

Novel approaches to handle Bioequivalence studies of extended release formulations in stringent regulatory environment

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This talk will be focused on understanding and resolving day to day problems faced by formulators and bio-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.

Key words: ER formulations, Novel approaches, BE, Tmax, Behavior of reference.

Biography

A globally renowned bioanalytical expert, Manish Yadav considered authority in the field of bioanalytical science from APAC mainly came in limelight at international level via his authoritative Review article on 'ISR' published in "Bioanalysis 2011" and then in the same year another review article on "Bioanalytical Method Development" published in Waters Chromatographic notes. Currently, he is dynamically contributing to 3 harmonization teams A1, A6 and A9 of Global Bioanalysis Consortium (GBC), BSAT-APA, CVG-Canada, CPhI Conferences, and various international organizations/institutes as bioscientists, speaker, organizing committee and board member through lectures, webinars and more than 50 invited talks in national/international conferences/workshops. Besides, Manish is actively serving JPBA, JCS, and JBB as reviewer and reviewed more than 50 research articles as of today.

His research contributions can't only be counted via his authorship to more than 31 research articles published in various reputed international journals but also developing regulated Bioanalysis, quality bioscientists (>200) and industry-academia synchrony in India. Manish has worked in the Bioanalytical field for over 15 years in companies such as Lambda, Torrent, Aurobindo, GVK-BIO and Veeda, Cadila 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 a bioanalytical lab for Aurobindo, and CROs like GVK-BIO and Veeda CR (Global CRO), and also conducted Aurobindo, GVK and Veeda CR's first HPLC-MS/MS experiment.

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