Mathematical Statistician
Department of Health and Human Services
Food and Drug Administration/Center for Biologics Evaluation & Research
Office of Biostatistics and Epidemiology

The Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Epidemiology is soliciting applications from statisticians to develop and advance expertise in the evolving Science of Patient Input to inform benefit-risk determinations for medical products. The position will offer the opportunity for statistical collaboration and research in the development and evaluation of blood products, cellular, tissue and gene therapies, and vaccines. The candidate may apply their expertise of quantitative and statistical methods in areas such as elicitation and use of patient preference information, development and use of patient reported outcomes (PROs) evaluated in clinical trials and other studies, benefit-risk assessments to inform regulatory decisions, etc.

The Office of Biostatistics and Epidemiology provides comprehensive statistical and epidemiological evaluation of data submitted in support of regulatory requirements. CBER mathematical statisticians work in an environment dedicated to the public health, upholding the highest scientific standards in review and research involving new biological products. The incumbent will be responsible for assessing proposed quantitative and qualitative approaches to elicit and use patient input such as PROs and patient preferences, and for developing innovative approaches suitable to the regulatory environment. He or she will collaborate with physicians and other scientists on the development of scientific and regulatory policy, and frequently have the opportunity to represent CBER in collaborations with outside groups. Initiative and ability to work independently and in multidisciplinary teams are highly desirable. Good written and oral communication skills are very important. The successful candidate will interact extensively with other FDA scientists and reviewers, industry scientists, and scientists in other government agencies and in academia. This person will represent CBER at meetings and workshops focusing on policies and methods related to the science of patient input.

Qualifications:
A degree that included 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: at least 24 semester hours of mathematics and statistics, including at least 12 hours in mathematics and 6 hours in statistics, plus appropriate experience or additional education.

Candidates may also be hired under Title 42. Title 42 209(g) Service Fellowship appointment: candidates must possess a Ph.D. or equivalent degree plus comparable post-doctoral health-related research/regulatory review experience.

Candidates for Civil Service or Commissioned Corps appointments must be U.S. Citizens. U.S. Citizens and non-U.S. Citizens may be eligible for service fellowship appointments.

Location: Silver Spring, Maryland

Salary Range: Salary is commensurate with education and experience. An excellent benefits package is also available.

How to Apply:
Please submit resume or curriculum vitae with cover letter. The position will be open until filled.
Food and Drug Administration, CBER/Office of Biostatistics and Epidemiology
Attn: Brian Hively, send e-mail to brian.hively@fda.hhs.gov. If you have any questions please call 240-402-8650.

Additional application procedures may be required.

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