

Welcome Message from Michel Mikhail

Ladies and Gentlemen!

We are honored and pleased to welcome you to the "8th World congress on Bioavailability and Bioequivalence: Pharmaceutical R & D Summit" this June 26- 27, 2017 in this beautiful city of San Diego, California.

First of all I would like to thank the organizers and the sponsors for the excellent work done to organize such a highly reputed event.

As you know the Pharmacokinetics science defines Bioavailability as a measurement of the extent of a therapeutically active moiety or medicine that reaches the systemic circulation and is therefore available at the site of action. If two medicines are bioequivalent ie demonstrating similar Pharmacokinetics in particular Cmax and AUC and there is no clinically significant difference in their bioavailability then we speak of bioequivalence. This is true for Generic drugs, and also for 2 different formulations of the innovator drug.

Bioequivalence studies are a surrogate marker for clinical effectiveness and safety data as it would normally be accepted that if plasma concentrations of the active ingredient of the generic and innovator medicines are the same, then their concentration at the site of action and therefore their safety and effectiveness will be the same. It is the physician and health professional that links PK and PD health sciences with the medical sciences and aims to ensure the safe and effective use of drugs in the therapeutic setting. The field of Pharmaceuticals is growing rapidly, influencing the safety and efficacy of the newly developed compounds. The significance can be gauged by the fact that it has made huge advancements over the course of time and is continuing to influence various sectors.

The conference will cover the following topics:

1. Clinical Trails
2. BA-BE CROs
3. Bioequivalence Studies
4. Assessment of Bioequivalence
5. Bioequivalence & Biowaivers
6. Bioequivalence studies GCP Inspection
7. Regulatory requirements for Biosimilars and difference with Generics
8. Bioequivalence study protocols : *In vivo/ In vitro* studies

I hope that during this conference, you'll gain new knowledge and ideas from all stakeholders and could translate into new advances and take-home messages that help you advancing in your day-to-day work.

On behalf of the conference organizers, it gives me great pleasure to welcome all participants to enjoy a rich and attractive scientific program.

Yours faithfully,
Dr. Michel Mikhail
Expert in Pharmacology Toxicology
Expert in Global Regulatory Affairs
Expert in Biosimilars