



Special Interest Group (SIG) Regulatory Sciences & Quality

- **Focus Group Dissolution/ Drug Release** (Chair Dieter Friedel, Germany, Maria Vertzoni, Greece):
 - After more than twenty years as chair of the focus group dissolution/drug release Dieter Friedel handed over the lead of the focus group to Maria Vertzoni. He will remain a member of the group.
 - continued to organize webinars:
 - Biorelevant Dissolution Testing on 16th Jan.2023, speaker was Maria Vertzoni, Greece
 - In vitro release of Semisolid Topical Dosage Forms on 5th September 2023, speaker was Flavian Radulescu, Romania
 - Real-time release for dissolution testing of an oral solid dosage form on 30th Nov.2023, speaker were Melanie Dumarey, AstraZeneca and Jobst Limberg, Germany
 - The FG contributed to the International Conference “From Science to Guidance and Practice”, Bucharest, Romania in October 2023
 - The FG works on the revision of the paper “Novel Dosage Forms
 - The Focus group Dissolution/Drug release meets in video conferences bimonthly. It comprises members from academia, industry, regulatory agencies (FDA, EMA, NIHS Japan), WHO, pharmacopoeias (USP, EDQM) from US, Japan, Greece, Ireland, Germany, France, Romania, Switzerland.

- **Focus group BCS and Biowaiver** (Chair Jennifer Dressman, Germany):
 - The Focus group published three biowaiver monographs in 2023:
 - A Kambayashi, M de Meijer, K Wegman, (...), VP Shah, J Dressman
[Biowaiver monograph for immediate-release solid oral dosage forms: Levamisole hydrochloride](#). J. Pharm. Sci. **112**: 634-639 (2023)
 - NA Charoo, DB Abdullah, DT Ahmed, (...), A Kambayashi, J Dressman
[Biowaiver monograph for immediate-release solid oral dosage forms: Levocetirizine dihydrochloride](#), J. Pharm. Sci. **112**: 893-903 (2023)
 - D Plano, N Rudolph, C Saal, B Abrahamsson, R Cristofolletti, ...J. Dressman
[Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Isavuconazonium Sulfate](#), J. Pharm. Sci. (2023) doi: 10.1016/j.xphs.2023.11.005

- Over 50 published Monographs have been published, which speaks to the long-year dedication of the group. Many of the monographs have been cited over 100 times.

Important to note is that in many countries, the approval of generics by the Biowaiver is contingent on having a positive assessment for biowaiving in a Monograph listed by the FIP on its website.

- The Focus group meets in a regular frequency.

➤ **Focus Group Bridging Studies** (Chair Oliver Hu, Taiwan)

- International Pharmaceutical Conference "Building Better Pharmaceutical Care with Technology" at the Taipei International Convention Center on October 25, 2023 with a number of international speakers including Mr. Paul Sinclair, President of the International Pharmaceutical Federation (FIP). This conference aimed to provide both domestic and international participants with insights into the innovative trends of technology in pharmaceutical development and pharmaceutical services on a global scale.
- FAPA Congress at Taipei International Convention Center on 2023/10/24~28. Pharmacists from over 20 countries attended. There were more than 50 symposia covering themes such as public health, medical supplies, society pharmacy, hospital pharmacy.
- 11th Joint Conference of Taiwan and Japan on Medical Products Regulation on October 5th, 2023 at National Biotechnology Research Park in Taipei. The conference aims to enhance the exchange of regulatory information between two sides, foster the cooperation between the bilateral officials and the industries, and assist the industry to expand the international market, while protecting the health and well-being of the public

Goals in 2024:

- Goal #1:

Organize and carry out 2 webinars on dissolution testing.

- Goal #2:

Work on the revision of the paper Dissolution/In Vitro Release Testing of Novel/Special Dosage Forms

- Goal #3:

Publication of Biowaiver monographs

- Goal #4:

Continue organizing international conference focus on harmonization of Southeast Asia, Japan, Korea Pharmaceutical regulations in Taiwan and neighbourhood city.