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An Update on Harmonisation of Bioanalytical guidances by GBC (Global Bioanalysis Consortium)

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The Global Bioanalysis Consortium (GBC) is a world wide organisation consisting of representatives of scientific associations with the mission to harmonize and merge existing or emerging bioanalytical guidances to create one, unified consensus document that can be presented to the regulatory bodies/health authorities in various countries.

The objectives of GBC is to bring together stakeholders from the pharmaceutical industry, contract research organizations and academia to share current understanding of bioanalysis guidelines, identify differences in these guidelines or differences in the interpretation or application thereof to routine regulated bioanalysis. GBC will also forward with recommendations to Health Authorities and regulatory bodies worldwide on globally agreed best practices for Bioanalytical Method Validation (BMV) and application of such methods/technologies to the analysis of drugs of all molecular sizes in support of clinical and nonclinical studies

Various topics on Chromatographic and ligand binding assays have been identified for harmonization of Bioanalysis guidelines. Each topic was assigned to a team lead and a total of 20 such teams have been formed. There are 11 teams which deal with topics common for chromatography and ligand binding assays, 6 teams for large molecules and 3 teams for small molecules. Each team has a team lead and members of each team discusses on the sub topics assigned. After detailed deliberations they are compiled and will be further discussed during the global conference to be held in Sep 2012 in Netherlands. All the Team leads will make presentations and discuss on all the topics. The progress on GBC will be presented.

Biography

Ravi sankar S did his Masters in Pharmacy at Birla Institute of Technology, Ranchi in 1989, and Ph.D in Pharmacy at MGR Medical University, Chennai, 1999. He has 22 years of experience in academics, pharma industry and contract research. He was associated with J.S.S. College of Pharmacy, Ooty and Aurobindo Pharma Limited, Hyderabad before holding the current assignment as Director of Quality Assurance for Clinical Development at GVK Biosciences, India, one of the leading CROs in Asia.

Ravi is the author of 36 research papers published in referred Journals and co-author of 72 papers presented in various national and international conferences. He has authored “Textbook of Pharmaceutical Analysis” for undergraduate pharmacy students. He has co-authored a chapter on Indian Regulatory requirements for BA/BE studies in “Generic Drug Product Development - International Regulatory Requirements”, edited by Izzy Kanfer and Shargel, published by Informa.

Ravi has delivered invited lectures in various scientific forums, including PBA 2001 and PBA 2009 symposiums, Chromatographic society of UK, APA 2010, APA 2011, BIOBIO2010 and BIOANALBIO2010 etc., He is the recipient of “Best outgoing B.Pharm student” and “Career Award for Young Teachers” from All India Council for Technical Education, New Delhi. His Biography appeared in Marquis “Who’s Who in Science and Engineering”, 6th Edition, 2001.

He is a member of Harmonizing team, of Global Bioanalysis Consortium, for S1 & S3 topics, representing Asia Pacific region. His expertise includes setting up of Quality systems for Bioavailability and Bioequivalence studies, meeting various regulatory requirements, like DCGI (India), ANVISA-Brazil, EMEA (Europe), WHO, MOH-Turkey, TPP (Canada) and USFDA. He is a trainer on Good Clinical Practice and Good Laboratory Practice.

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