



# International Conference & Exhibition Bioequivalence and Bioavailability 2010

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doi:10.4172/0975-0851.1000001

## TITLE

### RECENT ADVANCES IN THE EVALUATION OF BIOEQUIVALENCE

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Demonstration of bioequivalence (BE) between a test product and the reference listed drug (RLD) is a key component in the evaluation and market access for generic drug products. Depending on the drug and other factors, establishing BE can be costly, possibly the most expensive element in the development and approval of a generic drug product. Recent developments in pharmaceutical science and regulatory research are providing alternative approaches for the determination of BE, significantly reducing cost without increasing patient risk. One such development is the use of the Biopharmaceutics Classification System (BCS), to grant biowaivers for BCS Class 1 drugs, which are highly soluble and highly permeable. Biowaivers allow companies to demonstrate BE using in vitro dissolution studies, instead of the far more expensive in vivo human studies. An additional benefit is the reduction in unnecessary human testing. Potential extension of biowaivers to BCS Class 3 drugs is currently being studied. Another recent development is a new statistical approach proposed by the U.S. Food and Drug Administration (FDA) for the evaluation of highly variable drugs. The new approach recommends use of scaled average bioequivalence based on research conducted by the FDA. The new method is expected to significantly reduce the number of subjects in BE studies, resulting in major reduction in the cost of testing some generic drugs. The new approaches listed above will allow scientifically valid and more economical testing of generic drugs. This will increase competition, and significantly reduce the cost of generic drug products without increasing patient risk.