Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)

Application Period: June 14 to July 5, 2022

Position: Statistician

Series: AD-1530

Location(s): US, Determined upon selection

Work Schedule: Full time

Salary: $148,484 - $209,359

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 25%

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.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency 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 all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

Join FDA and serve on the frontlines protecting our nation's public health safety within the Office of Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the nation or around the world. Our employees inspect product facilities; investigate criminal violations; analyze lab samples; provide

administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

To view our ORA Vision, Mission, and Values please visit:
https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values

The FDA's Office of Regulatory Affairs is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts.

The position of Statistician serves as a technical advisor to the Associate Commissioner for Regulatory Affairs (ACRA) and the Deputy ACRA (DACRA), analyzing FDA/ORA-wide cost initiative requirements and functions. The incumbent serves as a focal point for various statistical, planning, evaluation, and performance measures of various ORA initiatives and projects. The statistician is a major authority on statistical methodology for field performance data in FDA activities. As a staff consultant and technical advisor to the ACRA and DACRA, ensures compliance of submitted research protocols with all applicable federal and FDA/ORA regulations guiding research as it relates to statistical analysis.

This position reports to the Deputy Associate Commissioner for Regulatory Affairs, DACRA

Duties/Responsibilities

Oversees preparation of all statistical reviews to the ACRA and DACRA and other authorities or entities as needed. Advises ORA staff on all issues related to scientific validity of a research protocol. Assists database and website developers in preparation of databases suitable for export for statistical analysis. Counsels investigators and staff on issues related to analytic scientific merit.

Guides investigative staff in a variety of research disciplines as they relate to statistics. Mentors and provides statistical educational development to ORA staff. Trains ORA staff members on performance of functions as it relates to evaluating statistical methodology.

Evaluates and analyzes the statistical validity of projects performed by the field activities. Formally reviews and assesses each project prior to the meeting with respect to all areas of statistical considerations such as, study design, statistical methodology, end point measures, reliability and validity of the instruments, stopping rule for safety monitoring, data collection and data analysis. Provides recommendations and/or corrective actions to ensure adequate and appropriate statistical procedures are used in said projects. Keeps staff informed of relevant outcomes.

Develops methodology and implements procedures and policies to improve the reliability and validity of statistical data collected and analyzed. Utilizes modeling and data analysis

methods in various studies and product quality assessment. Performs statistical studies, conducts appropriate computer programming related to assignments, and oversees the development of reports for such studies.

Responsible for ensuring that statistical validity of planning and evaluation analysis activities by solving statistical problems occurring in the data collection and summarizing processes. Initiates the design and development of data processing systems to control incoming data and data collection materials, resource of usage plans, planning end controlling tabulation and summarize methods.

Serves as a technical expert with respect to all phases of statistical planning and evaluation analyses relating to topics under consideration. Maintains contact with colleagues who are of the industry, Government and non-Government organizations. Represents ORA and FDA at professional meetings and conferences. Prepares papers, reports or other documents for presentation to professional groups, senior FDA Management, Program Directors, Field Committees, or for publications in professional journals.

Supports ORA staff by providing professional knowledge and skills through consulting, evaluating, and analyzing all aspects of statistical application of the protocols approved at FDA/ORA. Conducts sample size estimation and statistical power analysis to determine the minimal sufficient number of subjects required for the study. Applies comprehensive knowledge of biostatistical theory, principles, and techniques to adapt, combine, and develop statistical methodologies to analyze complicated data sets from a broad range of studies for a variety of data performance disciplines. Applies advanced statistical theories and comprehensive professional knowledge in conducting research to recommend improvements in study design and data collection and contributes to the plan and preparation of research protocols.

Performs statistical analysis for the data collected from the approved research. Communicates and interprets the statistical results to researchers to ensure that data are accurately reported to the scientific professional community. Participates as co-investigator and/or co-author of the research project assisted.

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 Cures 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 Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement: Bachelor's level degree is required but preference is given to candidates with a graduate or higher-level degree. Candidates must possess the required individual occupational requirements to qualify for the education requirements for the position. Please use the following link to review the statistician education requirements: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/1500/statistics-series-1530/

Professional Experience:

- In-depth knowledge of analysis tools and techniques to analyze and evaluate the efficiency and effectiveness of agency programs; select appropriate qualitative and quantitative techniques for a specific situation; and develop and apply new approaches for conducting complex, comprehensive studies which deal with major issues affecting program management.
- Expert knowledge of information technology principles sufficient to lead projects to automate processes and procedures and to disseminate programmatic information

- Conducts sample size estimation and statistical power analysis to determine the minimal sufficient number of subjects required for a study. Applies comprehensive knowledge of biostatistical theory, principles, and techniques to adapt, combine, and develop statistical methodologies to analyze complicated data sets from a broad range of studies for a variety of data performance disciplines.
- Mastery of and skill in applying advanced, analytical, mathematical, or statistical theories, principles, concepts, methods, and techniques related to statistical analysis; parametric and non-parametric analysis; computer modeling; decision theory; mathematical programming; regression analysis; business intelligence; data analytics; and economic analysis in order to design and develop the most appropriate techniques that enable the incumbent to solve problems, enhance performance, and/or increase efficiency and effectiveness
- Highly skilled to develop, implement, evaluate, and improve processes and procedures concerning ORA special studies and analyses.
- Expert knowledge of management and administrative goals, objectives, systems, regulations, guidelines, and processes of an HHS organization or major organizational unit.
- Comprehensive professional knowledge in conducting research to recommend improvements in study design and data collection and contributes to the plan and preparation of research protocols.
- Skill in verbal communication to make clear, convincing presentation; influence managers and other officials to adopt and implement recommendations; to gain cooperation and input from others on broad studies and projects; to lead presentations to high-ranking officials; to represent the organization at meetings, conferences, and on workgroups, and to provide technical assistance to Federal and non-Federal parties concerning programmatic activities.
- Expert written communication skills to prepare complex reports, briefings, position papers, policies, procedures, and guidelines.

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:
This position requires a Secret security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

Ethics Clearance Requirements

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy
The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.
Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy
Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable

accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

How to Apply: Applicants must submit a current resume, a current SF-50 redacted for complete SS# and birth year (for federal employees only), proof of degree or transcripts (with foreign credentials evaluation if applicable), and a brief (one-page or less) statement explaining your interest and qualifications for this position to the ORA Executive Recruitment Team at: ORA Executive Recruitment.

Announcement Contact

For questions regarding this Cures position, please contact Laura Ortiz.

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

FDA is an equal opportunity employer.