FIP/BPS/SIG Regulatory Sciences

FG: BCS (Biopharmaceutics Classification System) and Biowaivers

Chair: Prof. Jennifer Dressman (Germany)

Annual Report for 2015

Membership

The FG has nine members: three academic members (Jennifer Dressman, Peter Langguth and James Polli), three industrial members (Bertil Abrahamsson, Alan Parr, Tomo Tajiri), two with a regulatory affiliation (Rodrigo Cristofoletti, Mehul Mehta) and the Chair of the SIG Regulatory Sciences of FIP (Vinod Shah), four having residence in the USA, two in Germany, one in Sweden, one in the Netherlands and one in Brazil.

Activities

- Published two monographs, levatiracetam and nifedipine,
- Organized and conducted the Bioequivalence workshop in Buenos Aires (the Report has been published in the August issue of Dissolution Technologies)
- Commented on the FDA draft guidance on BCS-based Biowaiver.
- Organized a symposium at the FIP Annual Meeting in Düsseldorf

Bioequivalence Workshop in Buenos Aires

The Bioequivalence Workshop drew together almost 300 participants from all over South America to discuss the relative merits of different approaches to assessing bioequivalence of drug products in order to qualify them for a Marketing Authorization. The workshop contributed to advancing the pharmaceutical sciences and to enhancing the unique position of FIP as a global organization for scientists, as well as working to ensure that appropriate standards for registering drug products in Latin American countries are set and met, thus making a key contribution to public health in this important region.

FIP Annual Meeting in Düsseldorf

The title of the symposium was “Novel oral biopharmaceutics tools by the EU project OrBiTo” and was the brainchild of Dr. Bertil Abrahamsson (AstraZeneca).
Topics at this well-attended session included; *Screening drugs for supersaturation potential and precipitation risks* (Anette Müllertz, University of Copenhagen, Copenhagen); *Biopharmaceutical tools to predict the impact of supersaturation and precipitation on oral drug absorption* (Edmund Kostewicz, Goethe University, Frankfurt); *Gastrointestinal evaluation of enabling formulations in humans to understand intraluminal supersaturation and precipitation* (Joachim Brouwers, Catholic University Leuven); *Modeling the dynamics of fluids, pH, and bile salts in the upper GI tract:*

Towards adequate estimates of luminal drug concentration and super-saturation (Xavier Pepin, Sanofi-Aventis), *Drug-drug interactions during oral drug absorption. A European regulatory perspective* (Anna Nordmark, Swedish Medical Product Agency). The symposium brought attendees up to date on the latest biopharmaceutics tools for evaluating oral dosage forms.