

The Role of the Biopharmaceutics Classification System and IVIVC in the Approval of Oral Drug Products

In March 1998, a workshop with the title "The Role of the Biopharmaceutics Classification System and In Vitro-In Vivo Correlations in the Approval of Oral Drug Products" will be held in Frankfurt, Germany under the co-sponsorship of AAPS and APV in cooperation with CRS, EUFEPS and the FDA. This workshop is intended to provide a forum for discussion of current thinking in the FDA and the European regulatory authorities and industry in respect to the requirements for bioequivalence studies and when in vitro tests can be used as a surrogate for studies in man. Similar to a previous workshop held in Washington, D.C. in April, 1997, the first day will focus on appropriate study design and data analysis for implementing the BCS and its relevance to bioequivalence studies. The second day will focus on appropriate study design and data analysis for implementing the BCS and achieving in vitro / in vivo correlations. The third day will be devoted to a discussion of the regulatory issues, with

presentations by members of the FDA on the current guidances in this area as well as commentary on international perspectives and harmonization of regulations from representatives of key European organizations such as the European Medicines Evaluation Agency, WHO, the German authorities (BfARM) and the European Pharmacopeia.

The workshop Committee consists of Jennifer Dressman, Ph.D., Co-Chair (University of Frankfurt), Hans Lennernäs, Ph.D., Co-Chair (University of Uppsala), Gordon Amidon, Ph.D. (University of Michigan), Luc Balant, Ph.D. (University of Geneva), Henning Blume, Ph.D. (German Pharmacists' Central Laboratory), Robert Gurny, Ph.D. (University of Geneva), Vinod Shah, Ph.D. (FDA), and Roger Williams, M.D. (FDA). We look forward to providing a forum for the participants to deepen their understanding of issues important to bioequivalence and to lively discussion of application of the BCS concepts on the European scene.

WHEN:

23-25 March 1998.

WHERE:

Frankfurt/Main, Germany (Frankfurter Maritim Hotel)

WHO SHOULD ATTEND:

Industrial, academic and regulatory scientists working with models for oral drug absorption, those responsible for the development of dissolution tests for use in evaluating new formulations of compounds under development and of drugs already on the market, those interested in in vivo/in vitro correlation for oral drug products, and those responsible for the submission/evaluation of drug product dossiers.

COST: AAPS, APV, CRS and individual EUFEPS members 1,980 DM (about US\$1200), includes all meals, a reception and an information package. Non members may participate at a slightly higher cost.

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