



**Yong-Xi Li**

Medpace Bioanalytical Laboratories, USA

#### 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.

[y.li@medpace.com](mailto:y.li@medpace.com)

## A SENSITIVE METHOD FOR QUANTITATIVE ANALYSIS OF OLIGONUCLEOTIDE THERAPEUTIC DRUG IN HUMAN PLASMA BY LC-MS/MS METHODOLOGY

Synthetic and polymeric oligonucleotides (RNA, DNA and their analogs) have been developed in recent many years as therapeutic drugs against a wide range of diseases conditions. During the studies, a challenge step is bioanalytical analysis. Although Scientists have used many technologies, for example gels, capillary electrophoresis, high-resolution ion exchange chromatography and MALDI etc. for the analysis in biofluids since 1970s, successful bioanalytical technologies have been eventually focused on ELISA and LC-MS/MS methodologies. However the ELISA assay cannot distinguish, in the most cases, full length parent oligonucleotides from shortened species of their metabolites or other endogenous molecules, thus preventing it from being widely utilized in metabolism studies, especially for quantitation analysis. In our laboratories, we have developed or validated LC-MS/MS Methods for 13-mer to 20-mer oligonucleotides (and analogs) which are more accurately and specifically than ELISA methods developed at our laboratories in biological matrixes, e.g. plasma, urine, and tumor samples. In this presentation, our specified extraction procedures of oligonucleotides from plasma: liquid-liquid, solid phase SPE, and immunoprecipitation extractions will be discussed. Meanwhile LC-MS/MS conditions, ion pair reagents in UPLC and multi-charge species situation in mass spectrometer will be presented. Under our optimized conditions, 10-20 ng/mL of LLOQ were reached which is the one of most sensitive method. Methods are used for pre-clinical and clinical sample analysis in our laboratories.



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