



## TITLE 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)

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**Position:** Deputy Office Director

**Pay Plan-Series:** AD-1529

**Location(s):** Silver Spring, MD

**Travel Requirements:** 25% or less

**Application Period:** 02/12/2021 – 03/12/2021

**Salary:** Starting salary \$163,962 (Cures Band F)

**Area of Consideration:** United States Citizens or Nationals

**Relocation Expenses Reimbursement:** N/A

**Special Notes:** This position is being filled under an excepted 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 the authority. [Additional information on 21st Century Cures Act can be found here.](#)

**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.

The Office of Biostatistics (OB) provides CDER and other internal 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. Our mission is to protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.

We are recognized for excellence in the application and communication of statistical science in drug regulation and development. We play a central role in promoting innovative, science-based, quantitative decision-making throughout the drug development life-cycle.

**Position Summary:**

This position is located in CDER, Office of Translational Sciences (OTS), Office of Biostatistics. As the primary advisor to the Office Director, the incumbent exercises a high degree of statistical expertise in fulfilling the duties and responsibilities of the position. The Deputy Office Director shares fully with the Office Director in all responsibilities pertaining to planning, managing, and directing the work of the Office. This involves providing both administrative direction and scientific guidance to subordinate supervisors/team leaders within the component Office who in turn directs the regulatory activities of highly trained and skilled staff of scientific professionals. Planning, assigning, reviewing, and evaluating the work and performance of applicable supervisor and employees.

**Supervisory responsibilities:**

As a Supervisory Mathematical Statistician, the incumbent participates fully in the day-to-day operations of the Office and in the absence of the Director. The incumbent will act with full authority for all areas of responsibilities to the Office Director in carrying out the variety of scientific, technical and administrative duties required of the position. This entails an understanding of all projects underway as well as an intimate understanding of major policy matters.

**Duties/Responsibilities:**

Assists in managing an Office. Reviews the implementation of new laws and regulations that impact the mission of the Office. This includes responsibility for the initiation and implementation of new policies, systems, procedures, and organizational structure.

Participates fully in the overall management of the Office with emphasis on statistical matters and administration. Possesses knowledge of administrative program management principles and skills to carry out the mission, as well as addressing and solving unusual and often precedent setting problems associated with the Office regulatory review program segment(s). Initiates decision making processes and documents; and participates fully in discussions and decisions concerning other Office plans, programs, and activities, both in strategic planning and

in the actual determination, allocation, and administration of the Office program segment(s), functions and activities. Provides authoritative advice and assessment of the impact of actual and proposed Administration or Congressional actions on the program segment(s), functions, and activities.

Participates fully in planning, managing, organizing and directing all the operations, program segment(s), functions and activities of the Office including the formulation and establishment of the Office policies and goals, determination of organizational staff, and budget requirements, preparation of the budget, and allocation of Office resources necessary to accomplish the regulatory review mission of the Office.

Directs, oversees and coordinates the work of subordinate supervisors and/or team leaders; deals with high level officials and other organizations both within and outside the Agency; assures reasonable equity of performance standards and rating techniques developed by subordinate supervisors and/or team leaders. Recommends awards and bonuses for employees and changes in position classification; finds and implements ways to eliminate and reduce significant bottlenecks and barriers to production and promotes team building. Counsels and rates immediate subordinates.

Provides direct administrative and technical supervision to a group of employees including scientific, professional, technical, administrative and clerical support personnel assigned to the Divisions, ranging in levels from senior executive services to entry levels. Performs administrative and human resource management functions relative to the staff, including developing staffing plans and position descriptions, and identifying employee competencies necessary to meet organizational capabilities goals. Tracks recruitment and renewals and oversees interviews and selection recommendations.

**EEO Responsibility:**

The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to race, color, religion, sex, national origin, age, or disability. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Center in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employee's achievements; (4) career development of employees; and (5) full utilization of their skills.

**Equal Employment Opportunity Policy:**

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. [Click here to find out additional information about the Equal Employment Opportunity \(EEO\) for federal employees & job applicants](#) !

### **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.

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Learn more about [disability employment and reasonable accommodations](#) or [how to contact an agency](#).

### **Professional Experience/Desirable Qualifications:**

- Stature in the professional statistical community
- A commitment to the highest standard of public service
- A commitment for professional growth, development, and mentoring of scientific staff
- A commitment to outreach and collaboration with internal and external stakeholders

- A robust scientific background in translational sciences with a strong fundamental understanding of biostatistics and clinical medicine/therapeutics, and experience and/or knowledge of quality systems as they apply to the life cycle of drug development
- 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
- Proven ability to provide strong leadership and promote maximum potential of a large organization with a multicultural workforce
- Prior senior leadership experience and excellent interpersonal skills

**Desirable Education:**

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 doctoral-level degree from an accredited institution of higher learning, including: Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral degree widely recognized in the U.S. academe as equivalent to a Ph.D. The ideal candidate should possess a doctoral-level degree (Ph.D., M.D., Pharm.D.) in biostatistics or statistics/epidemiology.

**Conditions of Employment:**

**1. Security Clearance:**

This position requires a background check and the incumbent has access to documents and facilities.

**2. Ethics 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>.

**3. How to Apply:**

All qualified candidates should submit resume or curriculum vitae with cover letter by **March 12, 2021** to [CDEROTSHIRES@fda.hhs.gov](mailto:CDEROTSHIRES@fda.hhs.gov) Applicant resumes may be shared with other CDER

hiring officials who may have a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share.” For questions please contact [CDEROTSHIRES@fda.hhs.gov](mailto:CDEROTSHIRES@fda.hhs.gov)

Please reference **Office of Biostatistics-Deputy Office Director in the subject line.**

MD, MD/JD, MD/MPH, MD/PhD candidates are encouraged to apply.

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

*FDA is an equal opportunity employer.*

