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)

Application Period: October 24, 2022 – November 4, 2022

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: Division Director

Series: AD-1529

Location(s): Silver Spring, MD

Salary: $163,962 - $259,109 Commensurate with experience and education.

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

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 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.

The Office of Biostatistics is responsible for research and reviews across a range of therapeutic areas, including cardio-renal, oncology, rare diseases, and antimicrobial products. Incumbents have an opportunity to employ a broad variety of statistical procedures relevant to pre-clinical

and clinical evaluation decisions for new and generic drugs as well as new and biosimilar biologics and the emerging fields of quantitative risk assessment and pharmacogenomics. This position is located in the Division of Biometrics IX (DBIX), Office of Biostatistics (OB), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). The functions of the Center, Office, and Division are described in the FDA Staff Manual Guide. The incumbent serves as the Division Director of DBIX.

Duties/Responsibilities

As **Division Director** of Division of Biometrics IX (DBIX), Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), the incumbent is responsible for providing leadership on statistical reviews of regulatory submissions on malignant and non-malignant hematology products.

- Oversees the programs of the division which involves evaluating and applying new statistical methodology in support of scientific decisions regarding clinical studies and collaborates with other Center units requiring statistical expertise.
- Participates fully with the Office Director in planning, managing, organizing, and directing regulatory review operations, and statistical research activities of the division as carried out by Division supervisors/team leaders and highly trained and skilled staff (mathematical statisticians and support staff).
- Applies administrative and program management principles and skills to carry out the mission of the division and addressing and solving challenging and often precedent-setting problems. Seeks and develops the most cost effective and fiscally responsible methods to manage and lead day to day operations.
- In consultation with the Office Director, initiates and participates fully in discussions and decisions concerning division plans, programs, and activities, both in strategic planning and implementation. Provides authoritative advice and assessments of the impact of actual and proposed Administration or Congressional actions on the program segments, functions, and activities of the division.
- Develops and implements division policies and plans, makes critical decisions, and provides expert advice and counsel on cost-effective use of all resources including budget and manpower.
- Develops core competencies of review staff to maintain and render outstanding regulatory review, advice, policy, and publications and is responsible for identifying new scientific initiatives. Serves as subject matter expert and is a recognized authority and senior level expert with responsibility for improving efficiency in all aspects of daily operations of the Division. Incumbent leads, prepares, coordinates, and attends critical sponsor/internal meetings, supports, and promotes team leader and reviewer development, works with review staff in each team to identify interdisciplinary experts in respective therapeutic areas for consulting and managing office-level projects.
- Represents the division and Office in dealing and negotiating with individuals representing organizations such as the Congress; other Federal agencies; State, local, and foreign governments; the regulated industry; professional and industry

organizations; and public interest groups. Directs the preparation, clearance, and finalization of division responses to inquiries covering all aspects and activities of the division.

- Sharing fully with the Office Director, directs the preparation of analyses of the impact of proposed changes to Agency regulations which affect the functions, program segments, and activities of the division. Directs the implementation of new laws and regulations which affect the mission of the division including initiating and implementing new policies, systems, procedures, and organizational structures.

Supervisory Responsibilities

- Plans and sets long-range plans and schedules for the work of the division, assures implementation by DBIX supervisors and team leaders and organizations of the goals and objectives of the division, and determines goals and objectives that need additional emphasis.
- Supervises staff 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.
- Directs, oversees, and coordinates the work of all Division staff and team leaders and deals with high level officials of organizations both within and outside the Agency. 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.

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.*

Division Director, AD-1529 Series

Degree: 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

Our ideal candidate will possess:

- 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: Non-Sensitive/High Risk Level

If not previously completed, 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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 by **November 4, 2022**, 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 'OB Division Director' 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.

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