FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

> ***Scientists, Physicians, Veterinarians, Engineers, and Statisticians*** *who will analyze data and make conclusions regarding the safety and effectiveness of medical device products to assure patients have access to high-quality, safe, and effective devices.*

Working in these positions, you may:

- Review scientific data submitted in support of a variety of medical device submissions to ensure safety effectiveness, and compliance
- Provide scientific information and consultation to industry, academic, and laboratory scientists
- Write and evaluate guidelines concerning the data required in submissions to the Agency for medical devices and their marketing
- Review statistical methods for the analysis of data, primarily from clinical studies
- Suggest changes to clinical trial protocols, including statistical methods and trial design and conduct issues
- Work in collaborative, multidisciplinary groups

The skills and experience we're looking for depend on the types of medical device products being evaluated and/or generally vary by occupation. Please see below fields and specialty areas in which we are seeking qualified individuals.

Scientists:

- Biologist
- Chemist
- Computer
- Epidemiologist
- General Scientist
- Medical Technologist
- Microbiologist
- Physicist
- Toxicologist

Physician Specialties:

- Critical Care
- Dermatology
- General Hospitalist
- Infectious Disease
- Internal Medicine
- Neurology
- Ophthalmology (Glaucoma)
- Orthopedic Surgery
- Urology

Engineering Specialties:

- Artificial Intelligence
- Biomedical
- Chemical
- Computer
- Electrical / Electronics
- Human Factors
- Materials
- Metallurgical
- Mechanical
- Polymer
- Software
- Systems

We are seeking technical expertise for _some_ of our *Scientist* and *Engineering* positions in the following areas.
Across all job opportunities, expertise in critically reviewing scientific documents and skill in clearly communicating review results are essential.

- Clinical laboratory experience
- Hematology and Coagulation (i.e., platelet mapping, thromboelastography, factor assays, Bethesda titers)
- Manual microscopy
- Gene therapy/clinical trials for gene therapy
- Cell-based transduction assays
- Molecular immunology
- Molecular hematology
- Cancer biology
- Flow cytometry
- Next Generation sequencing (NGS) full workstream (wet lab through bioinformatics)
- Immunohistochemistry
- Digital pathology
- Good Manufacturing Practices (GMP) experience
- Sequencing/viral mutation experience
- Visual Neuroscience
- Optics of the eye
- Light hazard analysis, and mechanisms of light damage to the eye
- Low Vision
- Clinical psychophysical & optical testing
- Research experience with human participants including clinical trial design and management involving ophthalmic devices (e.g., surgical lasers, imaging devices, diagnostic visual tests, ocular implants)
- Experience in the manufacture, quality control, validation/ verification testing of ophthalmic optical devices (e.g., intraocular lenses and contact lenses)

We are seeking the following expertise for our *Mathematical Statistician* positions.
- Expertise in clinical trials and clinical studies
- Experience or expertise in survival analysis, general and generalized linear models, longitudinal data analysis, missing data methods, Bayesian methods, ROC analysis, diagnostic statistics, bioassay methodology, computational statistics, propensity scores, adaptive designs, genetic statistics, or development of statistical methodology
- Ability to provide consultation to diverse teams
- Skill in effectively interpreting and presenting complex information and concepts, in both written and oral formats