Design of Skin Adhesion, Irritation and Sensitization Studies for Bioequivalence Evaluation of Transdermal/Topical Drug Delivery Systems for Generic Drug Products
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This presentation will provide an overview of the different types of transdermal/topical drug delivery systems, and the design of skin adhesion, irritation and sensitization studies to meet regulatory requirements for generic submissions of these drug products. Adhesion and irritation/sensitization studies are required by regulatory authorities to demonstrate that the adhesion, irritation and sensitization properties of the generic test product are not inferior to those of the reference product (i.e., the test product is no worse adhering, no more irritating, and no more sensitizing than the reference product). Adhesion studies can be conducted within the PK or irritation studies, or as a standalone study. The scientific preference for separate adhesion studies with simultaneous applications of test and reference products will be discussed. The different subjective adhesion rating scales recommended by the different regulatory authorities will be presented, and a more objective “dot-matrix” methodology for adhesion will be proposed. Irritation and sensitization studies are typically combined into a single study, and include induction and challenge phases and, if necessary, a re-challenge phase; these studies require a sample size of 200 evaluable subjects to be able to detect the probability of sensitization in at least 1% of the general population, with greater than 80% power. The issues associated with the categorical rating scales for adhesion and irritation data will be introduced.