Statistician (1530)
Statistical Analyst

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF TRANSLATIONAL SCIENCES

The Office of Biostatistics (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. 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 regulatory submissions, e.g. Investigational New Drug (IND), New Drug Application (NDA), and Biologic License Application (BLA) submissions, prepare clinical trial analysis datasets, validate results, assis in modeling and simulation, data visualization, and other statistical analyses required to fully evaluate the evidence in submission.
- Collaborate with scientists from other centers and offices in FDA on a variety of computationally intensive projects to support and improve the efficiency of regulatory product review 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 to support programming-intensive review-related activities such as sensitivity analysis, Bayesian approaches, clinical trials modeling, Digital Health Technology (DHT), Real-World Evidence (RWE), 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 IND/NDA/ANDA/BLA 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: 15 semester hours in statistics (or in mathematics, at least 6 hours in statistics), and 9 hours in related field.
Proficiency with either R or SAS.
Familiarity with data science tools.
Candidates should also have excellent oral and written communication skills.
The ability to communicate statistical issues to non-statisticians is vital.

PREFERRED QUALIFICATIONS

Experience in clinical trials, epidemiology, genomics, DHT, RWE, Bayesian Modeling or risk assessment.
Familiarity with machine learning predictive techniques and natural language processing.
Strong skills in multiple programming environments.

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 in the Washington D.C. area.
Remote employment may be eligible.