

Special Interest Group (SIG) on Regulatory Sciences and Quality (RS&Q) Annual Report 2022

- **Focus group BCS and Biowaiver (Chair Jennifer Dressman, Germany):**
 - published biowaivers on levocetirizine and levamisole.
- **Focus Group Dissolution/ Drug Release (Chair Dieter Friedel, Germany)**
 - continued to organize webinars: In Vitro in Vivo (IVIVC) Correlations: Establishing a correlation between in vitro tests and in vivo product performance , 3rd Feb. 2022, Speaker was Patrick Marroum, AbbVie (USA)
 - The FG contributed to the International Conference “From Science to Guidance and Practice”, Bucharest, Romania in October 2022
 - 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 Quality (Chair: Masaru Kato, Japan)**
 - FG organized PSJ-FIP joint symposium at PSJ annual symposium in March.
- **Focus Group Bridging Studies (Chair Oliver Hu, Taiwan)**
 - Bridging study evaluation (BSE) of new drug applications according to the ICH E5 guideline has been implemented more than 20 years in East Asian region. In past two decades, the implementation of regulation and practical operations of BSE has critically facilitated the process of new drug development, review, and approval by TFDA.
 - Oliver Hu chaired the International Conference on the 20th Anniversary of Bridging Study Evaluation – Ethnic Factors in the Acceptability of Foreign Clinical Data in Global Regulatory Convergence aimed to overview the status and execution of the ICH E5 guideline, shared perspectives from regulatory, academia and pharma industry (Taipei, May 6, 2022).
 - Oliver Hu attended the International Conference “Asia Paving the Way in a New Regulatory World – What Does This Mean For Patients, Regulators, and Industry?” (17 - 21 OCTOBER 2022,VIRTUAL CONFERENCE) ;
 - Oliver Hu attended the 10th Joint Conference of Taiwan and Japan on Medical Products Regulation on October 20th, 2022.
- Exchange meetings with the focus group chairs.

Highlight: The regular webinars on dissolution testing are very well received and attended.

SIG goals for the 2023 calendar year

- Goal #1:
produce at least two more BCS-based biowaiver monographs

- Goal #2:

Organize and carry out 2 webinars on dissolution testing.

- Goal #3:

Prepare for the next consensus workshop on Bridging Study among Asia-Pacific Harmonization on Bridging Studies in Taiwan

- Goal #4:

Increasing interaction with BP and activating joint research.