



Special Interest Group (SIG) on Regulatory Sciences and Quality (RS&Q) Annual Report 2021

- **The Focus Group Quality** (Chair Masaru Kato, Japan) organized an online conference on June 4th. The topic of the conference was “medical care of with/post corona era.”
- **The Focus Group Clinical Bridging Studies** (Chair Oliver Hu, Taiwan) held a Conference on International Medical Devices (Drugs and Devices) Regulations in Taipei, Taiwan and invited experts from academia, government officers, and representatives from US FDA, Israel Ministry of Health, Germany, and Korea.
The goals of this platform were the following:
 1. Develop harmonization schemes of pharmaceuticals’ regulations for the ASEAN member countries.
 2. Accelerate of achieving the objective of ASEAN Free Trade Area (AFTA).
 3. Reduce technical barriers of trade and improve drug quality, safety and efficacy.
- **The Focus group BCS and Biowaivers** (Chair Jennifer Dressman):
 - has bi-monthly (by video conference) to discuss ideas and work on publications and workshops.
 - published two Biowaiver monographs last year (Sitagliptin and Carbamazepine), which represented the major part of the work.
 - Members of the focus group organized an ICH-M9 -related symposium focussing on Permeability measurements. (ICH M9: biopharmaceutics classification system based biowaivers)
- **The Focus group Dissolution/Drug release (Chair Horst-Dieter Friedel, Germany)**
 - organized and carried out a webinar with the title “FIP Guidelines for Dissolution Testing of Solid Oral Products” in June.
 - New members joint the Focus group Dissolution/Drug release, so that 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. The group met in video conferences in a regular frequency.
- Exchange meetings with the focus group chairs.

Goals in 2022:

- Goal #1:

Submit proposals for symposia for the PSWC 2023

- Goal #2:

Organize a joint forum between PSJ (Pharmaceutical Society of Japan) and FIP at the annual meeting of the PSJ.

- Goal #3:

Prepare for the next consensus workshop on Bridging Studying among Asia-Pacific Harmonization on BS in Taiwan.

- Goal #4:

Continuing to follow the current and changes of Regulations of Asia-Pacific countries, especially China.

- Goal #5:

Organize and carry out 2 webinars on dissolution testing.