



Pharmacology/Toxicology Reviewer Vacancies at FDA/CBER/OTAT

The Pharmacology/Toxicology Branches in the Division of Clinical Evaluation and Pharmacology/Toxicology in the Office of Tissues and Advanced Therapies in the Center for Biologics Evaluation and Research (**CBER/OTAT**; Silver Spring, Maryland) are searching for outstanding scientists and biomedical engineers with training and/or experience in pharmacological, toxicological, biological, and/or veterinary sciences to join our team of Scientific Reviewers. Involvement in research projects investigating tissue-engineered, stem cell therapy, and/or gene therapy products, and experience conducting experiments in animals is beneficial.

The Pharmacology/Toxicology Branches are responsible for review of a wide variety of advanced therapies, including stem cell and stem cell-derived products, functionally-mature and differentiated cells, gene therapies, products for xenotransplantation, blood- and plasma-derived products, and combination products.

The scientist or engineer will serve as the pharmacology/toxicology expert on a multidisciplinary review team that typically consists of product, clinical, and pharmacology/toxicology reviewers. Their primary responsibility will be the evaluation of preclinical data (e.g., *in vitro* and animal studies) during premarket review of investigational products. The pharmacology/toxicology reviewer provides feedback to sponsors regarding the design of their preclinical development program prior to investigational submissions. Additionally, they will review the preclinical data in investigational regulatory submissions to determine if there is adequate support for the rationale and safety of product administration in the proposed clinical population. The reviewer is also responsible for the review of the nonclinical sections of Biologics License Applications (BLAs) and Premarket Approval (PMA) applications. The regulatory reviews require written analyses and recommendations, as well as verbal communication of recommendations. Presentation at various scientific meetings is also an important aspect of the position.

The FDA offers:

- Excellent Federal Government Benefits Package (e.g., health insurance, life insurance, and retirement savings plan)
- Professional development opportunities and paid travel expenses to national professional meetings

If you are interested, please e-mail a copy of your curriculum vitae with a cover letter to Mercedes Serabian at mercedes.serabian@fda.hhs.gov.