Advisory Committee for Pharmaceutical Science
Pharmacology Toxicology Subcommittee Meeting
June 10, 2003

Topic # 1 Overview of Toxicogenomics at the Drug Development and Regulatory Interface

Lesko, LJ, et al Pharmacogenetics and pharmacogenomics in drug development and regulatory decision making: report of the first FDA-PWG-PhRMA-DruSafe Workshop. J Clin Pharmacol 43(4): 342-58, 2003

Woodcock, J., Drug development and regulation in the age of pharmacogenomics, Presentation to the FDA Science Board. April 25, 2003.

Topic # 2 Toxicogenomic Data Quality and Database Issues

Petricoin, EF III et al. Medical applications of microarray technologies: A regulatory science perspective. Nature Genetics. supplement 2002; 32:474-479.

Topic # 3 CDER FDA Product Review and Linking Toxicogenomics Data with Toxicology Outcome

Brazma, A. et al., Minimum information about a microarray experiment (MIAME) - toward standards for microarray data. Nature Genetics 2001; 29:365-371.

CDER Guidance for Industry. Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products. November 1995.