

CONFERENCE

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Similarities and Differences between Bioanalytical and Non-Clinical Dose Formulation Validation and Analysis

AUTHORS

Yuan-Shek Chan

ABSTRACT

Non-clinical dose formulation analysis methods are mainly used to verify the intended concentration of test article, while bioanalysis methods are to determination of the concentration of drugs and their metabolites in biological matrix from incurred samples. Despite the clear differences between the two, one of the commonly referenced regulatory guideline for Non-Clinical dose formulation validation and analysis is FDA Guidance for Industry: Bioanalytical Method Validation, May 2001. This is in part due to the lack of regulatory guidance on the Non-Clinical dose formulation validation and analysis, and in part due to the fact that many of the practitioners in the area of dose formulation analysis are bioanalytical scientists. Understanding the similarities and differences between these two analytical fields are critical for practitioners and for the development of a guidance specific for dose formulation validation and analysis.