

## Impact of reactant formulation agents on regulated bioanalysis: A novel approach to develop a robust bioanalytical method

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This talk will be focused on understanding and resolving day to day problems faced by bioanalytical scientists to develop a robust bioanalytical method. Recent bioanalytical research findings and our collective experience showed that certain functional groups for example carboxylic acid readily reacts with commonly used formulation agents (sorbitol or glycerol) to form monoesters. Such observations emphasize that the knowledge of bioanalytical science and its correlation to other allied sciences like formulation is also important to have a complete picture of predicted or unpredicted issues associated with the long term performance of bioanalytical method thus gives an edge to evaluate and investigate the impact of formulation constituents and their concentrations (may vary formulation to formulation) on quantitation, and at the same time provide an insight for the development or modification of not only bioanalytical method but also for the formulation development.

Based on these aforementioned facts, it is recommended to test the effect of formulation recipients/dosing vehicles on the estimation of targeted analyte(s) during method development. This will help to reduce the method development stretch and improve the quality of investigations in post analysis phases and thereby enhance the overall quality and reliability of a bioanalytical method.

### Biography

Manish S. Yadav is having more than 10 years of Bioanalytical and 5 years of Clinical research Experience and is considered authority in the field of bioanalytical science from Asia Pacific (APAC) region. Currently he is heading CRO, Alkem Labs Ltd, Mumbai, and contributing to 3 harmonization teams-A1, A6 & A9 of GBC, BSAT-APA, CVG-Canada, CPhI Conferences, Omics group and various international organizations as speaker and/or organizing committee. He has delivered >50 invited talks in national and international conferences. Moreover, he is actively serving JPBA, JCS and JBB as reviewer, and reviewed ~50 research Manuscripts as on today. His research contributions are not limited to his authorship to >35 research articles published in various reputed international journals but also developing regulated bioanalysis, quality bioscientists (~200) and industry-academia synchrony in India. During his professional research carrier, Manish has worked for CROs and Pharma companies and handled more than 375 molecules and 850 BA/BE studies, 20 Clinical Trials and a few Phase I studies. He was the key player in setting up and run bioanalytical labs of Aurobindo, GVKBIO and Veeda CR, Cadila & Alkem; and CROs like GVK-BIO and Veeda CR, and also executed Aurobindo, GVK and Veeda CR's first HPLC-MS/MS experiment.

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