BABE-2013

OMICS Group Conferences
Accelerating Scientific Discovery

4th World Congress on
Bioavailability and Bioequivalence:
Pharmaceutical R & D Summit

May 20-22, 2013 DoubleTree by Hilton Beijing, China

In Vivo and *In Vitro* bioequivalence testing – Recent development for generic approval in the United States

Shein-Chung Chow

Duke University School of Medicine, USA

Abstract

When an innovative drug product is going off patient, pharmaceutical companies may file an abbreviated new drug application (ANDA) for generic approval. In 1984, the United States Food and Drug Administration (FDA) were authorized to approve generic drug products under the Drug Price Competition and Patent Term Restoration Act. For approval of generic drug products, the FDA requires that evidence of average bioequivalence in drug absorption be provided through the conduct of bioequivalence studies. As indicated in 21CFR320.24, bioequivalence may be established by *in vivo* (e.g., pharmacokinetic, pharmacodynamic, or clinical) and *in vitro* studies or with suitable justification by *in vitro* studies alone. In this presentation, an overview of statistical considerations including study design, criteria, and statistical methods for assessment of bioequivalence in terms of *in vivo* or *in vitro* bioequivalence testing will be provided. For *in vivo* bioequivalence testing, in addition to average bioequivalence, the concept of population bioequivalence and individual bioequivalence for addressing drug interchangeability will also be discussed. For *in vitro* bioequivalence testing, an overview regarding some *in vitro* tests such as dose or spray content uniformity through container's life, droplet and drug particle size distribution, spray pattern, plume geometry, priming and repriming, and tail off profile that are commonly employed for local action drug products such as nasal aerosols and nasal sprays products will be provided. Recent development and future research topics will also be discussed.