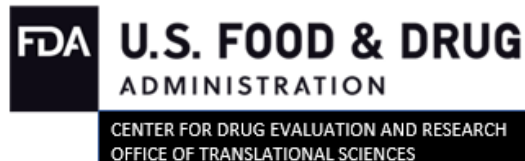


Statistician (1530) *Statistical Analyst*



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.