procedure. Performs verifications and validations of new chemistry methods.

Serves as a technical expert and scientific advisor in the specialty area of chemistry instrumentation and analytical software applications. The incumbent is responsible for addressing methodology problems encountered by other ORA field professionals. Troubleshoots instrumentation issues and problems that arise when evaluating data such as contamination control, poor sensitively, reasons for Quality Control failures, incomplete extraction, and other method performance problems. Participates in internal planning to make recommendations to management related to the future needs of the laboratory such as new analytical instruments and methods of analysis.

May be required to organize and present seminars and training sessions on specialized chemistry instrumentation and technical areas specifically related to analytical methods and research. As needs dictate, training may be given at any FDA location. Training may be provided to visiting foreign scientists, other Federal, state, and local government agencies as well as FDA personnel. May participate in interagency programs in training and quality assurance that involves area of specialty. Writes professional reports of findings and offers them for publication in recognized scientific journals and in-house bulletins. When requested, reviews methods to be used by the agency in the United States Pharmacopoeia and other compendia, and the scientific papers offered by other scientists for publication and judges the level of their contribution to present knowledge in specialty area and their suitability for publication. Testifies in court as an expert witness in specialty field.

Supervisory Responsibilities: This is not a supervisory role.

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.
- 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.

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Title 21 appointments. The FDA OTS will use the basic requirements defined in the Title 21 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.

To qualify for this Title 21 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: Candidates must possess a bachelor's degree or higher in chemistry, biochemistry, or molecular/cellular biology. The degree must be from an accredited program or institution.

Additional Requirements:

- This position requires up to 25% travel.
- The work requires some physical exertion, while working in labs such as, recurring bending, crouching, stooping, stretching, reaching, or similar activities while wearing protective clothing and gear.
- Work environment involves regular and recurring exposure to irritant chemical and biological hazards, toxic and flammable solvents, high voltage electronic equipment and in some cases intense electromagnetic radiation. Special precautions may be required,

and the scientist may be required to use protective clothing and gear such as a laboratory coat, safety glasses, gloves, mask, etc.

Desired Education: Advanced degree.

Desired Skills and Professional Experience:

- Master and skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply experimental theories and new development applications to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques.
- Mastery of the principles, theories, and practices of a specialized instruments for the chemical analysis of target compounds in FDA regulated products.
- Fully knowledgeable on the ISO 17025 standard as it applies to the laboratory programs incumbent is assigned to or supports.
- Comprehensive knowledge of Federal laws, agency regulations and guidelines in their specialized field and of FDA regulatory programs to sufficiently evaluate and incorporate the latest developments and changes in the specialized instrument field into the agency guidelines and criteria.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. 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 FDA employee, you are not exempt from transcript requirements.

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

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

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

The United States Government does not discriminate in employment based on 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

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 need accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request 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.

How to Apply

Applications will be accepted by all qualified applicants. Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current resume, SF-50 (redacted for SSN and birth year, for federal employees only) and college transcript(s) (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through March 18, 2024. Applicants must reference 4-Chemist-Irvine in the email subject line.

Announcement Contact

For questions regarding this Title 21 position, please contact:
ORAExecutiveandScientificRecruitment@fda.hhs.gov

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FDA is an equal opportunity employer.