



International Conference & Exhibition on Analytical and Bioanalytical Techniques 2010

ANANBIOANAL - 2010

Pharmaceutical R & D Summit

doi:10.4172/2155-9872.1000099

Focus on Challenges in Regulated Bioanalysis; Case Studies

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Guidance from various regulatory authorities has helped significantly in the standardization of how to approach about regulated quantitative bioanalysis of small molecules. However there are some interpretation differences which are leading to dissimilar practices among bioanalytical scientists. Good scientific rationality must exist and assessment performed should be case specific.

There are many hot topics viz, Ion Suppression, Matrix Effect, Contamination Criteria, multi analytes, failed run investigation, Regression Type, Stability, Repeats and ISR.

Impact of above said areas on outcome of the bioequivalence study was incorporated in the current presentation in the form of case studies.