

Annual Report 2017

The group has 13 members, 6 from industry, 4 from regulatory affiliations, 2 from pharmacopoeial organisations, 1 from academia, 5 having residence in Europe, 7 in the United States, and 1 in Japan. The focus group members have regularly (every 6-8 weeks) teleconferences.

- FG BCS and Biowaiver held a workshop in Chile on Bioequivalence in April 2017 (<http://www.workshopbioequivalencia.cl/>). A report on the workshop was published in the November issues of Dissolution Technologies. We also supported the FG Dissolution's workshop in Nurembourg in September.
- Further, we are the cosponsors of two symposia at the Glasgow 2018 FIP Annual Meeting: one on Global Harmonization of Drug regulations (with IPS) and one on Biologicals and Gene Therapy.
- Three Biowaiver monographs were published: Amoxicillin, Enalapril and Folic acid. Another Monograph, Proguanil, has been submitted to J Pharm Sci.
- The topic of Biowaiver has been taken up by ICH. One of our members, Mehul Mehta, is the lead representative for the FDA. Another member, Tomo Tajiri, has been able to keep us up to date on the Japanese contributions.

We continue to publish Biowaiver monographs at a very productive rate and are approaching our 50th Monograph. These monographs provide valuable guidance and input to the approval procedures (primarily) for drugs on the WHO List of Essential Medicines and thus contribute substantially to the aim of making medicines affordable to all those who need them. (Keyword for contribution is "promoting global health")