



## *Invited Speaker*



**Dr. Thomas Mathew**

Presidential Research Professor

University of Maryland, Baltimore County

### “The Assessment of Bioequivalence: A Statistical Overview”

**Monday, November 18, 2013 • MSC BE5 • 4:00pm**

The topic of bioequivalence deals with procedures for testing the equivalence of two drug products: typically, a generic drug and a brand name drug on the market. Bioequivalence testing consists of showing that the concentration of the active drug ingredient that enters the blood is similar for the two drugs. Area under the time-concentration curve, or the AUC, is usually used for this purpose, and the data are obtained based on cross-over designs. In the talk, the bioequivalence problem will be introduced, its history will be discussed, and examples will be provided. Statistical criteria that are used for bioequivalence testing, especially the criterion of average bioequivalence, will be discussed. Methodology for testing the hypotheses of average bioequivalence will be addressed. The emerging area of equivalence testing in the context of biosimilars will be briefly touched upon.