Statistician (1530)
Statistical Analyst

The Office of Biostatistics 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. To support our Center’s mission, we provide statistical leadership, expertise, and advice to ensure that safe and effective drugs are available to the American people.

DUTIES AND RESPONSIBILITIES

- Work with a multidisciplinary review team to provide statistical programming and data management support, assess the quality and completeness of submissions, prepare clinical trial analysis datasets, validate sponsor results, assist in modeling and simulation, and suggest possible additional statistical analyses required to fully evaluate the evidence in the submission.
- Collaborate with scientists from the Office of Pharmaceutical Quality, statistical reviewers in OB, and management on a variety of computationally intensive projects to support and improve the efficiency of regulatory product review, evaluation of pharmaceutical quality and applied regulatory research.
- Use machine learning and natural language processing to assess internal and external data sources to support assessment of quality intelligence throughout the product life cycle.
- Develop, validate, implement, document, maintain and support programming tools and software according to standards and accepted validation procedures; Support efforts to develop, document and apply reusable code and/or tools.
- Develop software using the appropriate statistical programming packages for statistical reviewers to support programming-intensive review-related activities such as sensitivity analysis, Bayesian approaches, clinical trials modeling, genomic studies, psychometric Clinical Outcome Assessment (COA) validation, and simulation.
- Promote and improve the Center data standards initiatives mandated by the Prescription Drug User Fee Act; Monitor the quality of the implementation of data standards used in New Drug Application submissions.
- Apply your skills to address unique and precedent-setting problems, while refining your consulting, communication, and presentation skills.

REQUIRED QUALIFICATIONS

- Master’s degree in statistics or biostatistics, including at least 6 hours in statistics and 9 hours in mathematics or related fields.
- Familiarity with R, SAS, data science tools, machine learning predictive techniques and natural language processing.

PREFERRED QUALIFICATIONS

- Experience in clinical trials, epidemiology, genomics, or risk assessment. Strong skills in multiple programming environments.
- Candidates should also have excellent oral and written communication skills.

The ability to communicate statistical issues to non-statisticians is vital. Candidates must be U.S. citizens.

BENEFITS

- Health and Life Insurance
- Long-term Care Insurance
- Dental and Vision Insurance
- Annual and Sick Leave
- Paid Holidays
- Flexible Spending Accounts (FSA)
- Federal Retirement Plan
- Thrift Savings Plan (401k)

WORK/LIFE BALANCE

- Telework & Alternative Work Schedules
- Child Care Center | Fitness Center
- Employee Assistance Program/Resource Groups
- Commuting and Transportation Programs

ARE YOU INTERESTED IN WORKING AT FDA?
SEND YOUR RESUME OR CURRICULUM VITAE TO:
CDEROTSHires@fda.hhs.gov

LOCATIONS

Statisticians are located at headquarters in the Washington, D.C. area.
Mathematical Statistician (1529)

The Office of Biostatistics is seeking individuals with strong statistical methodology skills and an interest in biomedical applications to serve as mathematical statisticians. Incumbents work with multidisciplinary teams of review scientists in a dynamic, highly challenging, and innovative atmosphere of development, evaluation, and research of drug and therapeutic biologics. The Office of Biostatistics is responsible for reviews in all therapeutic areas CDER supports and can be as diverse as cardio-renal, oncology, 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.

**DUTIES AND RESPONSIBILITIES**

- Evaluate and advise on protocols for clinical studies and assess the evidence for safety and efficacy from clinical studies submitted in drug and biologics applications
- 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.
- Work with multidisciplinary teams of review scientists in a dynamic, highly challenging, and innovative atmosphere of development, evaluation, and research of drug and therapeutic biologics.
- Refine your consulting, communication, and presentation skills and present at domestic and international professional meetings
- Engage in an active collaborative regulatory research program which will allow you to advance your skills and professional development.
- Interact with national, international, public, and private organizations on statistical issues, and help develop guidance for the pharmaceutical industry.

**QUALIFICATIONS**

Applicants should possess an advanced degree with specific coursework in Statistics, Biostatistics or Mathematical Statistics. Applicants with a doctoral degree and associated experience are highly desirable. In addition to a background in statistics, applicants should have an interest in biostatistics, clinical trials, epidemiology, genomics, or risk assessment.

The ability to communicate statistical issues to non-statisticians is vital.

Non-US citizens may apply for term appointments.

**BENEFITS**

- Health and Life Insurance
- Long-term Care Insurance
- Dental and Vision Insurance
- Annual and Sick Leave
- Paid Holidays
- Flexible Spending Accounts (FSA)
- Federal Retirement Plan
- Thrift Savings Plan (401k)

**WORK/LIFE BALANCE**

- Telework & Alternative Work Schedules
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**LOCATIONS**

Mathematical Statisticians are located at headquarters in the Washington, D.C. area.

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FOOD AND DRUG ADMINISTRATION ● CENTER FOR DRUG EVALUATION AND RESEARCH ● OFFICE OF TRANSLATIONAL SCIENCES