Pradip K Mazumder, J Bioequiv Availab 2013, 5:3
http://dx.doi.org/10.4172/0975-0851.S1.015

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

Impact of OMICS technologies in BA/BE study

Pradip K Mazumder
Krish Biotech, India

The neologism omics informally refers to a field of study in biology ending in-*omics*, such as genomics, proteomics or metabolomics. The related suffix -ome is used to address the objects of study of such fields, such as the genome, proteome or metabolome respectively. The approval process of a generic drug entails the assessment of bioequivalence in drug absorption which is usually considered as a surrogate for evaluation of drug efficacy and safety in clinical studies. For some generic drug products, the United States Food and Drug Administration indicates that the assessment of similarity between dissolution profiles may be used as a surrogate for assessment of bioequivalence (1). The nuances of regulatory process for marketing authorization of biosimilars is currently under progress in certain countries. In the EU, EMEA has clearly defined the process including overarching and product-specific guidelines, which includes clinical testing. The evaluation of Biosimilar products need to be based on comparability criteria, including at least molecular characterization, biological activity relevant for the therapeutic effect and relative bioavailability ("bioequivalence"). Disruptive technologies like Genomic Microarrays assays might be useful to compare biopharmaceuticals obtained from multiple sources (2). Impact of enabling OMICS technologies in BA/BE study is discussed. References cited are duly acknowledged in discussion.

Biography

Dr. Pradip K Mazumder is currently engaged as an Advisor in Krish Biotech & Krishi Rasayan group of Companies based in Kolkata, India. Mazumder obtained his Ph.D. from Indian Veterinary Research Institute in 1991. Dr. Mazumder obtained his post doctoral experiences from Human Molecular & Genetics, School of Medicine, University of Utah, Salt Lake City, USA.

Dr. Mazumder's research interest includes myocardial energetics with special reference to cardiomyopathy in Diabetes and obesity, molecular mechanism of type II Diabetes and obesity, NO biology. Dr. Mazumder published extensively in peer reviewed journals. He spearheaded many international collaborations in drug discovery & development in the field of metabolic and cardiovascular disorders.

Dr. Mazumder is passionate about international collaborations, partnership and alliances in Pharmaceutical, Biotechnology and Agriculture sectors. Currently he assists medium and small enterprises with strategic planning, project financing, turnaround, structural and transformational changes. He enjoys global affairs, non profit organizations, music and sports.

pradipgamma@hotmail.com