dx.doi.org/10.14227/DT040197P10

AAPS/CRS/FDA Workshop on Scientific Foundation and Applications for the BCS and In Vitro-In Vivo Correlations

APRIL 14-16, 1997
CRYSTAL GATEWAY MARRIOTT
ARLINGTON, VA

Goals and Objectives

During the past several years, the FDA and other international regulatory agencies have been developing guidelines for using in vitro data as a basis for maintaining drug product bioequivalence. The FDA has issued a guidance for scale up and post-approval changes, SUPAC, and has recently released guidances for Dissolution Testing of Immediate Release (IR) and In Vitro-In Vivo Correlation for Extended Release (ER) oral dosage forms. Included in the SUPAC and IR guidances is a Biopharmaceutics Classification System (BCS) that is used to set the bioequivalence standards a drug product must meet. This conference will provide the attendees with the background and current status of these guidelines and the BCS. In addition, it will focus on the future needs, i.e., where there are gaps in our knowledge and where more investigations are needed to establish quantitative guidelines. The conference will provide industry, academic and regulatory scientists with current knowledge of regulatory standards and serve as a forum for discussion of current issues and needs for regulatory research and guidelines.

This workshop will also provide participants with:

- Current methodologies in intestinal permeability determination;
- The strengths and weaknesses of the permeability methodologies;
- How to use the methodologies to determine a permeability class for a drug;
- Choice of reference compounds to include as standards for permeability correlations
- How to determine the solubility class of a drug;
- How to classify a drug with pH dependent solubility;
- Special cases in establishing a biopharmaceutics classification
- Dissolution testing for immediate release dosage forms;
- Gastrointestinal variables that affect absorption;
- IVIVC for modified release dosage forms;
- In Vitro and In Vivo methodologies for establishing IVIVCs;
- In Vitro dissolution methodologies;
- The impact of the guidance process-industry, FDA and academic views;
- Current issues in biopharmaceutics classification and IVIVC;

and

- Needs and future developments in drug product quality regulation.

For additional information about this workshop contact:

American Association of Pharmaceutical Scientists
1650 King Street, Suite 200
Alexandria, Virginia 22314-2747

Tel: 703-548-3000 Fax: 703-684-7349
On-Line: HTTP://WWW.AAPS.ORG