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: October 10, 2023 – October 20, 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: Staff Director

Series: AD-0601/0696

Location(s): Silver Spring, MD

Salary: Starting at $176,973

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 (OTC) and prescription

drugs, including biological therapeutics and generic drugs.

The Office of Translational Sciences (OTS) promotes and facilitates scientific collaboration and innovation in drug regulatory review across CDER, assuring the validity of clinical trial design and analysis in regulatory decision making, overseeing bioequivalence inspections to ensure the availability of safe and effective generic equivalents of investigational drugs, and providing innovative and reliable solutions that improve and strengthen the scientific review process.

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. Protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products. OB is 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.

Duties/Responsibilities

As an **Staff Director for the Project Management Staff (PMS)** within the Office of Biostatistics (OB) Immediate Office, the incumbent provides OB with the expertise, regulatory project management, and leadership necessary to support the regulatory affairs needs of OB, execute the operational activities of OB to promote excellence and consistency across OB, Lead, coordinate, and execute cross cutting OB and CDER initiatives to address unmet needs, support regulatory review, research, and workload management, and build tools and knowledge management systems to enable scientific and policy analysis.

- Provides technical direction, oversight, and leadership to subordinate Consumer Safety Officers, Regulatory Health Project Managers, and Senior Regulatory Health Project Managers and fully supports the OB Immediate Office.
- Communicates with OB, Office of Clinical Pharmacology (OCP) and Office of New Drugs (OND) review divisions on regulatory matters in order to resolve issues related to product applications; facilitates gathering technical information for reviewers, explains regulatory requirements and communicates on product applications to ensure compliance with all legal, regulatory and policy requirements.
- Ensures industry compliance standards are followed and tracks all regulatory required FDA legislation, including the Food and Drug Administration Amendments Act (FDAAA). FDAAA has enabled changes to product labeling, while conducting post marketing studies for review of non-compliance.
- Ensures compliance with Good Review Manufacturing Principles and Practices (GRMPPs), 21st Century Review requirements. Additionally, ensures Prescription Drug User Fee Act (PDUFA) goals and deadlines are met.
- Provides oversight of OB regulatory project management activities including development of project plans and performance goals. Assures timely completion of

project activities and resolution of conflicts to avoid delays in achieving goals.

- Provides direction, assigns tasks, and establishes time frames for completion of work products to the Project Management Staff; monitors staff progress; facilitates the discussion of issues arising during completion of work products; guides development of actionable recommendations from work products to assure alignment with Office policy; brings groups to consensus.
- Serves as the manager in OB responsible for coordinating meetings with the Statistical Policy Council, Biostatistics Leadership Team, and Senior Leadership Team. Ensures the timely development of meeting agendas and provides actions items from the meetings.
- Serves as an advisor and spokesperson for the OB Immediate Office on regulatory affairs. Fosters open communication of concerns, problems, expectations, and information.
- Provides project oversight of OB Working Groups and Committees including but not limited to the OB Pediatric Studies Committee, OB Bayesian Statistics Committee, OB Safety Benefit Risk Working Group, OB Estimands Working Group, and OB Digital Health Technology Working Group.
- Directs special projects or activities of concern to OB that may involve the coordinated effort of Office of New Drugs or the Division of Biostatistics in the Center for Biologics Evaluation and Research. Performs such projects or activities individually or establishes work groups as needed. Develops and presents outcomes and any recommendations resulting from the projects or activities.
- Ensures consistent and efficient knowledge management across OB utilizing existing tools such as the OB ColdFusion database and exploring and building novel systems, as needed.
- Serves as liaison to external entities such as the Eastern North American Region of the International Biometrics Society, American Statistical Association, academic institutions, other international regulatory agencies, and the public in the gathering of information related to OB led programs and initiatives.
- Monitors, coordinates, and advises on sensitive, controversial, complex, and precedent setting issues of particular concern to the Office of Biostatistics. Extends and modifies approaches, precedents, and methods to solve a variety of the issues.
- Exercises leadership in ensuring standardization of workload and research management across the Office of Biostatistics components. Applies extensive knowledge of FDA and CDER policies and procedures in order to identify and resolve inconsistencies and to make recommendations on strategic initiatives to senior Office leadership. Provides regulatory project management advice, guidance, assistance, interpretations, and recommendations to the Office Director/Deputy Director, Division Directors, scientists, Agency representatives, and others.
- Ensures personnel receives appropriate training and stays abreast of advances in OB policies and standard operating procedures, drug development, and the review processes. Mentors subordinate staff on regulatory project management strategies. 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.

Supervisory Responsibilities: Manages the OB Project Management Staff, providing leadership, oversight, supervision, and evaluation of staff. Provides specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the Project Management Staff of the Office of Biostatistics.

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:

Consumer Safety, AD- 0696 Series

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

Desired Education:
Our ideal candidate should possess a bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Professional Experience:
Our ideal candidate will possess:

- Demonstrated experience advising others in the application of Center and/or Agency rules, regulations, guidelines, and procedures.
- Demonstrated experience applying leadership principles and concepts sufficient to serve as the Associate Director.
- Experience leading a diverse group technical and professional staff.
- Demonstrated experience providing guidance and consultation to enforce regulatory objectives.
- Demonstrated experience in providing authoritative guidance and consultative services to internal and external staff members or other organizations.
- Demonstrated ability to communicate orally, including responding to congressional inquiries and collaborating with a diverse group of scientist or staff from both public and private organizations.
- Demonstrated ability to communicate in writing, including utilizing visual communication skills to develop policy guidance for use by counterparts and respond to congressional inquiries.
- Demonstrated ability to develop networks and build alliances; collaborate across boundaries to build strategic relationships and achieve common goals.

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:

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.

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 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 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 20, 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 'Staff Director' in the subject line of the email.

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

FDA is an equal opportunity employer.