Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Analytics and Benefit-Risk Assessment (DABRA)
Benefit-Risk Assessment Branch (BRAB)

Application Period: May 6, 2024 – May 15, 2024

Area of Consideration: The Public.
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: Branch Chief

Series: 0401 (Biologist), 0601 (General Health Scientist), 1529 (Mathematical Statistician), 1530 (Statistician)

Location: White Oak Campus, Silver Spring, MD

Salary: Starting at $139,395 and is set commensurate with education and experience.

Telework Eligible: Yes – as determined by agency policy.

Travel Requirements: 25% or less

Title 21 Band: D

Full Performance Band Level: D

Work Schedule: Full Time

Bargaining Unit: 8888

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 or Agency) 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 Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The Office of Biostatistics and Pharmacovigilance (OBPV) provides comprehensive statistical, pharmacovigilance, and epidemiological evaluation of data submitted to the Center in support of regulatory requirements. OBPV evaluates the safety

and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, statistics, medicine, risk analysis, public health, genomics, and other scientific areas.

The Division of Analytics and Benefit-Risk Assessment (DABRA) improves the efficiency, consistency, and rigor of the methods used by the office to evaluate the safety and effectiveness of CBER regulated products and develops and applies new methods and tools for improving observational epidemiological studies, data mining, and comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products. DABRA leads the OBPV's programs on quantitative benefit-risk assessment, Real-World Evidence (RWE), and analytics and informatics projects, work that supports the office's review, regulatory and public health missions. DABRA also operates the High-performance Integrated Virtual Environment (HIVE), which consists of a high-performance computing cluster (HPC) with petabyte scale high-availability storage; a sophisticated web-based genomics analysis platform; support for machine learning in Python and R; and a team of expert bioinformaticians, computer scientists, and software developers. DABRA works with OBPV, other CBER offices, and across the centers to conduct Digital Health Technology (DHT)s-related reviews and activities. These activities include but are not limited to, development of DHTs guidance and participating in public and industry meetings on DHTs-related topics and discussions.

The Benefit-Risk Assessment Branch (BRAB) leads the OBPV's programs on quantitative benefit-risk assessment work that supports the office's review, regulatory, and public health missions. BRAB conducts quantitative benefit-risk assessment to support regulatory decisions and reviews benefit-risk assessments submitted with biologics license applications or other submissions.

Duties/Responsibilities

The incumbent serves as the Branch Chief for the Benefit-Risk Assessment Branch (BRAB) within the Division of Analytics and Benefit-Risk Assessment (DABRA) under the Office of Biostatistics and Pharmacovigilance (OBPV) and manages daily operations of the Branch. The incumbent reports to the DABRA Division Director. The incumbent is responsible for developing, implementing, coordinating, reviewing, and providing advice and guidance to Office and Center staff on Benefit-Risk Assessment to improve the efficiency, consistency, and rigor of the methods used by OBPV to evaluate the safety and effectiveness of CBER regulated products.

Specifically, the Branch Chief will:

- Lead OBPV's programs on quantitative benefit-risk assessment work that supports the office's review, regulatory and public health missions.
- Manage the development and application of new methods and tools for improving observational epidemiological studies, data mining, and comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products.
- Oversee the review of benefit-risk assessments submitted with biologics license applications or other submissions.
- Establish and coordinate policy and program objectives for benefit-risk assessment for the FDA, the Department of Health, and Human Services (HHS) and other Government agencies.
- Plan, conduct, and review the Branch's technical scientific research on the benefit-risk assessment aspects of Investigational New Drug (INDs) applications, Biologics License applications (BLAs), supplements and amendments and other biologics research, in accordance with the Public Health Service Act (PHS) and the Food, Drug, and Cosmetic Act to ensure the efficacy, safety, purity, sterility, and potency of biologic vaccine, allergenic, and related biological products.
- Maintain current knowledge of the professional scientific literature and developments in benefit-risk assessment.
- Serve as peer reviewer for assessments, analyses and studies conducted by other governmental, academic, private, and public sources and studies from international sources and governments.
- Represent the office in discussions, meetings, and conferences related to benefit-risk assessment and attend special conferences, hearings, etc., related to the statistical community and participates in activities of relevant professional societies.
- Use a variety of software systems for statistical analysis, epidemiological studies, simulation and/or benefit-risk modeling, report writing, and communications.
- Supervise staff workload; define technical work requirements, milestones, and deliverables; manage Branch resources, and identify strategic objectives for the Branch to ensure the organization's strategic plan, mission, vision, and values are communicated to the team.
- Evaluate employee accomplishments; review drafts and approve final documents; and present the Branch's work to

senior management and other offices.
- Provide trainings and techniques in team building and arrange specific technical training for individuals or teams as necessary.
- Work with the DABRA leadership to manage contracts, budgets, personnel matters, and other management needs.
- Perform other duties as assigned.

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 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 or the below Education Requirements 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:

0401 Series (Biologist)

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

0601 Series (General Health Scientist)

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

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 at the time the degree was obtained.

1529 Series (Mathematical Statistician)

Candidates must possess a bachelor's degree or higher in mathematics, biostatistics, statistics, or in a related math field. Degrees in math education are not related. The degree must be from an accredited program or institution.

1530 Series (Statistician)

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Degree: that included 15 semester hours in statistics (or in mathematics and statistics, provided at least 6 semester hours were in statistics), and 9 additional semester hours in one or more of the following: physical or biological sciences, medicine, education, or engineering; or in the social sciences including demography, history, economics, social welfare, geography, international relations, social or cultural anthropology, health sociology, political science, public administration, psychology, etc. Credit toward meeting statistical course requirements should be given for courses in which 50 percent of the course content appears to be statistical methods, e.g., courses that included studies in research methods in psychology or economics such as tests and measurements or business cycles, or courses in methods of processing mass statistical data such as tabulating methods or electronic data processing.

OR

Combination of education and experience -- courses as shown above, plus appropriate experience or additional education. The experience should have included a full range of professional statistical work such as (a) sampling, (b) collecting, computing, and analyzing statistical data, and (c) applying statistical techniques such as measurement of central tendency, dispersion, skewness, sampling error, simple and multiple correlation, analysis of variance, and tests of significance.

Desired Professional Experience, Skills, and Education:

- Ph.D. or equivalent terminal degree in the sciences, health sciences, statistics, or a closely related field.
- Relevant benefit-risk assessment experience in biological product review.

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: 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.

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

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

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

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), latest signed PMAP (if applicable), a copy of your unofficial transcripts (if applicable), and letter of interest with ***"Title 21 CBER/OBPV/DABRA/BRAB Branch Chief"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **May 15, 2024**.

Announcement Contact

For questions regarding this Cures position, please contact CBERHumanCapital@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.