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Title: Challenge in Bioanalytical methodology for Long-Acting Delivery Therapies

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Abstract:

Long-Acting therapies always attract many scientist's attentions and they are also the most important drug research and development areas as well. For example, especially in diabetic and oncology fields etc. long-acting medicines will play an important role on all aspects of improving the diseases and reducing patient's sufferings. However, challenge in bioanalytical methodologies for such specially formulated drugs are significant, especially for determination of concentrations of the drugs, and as well as their metabolites in plasma, serum or tissue. Therefore, development of a reliable bioanalytical method will be extremely important for the PK/PD clinical studies and for pre-clinical studies in the drug development processes. In this presentation, the bioanalytical methods developed in our laboratories and their related results for long-acting insulin analogue-glargine (Lantus) and Liposomes formatted Doxorubucin will be introduced. Especially when high sensitivity LC-MS/MS systems are used in the methods, the challenges in biofluid extraction procedures, HPLC conditions, and as well as parameters for mass spectrometry are discussed as examples. For such successfully developed and validated methods following US FDA and European EMA guidance, they are successfully used in clinical trial studies for their PK/PD assessments

Biography

Yong-Xi Li has completed his Postdoctoral trainings at Kansas State University, Cornell University, USA. Currently he is Executive Director at Medpace Bioanalytical Laboratories after he served as vice presidents at XenoBiotic Labs and Ricerca Bioscience. His experiences are focusing on bioanalysis: TK, PK, ADA, Nab (and Cell base Nab), PD markers including method developments, validations, sample analysis for small molecule, protein and antibody therapies. He and his group developed many such applications by using LC-MS/MS and immunoassays (ELISA, ECL and Flow cytometry.....). He is author, co-author of more than 150 papers, book, presentations in reputed journals, and conferences. He is also serving as an organizing committee member for one of biotech conferences.

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