International Conference Summary: Regulatory Workshop On Bioequivalence And Dissolution

The International Regulatory Workshop on Bioequivalence and Dissolution was held in Istanbul, Turkey on November 29-30, 2004, under the auspices of AAPS (American Association of Pharmaceutical Sciences), TUFTAD (Turkish Pharmaceutical Technology Scientists' Association), and FIP (Federation International Pharmaceutique). Approximately 250 participants from Turkey and seven (7) other countries attended the workshop. The participants included representatives from national and international pharmaceutical industry, university and official drug regulatory affairs. The purpose of the workshop was to bring together experts from around the world who specialize in drug dissolution and bioequivalence studies and regulations, and to provide a neutral platform to discuss these issues. Dr. Vinod P. Shah, United States Food and Drug Administration, and Prof. Yilmaz Capan, Hacettepe University, Turkey, were the co-directors of the workshop.

Prof. Nevin Celebi (Gazi University, Turkey) spoke on "Regulatory Concerns in Bioavailability (BA) and Bioequivalence (BE)" and focused on the fundamentals of BA and BE, as well as specific issues encountered during such studies.

Prof. Capan spoke on "Issues and Challenges in the area of BE and Dissolution" highlighting the prerequisites and challenges in in vitro dissolution testing, significance of and issues in BE. He also discussed the future perspectives and challenges facing Turkey regarding these issues.

Prof. Leslie Benet (University of California, San Francisco, USA) lectured on "Concerns of Healthcare Practitioners and Patients" and emphasized the current difficulties in determining bioequivalent drugs, such as high drug variability and intrasubject variability and the criteria for BE evaluation procedures.

Dr. Shah gave two lectures "Regulatory Requirements for Oral Drug Products" and "Extending the Role of Dissolution in Regulating Pharmaceutical Drug Products." The first lecture covered the pharmacokinetic study designs for BE procedures, emphasizing both the conventional and unconventional oral dosage forms, while the second lecture was on dissolution testing, giving case studies as examples.

Prof. Nursen Unlu (Hacettepe University, Turkey) lectured on the "Regulatory Concerns and Challenges in BA/BE in Turkey" with a focus on the criteria regarding BA/BE applications and the challenges faced during the evaluation process.

Dr. Kamal Midha (University of Saskatchewan, Canada) spoke on "The Fundamentals of Average Bioequivalence (ABE), Proof of Concept" and with the use of case studies emphasized the average BE concept, study designs, and proof of concept.

Prof. Panos Macheras (University of Athens, Greece) lectured on "The Assessment of ABE of Highly Variable Drugs" and covered current approaches for ABE and its drawbacks, scaled BE limits and novel scaled approach.

Prof. Salomon Stavchansky (University of Texas at Austin, USA) presented a lecture titled "Pharmaceutical Equivalents of Biologics – Is It Feasible?" and gave a broad insight on the challenges and opportunities facing follow-on protein pharmaceuticals, including the regulatory challenges regarding this issue.

Prof. Gordon Amidon (University of Michigan, USA) spoke on "BCS – Concepts and Application for Biowaiver" and presented an in-depth analysis of the Biopharmaceutics Classification System (BCS) and its relation to dissolution studies.

Prof. Hans Junginger (Leiden University, the Netherlands) presented a lecture on "Cell Culture Model as a Screening Tool for Possible Prediction of Drug Absorption" and highlighted the use of the Caco-2 cell culture model for permeability measurements, selection of internal standards, effects of transporters and efflux pumps, and safety and toxicity aspects.

Prof. Patrick P. DeLuca (University of Kentucky, USA) spoke on the topic "Drug Release Design for Microparticles" and gave a detailed description of the in vitro release methods for these novel systems and highlighted the future development and regulatory challenges.

Prof. Imre Klebovich (Semmelweis University, Hungary) presented a lecture on the "Role of Different Type Pharmacokinetic/BE Studies in Drug Development for Human Use", with a focus on the conditions requiring and not requiring BE studies and also pharmacokinetic interaction studies.

Each day ended with a panel discussion to address various issues raised during the presentations. For more detailed information on the workshop and TUFTAD, please visit the TUFTAD website (www.tuftad.org.tr) or contact Prof. Capan at ycapan@hacettepe.edu.tr.