

FIP FG on BCS & Biowaiver Annual Report 2013

MEMBERSHIP

The FG currently has 8 members: 3 academic members (Jennifer Dressman, Peter Langguth and James Polli), 2 industrial members (Bertil Abrahamsson, Alan Parr), 2 with a regulatory affiliation (Rodrigo Cristofolletti, 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 and one in Brazil. It is with regret that we acknowledge that Dr. Yomoto is no longer able to participate in the FG and the FG would like to thank her for her efforts as a FG member over the last several years.

ACTIVITIES

Biowaiver monographs

Published in hard copy format in 2013

Efivarenc
Zidovudine
Amodiaquine (was on-line in 2012)

Published online or Accepted:

Piroxicam
Bisoprolol

Plans for 2014:

Submissions of Biowaiver Monographs on:

- Codeine
- Enalapril
- Fluconazole
- Nifedipine
- Folic acid
- Hydrochlorothiazide
- Levetiracetam
- 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
J. Pharm. Sci **103**: 65-70 (2014)

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 submitted symposium proposals for Bangkok 2014, one of which was accepted.

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. In vitro and pharmacokinetic studies were completed in 2013. The first publication has been submitted.

Comments on regulation of Biowaivers

The Focus Group has been involved with the drafting of revisions to the WHO guidances on approval of multisource (generic) drug products and on the BCS based biowaiver. These discussions will continue in 2014.

Planned Activity for 2014

Prepare a poster and/or short article on the Impact of Biowaiving