MEMBERSHIP
Dr. Tomo Tajiri was selected to replace Chikako Yomoto as the Japanese representative in the FG. Tomo works for Astellas (currently on assignment in the Netherlands) and has close ties to the Japanese working group on matters relating to BCS. Thus, the FG now has 9 members: 3 academic members (Jennifer Dressman, Peter Langguth and James Polli), 3 industrial members (Bertil Abrahamsson, Alan Parr, Tomo Tajiri), 2 with a regulatory affiliation (Rodrigo Cristofoletti, Mehul Mehta) and the Chair of the SIG Regulatory Sciences of FIP (Vinod Shah), 4 having residence in the USA, 2 in Germany, one in Sweden, one in the Netherlands and one in Brazil.

ACTIVITIES

Biowaiver monographs

Published in hard copy format in 2014
- Piroxicam
- Bisoprolol fumarate
- Codeine phosphate
- Fluconazole

Published online or Accepted:
- Levetiracetam

Plans for 2015:
Submissions of Biowaiver Monographs on:
- Enalapril
- Nifedipine
- Folic acid
- Hydrochlorothiazide
- Ribavirin
- Carbamazepine

Other Publications
A. Sediq, M. Kubbinger, P. Langguth, J. Dressman
The Impact of the EMA change in Definition of „Dose“ on the BCS Dose:Solubility ratio: A review of the Biowaiver Monographs

Feedback mechanism on Biowaiver monographs
The Discussion Forum continues to serve as a Question & Answer Forum and provide a platform for exchange of views and data on biowaiving.

Lecturing & Workshops
The FG organized a symposium for the FIP Annual Meeting in Bangkok 2014 “Technological approaches to improving patient access to medicines”.
At the same meeting we presented a poster on “Utilization of BCS Based Biowavers for approval of drug products: current practice”
Research

Biothree

BIOTHREE is a research project of RIVM (National Institute of Public Health and the Environment) of The Netherlands, in cooperation with the University of Mainz and also supported partly by FIP. The first publication has been published:

Marlies Kubbinga, Laura Moghani, Peter Langguth
Novel insights into excipient effects on the biopharmaceutics of APIs from different BCS classes: Lactose in solid oral dosage forms

Comments on regulation of Biowaivers

The Focus Group contributed to drafting of revisions to the WHO guidances on approval of multisource (generic) drug products and on the BCS based biowaiver.

Planned Activities for 2015

Workshop in Buenos Aires (March 5-6)
Implementation of Biowaivers based on the Biopharmaceutics Classification System
Chaired by Prof. Pablo Quiroga
National University of La Plata and sponsored jointly by FIP and AAPS.

*The FG is honored to have FIP CEO Luc Besancon provide opening remarks at this formative workshop in South America.*

Symposium at the Annual Meeting in Düsseldorf
Novel oral biopharmaceutics tools by the EU project OrBiTo
Organizer Dr. Bertil Abrahamsson