2Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Translational Sciences (OTS)
Office of Biostatistics (OB)
Division of Biometrics DBIII (DBIII)

Application Period: 6/21/2021-7/21/2021

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: Supervisory Mathematical Statistician

Series: 1529

Location(s): Silver Spring, MD

Salary Range: $144,128 - $223,533

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Relocation Expenses Reimbursement: N/A

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 compensated 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 (FDA) 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 are safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

This position is located in the Division of Biometrics III (DBIII), Office of Biostatistics (OB), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). DBIII is the division responsible for the review of submissions for new drug and biologic products in the areas of allergy, critical care, dentistry, dermatology, gastroenterology, hepatology, nutrition, pulmonology, rheumatology, and transplant medicine in the United States and for the oversight of clinical outcome assessment (COA) review and the review of other forms of patient experience data within the OB. The functions of the Center, Office, and Division are described in the FDA Staff Manual Guide. The incumbent serves as a Supervisory Mathematical Statistician in the DBIII.

Duties/Responsibilities

The incumbent serves as the Supervisory Mathematical Statistician in the DBIII, OB and participates with the Division Director and Deputy Division Director in the process for the evaluation and regulatory decision recommendations of New Drug Applications (NDAs), Biologics License Applications (BLAs), and other types of submissions pertaining to drug and biologic products handled by the division.

Serves as a statistical discipline signatory on behalf of the Director in applications involving patient focused drug development (PFDD), biomarkers, real world evidence, rare disease, complex adaptive or Bayesian designs, and/or observational studies, in new and supplemental drug and biologic applications, investigational new drug applications, qualification, and similar programs.

In conjunction with the Division Director, the incumbent directs and coordinates the work of assigned divisional staff, through the respective scientific discipline team leader(s) to secure written evaluations of a variety of scientific applications, submissions, and reports, with concentration on clinical outcome assessments (COAs), patient preference information (PPI), biomarkers, estimands and missing data, covariate adjustment, safety and benefit-risk evaluation, rare disease, and/or complex adaptive and Bayesian designs.

Assists in the overall management and direction of a professional pre-market Division, with emphasis on PFDD, biomarkers, safety and benefit-risk evaluation, and complex adaptive and Bayesian designs which is a major portion of CDER premarket review and impacts directly on the Agency's mission to protect the public health. Concentrates on review and evaluation of PFDD including COAs and PPI, biomarkers including biomarker qualifications, safety and benefit-risk, rare disease, and/or complex adaptive or Bayesian designs.

Assists the Division Director in organizing work, establishing priorities, and administering division operations. This includes operating through the team leaders to render guidance on policy and administrative matters and taking responsibility for the productivity of the division and quality of work product within the division.

Coordinates implementation, within the division, of policy decisions and determinations made by the Division Director and higher level managers of the OB with a focus on PFDD, biomarkers, safety and benefit-risk evaluation, and/or complex adaptive and Bayesian designs.

Coordinates issues to be brought to the attention of the Statistical Policy Council (SPC) and takes necessary action to follow-up on the implementation of recommendations made by them, particularly with respect to the statistical evaluation of PFDD related programs, biomarkers, safety and benefit-risk, and/or complex adaptive and Bayesian designs.

Participates in conferences with representatives of the regulated industry to discuss problems pertaining to the statistical evaluation of efficacy, safety and other related issues associated with investigations and marketing of human drugs which fall within the division's area of functional responsibility. In addition, the incumbent will on occasion have contact with the news media, consumer groups, professional organizations and other governmental agencies concerning these issues and ensures communications are cleared. This external outreach will be focused on PFDD, biomarkers, estimands, safety and benefit-risk evaluation, and/or complex adaptive and Bayesian designs although other topics may arise.

The incumbent is assigned individual reviews and evaluation responsibility for suitable portions of NDA, BLAs, INDs, etc. within their area of responsibility.

Supervisory Responsibilities: The incumbent participates with the Director and Deputy Director in aspects of managing functions within the division such as directing the drug group under regulatory authority of the Division through team leaders providing expertise at the division level. Supervises subordinate team leaders and employees with an approximate supervisory span of control ranging from eight to ten staffers responsible for performing the varied and broad regulatory review functions of the division related to the highly complex requirements of the Agency which are constantly changing and often involve extensive coordination. Twenty-five percent or more of the workload of the division is at the GS-13 level.

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 supervisory 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.

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: Candidates must meet the education requirements in a scientific discipline and in the Mathematical Statistician 1529 series that is directly related to the position being filled and in accordance with the Office of Personnel Management (OPM) qualification standards. At a minimum, the candidate must possess a degree that includes 24 semester hours of mathematics and statistics, of which at least 12 semester hours were in mathematics and 6 semester hours were in statistics, or a combination of education and experience that includes 24 semester hours of mathematics and statistics, of which at least 12 semester hours were in mathematics and 6 semester hours were in statistics.

Desired Education: The ideal candidate should possess a doctoral-level degree in biostatistics or statistics/epidemiology from an accredited institution of higher learning or other research doctoral degree widely recognized in U.S. academe as equivalent to a Ph.D.

Professional Experience:

- Ability to provide managerial leadership for a technical administrative program.
- Ability to conduct statistical research and review of studies submitted in support of regulatory qualification, drug, or biologic applications.
- Ability to evaluate and apply statistical methodology to provide scientific support for regulatory decisions regarding mathematical scientific initiatives.

- Ability to function within a regulatory environment and problem solve to meet challenging demands.
- An understanding of Federal Regulations related to the work of the Center for Drug Evaluation and Research,
- Prior senior leadership experience and excellent interpersonal skills.

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 background check and the incumbent has access to documents and facilities.

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

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

All qualified candidates should submit resume or curriculum vitae with cover letter by 7/21/2021 to: CDEROTSHIRES@fda.hhs.gov. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancies. Candidates can opt out of this process by annotating resume with “do not share.” For questions please contact CDEROTSHIRES@fda.hhs.gov.

Please reference Job Reference ID: **Division of Biometrics DBIII (DBIII) - Supervisory Mathematical Statistician** in the subject line.

Announcement Contact

For questions regarding this Cures position, please contact CDEROTSHIRES@fda.hhs.gov.

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

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