Members of the Focus groups Dissolution/Drug Release and BCS Biowaivers worked in the ICH Expert Working Group (EWG) of ICH M9 “Biopharmaceutics classification system-based biowaivers”. The core guideline and annex with Q&A reached step 4 in November 2019 and will now be implemented in the regions. Brazil, China, Europe, US, Canada, Singapore, Japan, Korea, Switzerland, WHO, Mexico, Taiwan, and Australia participated in the ICH EWG.

The ICH M9 Guideline and Q&As provide recommendations to support the biopharmaceutics classification of medicinal products and to support the waiver of bioequivalence studies. Biopharmaceutics classification of the drug substance is based on solubility and permeability. Drug products are eligible for a BCS-based biowaiver, when they meet the criteria for drug product composition and in vitro dissolution performance. BCS-based biowaivers are limited to immediate release, solid orally administered dosage forms or suspensions designed to deliver drug to the systemic circulation.

This Guideline will reduce the costs and time of development and prevent unnecessary exposure of mostly healthy volunteers to medicinal products, as in vivo studies to prove the biopharmaceutical quality of the medicinal product would not be needed, and therefore, facilitate the patient’s access to medicines or post-approval changes.

This is an excellent example of the collaboration of the focus groups.

For Ondansetron a new biowaiver monograph was published. Biowaiver monographs are literature reviews, in which publicly available data are gathered and organized to address the question of whether a biowaiver can be recommended for a new formulation of that API.

The SIG is particularly proud of the ICH M9 “Biopharmaceutics classification system-based biowaivers” where the requirements for biowaivers will be harmonized. This facilitates the patient’s access to medicines.

Goals for 2020:

- Goal #1:
  The SIG plans to reactivate the hands-on dissolution workshops. The ‘Hands-on-Dissolution’ Workshops are designed to bring pharmaceutical scientists round the globe up-to-date with respect to the latest developments in dissolution technologies, applications of dissolution to pharmaceutical
products and the relevant regulations. It combines theoretical aspects with practical exercises with the dissolution equipment.

• Goal #2:
Continue to publish biowaiver monographs. For 2020 it is planned for moxifloxacin, cephalexin, levimasole and carbamazepine.
• Goal #3:
Submit proposals from the SIG for symposia at the Annual conference 2021 in Brisbane.