



Special Interest Group (SIG) on Regulatory Sciences and Quality (RS&Q) Annual report 2020

- A FIP forum with the title “Collaboration of pharmacists and pharmaceutical scientists in patient empowerment at global levels” was organized at the annual meeting of Pharmaceutical Society of Japan (PSJ) in March. Mr. Dominique Jordan (FIP chair) was a speaker of the forum. Due to the outbreak of COVID-19, the forum was not held but the titles, authors and abstracts have been published.
- A webinar with the title “Qualification of dissolution apparatus” was organized and carried out in December.
- Biowaiver guidelines were published: Cephalexin Monohydrate, Moxifloxacin hydrochlorid (submitted)
- Several symposia for the annual conference in Brisbane 2021 were developed and submitted to the organizers:
 - Health in Daily life
 - New trends for medicines of the future
 - Biosimilar and Nanosimilar
 - Good drugs for everyone, everywhere
 - How globally harmonized regulatory approaches can facilitate patient access to affordable medicines
- The SIG submitted comments on draft guidelines, such as WHO working document: Dissolution test for solid oral dosage forms
- New members joined the Focus group Dissolution/Drug release, so that it comprises members from academia, industry, regulatory agencies (FDA, EMA, NIHS Japan), pharmacopoeias (USP, EDQM) from US, Japan, Greece, Ireland, Germany, France, Romania. The group met in video conferences in a regular frequency.

Goals in 2021:

- Goal #1: Organize and carry out 2 webinars on dissolution testing.
- Goal #2: Submit proposals for symposia for the annual conferences
- Goal #3: Organize a FIP forum at the annual meeting of Pharmaceutical Society of Japan (PSJ)