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Novel approaches to handle BA/BE studies of extended release (ER) formulations for highly regulatory markets

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This talk will be focused on understanding and resolving day to day problems faced by formulators, bio-scientist, and pharmacokinetic scientist to develop a successful extended release (ER) formulations from bio front. Further, this will certainly be able to answer some of long pending questions related to handling of major problems associated with the development of ER formulations.

Basic tips and a few case studies will be shared to understand the novel and practical approaches to handle aforementioned problems and to provide a scientist a smooth ride from inception of product development to the completion of successful pivotal BE study.

Biography

Manish S. Yadav is the AVP & Head of Clinical Research & Bioanalysis, Alkem Labs Ltd., India. Having more than 15 years of bioanalytical and clinical research experience, he is considered authority in bioanalytical science from 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 more than 50 invited talks in national and international conferences. Moreover, he is actively involved in research and has published more than 35 original research articles. He is serving as reviewer to JPBA, JCS and JBB, and has reviewed more than 50 manuscripts as on today. He has 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. His research interests are regulatory and discovery bioanalysis using LC-MS, bio-assay reproducibility, endogenous and exogenous biological components associated matrix effects, drug discovery, bioavailability/bioequivalence and contract research.

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