Title 21 Vacancy Announcement
U.S. 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)

Application Period: September 20, 2023 - October 4, 2023

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: Deputy Division Director (Supervisory Mathematical Statistician)

Series: AD-1529

Location(s): Silver Spring, MD

Salary: Starting at $155,700

Work Schedule: Full-Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 (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 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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Translational Sciences (OTS) is to empower a diverse, collaborative, and high performing workforce to champion innovation and advance global human drug development.

The mission of the Office of Biostatistics (OB) is to provide CDER, FDA and external stakeholders with statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs and therapeutic biologics for the American people and to protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.

Duties/Responsibilities

As the **Deputy Division Director (Supervisory Mathematical Statistician)**, the incumbent serves as the Division of Biometrics III (DBIII), Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research and provides professional leadership and direction to subordinate supervisors and division staff. In this capacity, the incumbent is responsible for planning, coordinating, and evaluating the administrative and technical programs and activities.

- Provides statistical, methodological, and data management information and advice.
- Renders guidance on policy and administrative matters, particularly as it pertains to clinical outcome assessments (COAs), biomarker qualifications, real world evidence (RWE) and complex adaptive and Bayesian designs.
- Participates with the DBIII Director, in the process for the evaluation and regulatory decision recommendations of new drug applications (NDAs), biologics license application (BLAs), and other types of submissions pertaining to drug and biologic products handled by the division.
- Advises the Office Director, Center Director, and other FDA officials on the statistical aspects of FDA's regulatory responsibilities in the areas of drug and biologic products as put forth in the Federal Food, Drug and Cosmetic (FD&C) Act.
- Establishes statistical policy for the Center. Provides expert mathematical and statistical consultation to and collaboration with higher level scientists and/or engineers within the FDA and CDER and is responsible for selecting and implementing appropriate methods of data collection, summary, and analysis.
- 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 DB responsibility. Occasionally has contact with the news medical, consumer groups, professional organizations, and other governmental agencies concerning these issues. This external outreach is focused on COAs, biomarker qualifications, real world evidence (RWE) and complex adaptive and

Bayesian designs.

- Interacts with internal and external groups to determine the most critical areas for new statistical regulatory initiatives and the most effective rapport with industry, academia, appropriate Federal agencies, and national or international research and regulatory agencies on study design and statistical issues.
- Develops expertise and takes a statistical disciplines signatory role in applications involving COAs, biomarker qualifications, real world evidence (RWE) and complex adaptive and Bayesian designs in new and supplemental drug and biologic applications.
- Prepares authoritative summaries of the statistical information. Serves as an expert and consultant in the development of new statistical methodology or the adaptation of new methods to the regulatory process.
- 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 the SPC, particularly with respect to the statistical evaluation of COAs, biomarkers, real world evidence (RWE) and complex adaptive and Bayesian designs.
- Coordinates cross-cutting issues vital to the Center's mission while collaborating with other statistical Centers within the Federal and interacts with national and international scientific groups.

Supervisory Responsibilities: The incumbent participates with the Division 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 supervisors and employees 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.

Manages and directs a professional regulatory review program segment(s) which is a major portion of a Center regulatory review office and impacts directly on the Agency mission to protect the public health. The program segment(s), functions, and activities of the division directly and significantly impact the work of the regulated industry, other Federal agencies, State, local and foreign governments, industry and professional organizations, public interest groups, and the general public.

Evaluates budget estimates and justifications and makes appropriate recommendations to the Office Director. Determines the best approach and solution for resolving budget problems and plans for long range staffing needs. Identifies new ways to manage constrained resources, e.g., changes in procedures or standards to conserve resources without affecting the quality of output.

Directs, oversees, and coordinates the work of subordinates and team leaders. Assures reasonable equity of performance standards and rating techniques developed by subordinates. Makes and approves selections for subordinate non-supervisory positions. Recommends selections for subordinates and leader positions. Reviews and approves or disapproves leave requests. Hears and resolves group grievances and serious employee complaints. Reviews and approves serious disciplinary actions. Recommends awards and bonuses for employees and changes in position classification subject to higher level approval.

Provides direct supervision to a group of employees in multiple-grade interval positions of various levels of skill and experience in achieving program goals, including planning, managing, and directing their work. Performs administrative and human resources management functions relative to the staff. Tracks recruitment and renewals and oversees interviews and selection recommendations. Identifies employee competency gaps.

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. 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.

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:
Mathematical Statistics, AD-1529 Series

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education:
Our ideal candidate will possess at least a doctoral-level degree in biostatistics or statistics/epidemiology/mathematics from an accredited institution of higher learning.

Professional Experience:
Our ideal candidate will possess:

- Experience serving as an expert and consultant in the development of new statistical methodology or the adaptation of new methods to the regulatory process.
- Skill in providing managerial leadership for a technical administrative program.
- Experience conducting statistical research and review of studies submitted in support of regulatory drug or biologic applications.
- Experience evaluating and applying 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; ability to organize and motivate people in the successful accomplishment of routine tasks.

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: Non-Sensitive/High Risk

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 the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

Applicants should submit a letter of interest (cover letter) and current resume or curriculum vitae by **October 4, 2023**, to: CDEROTSHires@fda.hhs.gov. Please adhere to the following submission protocol:

- **Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name**
- **Reference 'Deputy Division Director DBIII' in the subject line of the email.**

Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume or email with "do not share".

Announcement Contact

For questions regarding this Cures position, please contact the Office of Translational Sciences recruitment and outreach liaison at CDEROTSHires@fda.hhs.gov.

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

FDA is an equal opportunity employer.