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Regulated analysis/bioanalysis (GxP) for clinical research and commercialization from global perspectives

Michael Zhou
Senior Principal Consultant, USA

The advances in regulations have increasingly brought to a global attention with recent harmonization effort. It has become truly critical to success in new drug applications (NDAs) as well as Abbreviated New Drug Applications (ANDAs) by implementing GxP in development processes. There are similarities and differences in GxP regulations and principles from worldwide standpoint. However, a common goal and objective is to ensure the integrity, accuracy and reliabilities of data generated from various R&D and commercialization processes. Analytical and bioanalytical laboratories play a vital role in above mentioned studies and processes for regulatory compliance, data submissions and approval consideration. The applicability, differences and critical aspects of GxP will be elaborated in this presentation to clarify the importance of technical and regulatory elements for bother sponsors (developers) and CROs (service providers) from global perspectives.

Biography

Michael Zhou is currently senior VP of Drug Development at Pars Pharma and previously as Senior Director of R&D at BioAnalytical Systems, Inc., with most recent roles as Senior Associate at Lachman Consultants and Director of Bioanalytical Chemistry/DMPK at Synta Pharmaceuticals Corporation. He previously held positions at DuPont, Purdue Pharma LP, Johnson & Johnson, Cardinal Health, and Scynexis with increasing responsibilities for analytical, bioanalytical and DMPK R&D in support of drug/product discovery and development. His career has focused on analytical and bioanalytical R&D plus DMPK programs for over 25 years, with expertise in regulatory compliance such as GLP, GCP, GCLP, cGMP regulations (or GxPs), and ICH, AMV and BMV guidelines. During his career tenure, he has gone through a few FDA audits with great success. He has been actively involved in organizing conferences, speaking at presentations and sharing his knowledge at workshops / short courses for numerous national and international proceedings. He serves as a member of scientific steering committees for PBA and NABF, and is a member of AAPS, ACS, ASMS and AACR. He authored over 40 research articles and 2 book chapters in the areas of analytical/bioanalytical chemistry. He is a peer-reviewer for several renowned technical journals including J. AOAC International, J. Analytical Chemistry, J. PBA, and J. Chromatogr. B, etc. He serves as an editorial board member for "Bioanalysis," edited by Future Science Group of London, UK. He was retained by John Wiley and Sons (a world renowned scientific publisher) for a book entitled "Regulated Bioanalytical Laboratories: Technical and Regulatory Aspects from Global Perspectives" (published in January 2011). He received his Ph.D. from the University of Delaware under the supervision of Dr. Donald L. Sparks, Chair and DuPont Professor.

mzhou@ion-e.com