

Redacția: București, str. Traian Vuia 6, sect. 2, cod 020956

www.FarmaciaJournal.com

VOL. 69, nr. 2, 2021

**The 5th Conference on
The Global Harmonization Initiative,
December 7 - 8, 2021 • Amsterdam • Netherlands**



The Global Bioequivalence Harmonisation Initiative is intended to support the process of global harmonization *via* scientific discussion among international stakeholders. Therefore, a series of international conferences was founded by EUFEPS in collaboration with AAPS supported from the beginning by the European Medicines Agency (EMA) as well as the U.S. Food and Drug Administration (FDA).

Regulators and speakers from other countries/regions, e.g., Canada, Chile, China, India, Japan, Jordan, Mexico, and Brazil, will be invited to the discussions. Such global participation presents an ideal platform for scientists from regulatory agencies, pharmaceutical industry and academia to exchange their experience and scientific viewpoints: scientific consensus should constitute the most appropriate basis for harmonisation.

The Organizing Committee of the 5th GBHI Workshop is now presenting the topics, date and venue of the next conference. After the 4th conference in Washington in 2019, now

Amsterdam has again been selected as the location. The conference is planned as a hybrid conference in which some participants can attend at the venue - depending on the severity of the COVID-19 pandemic in Europe and worldwide - while offering virtual access to all those who cannot manage to travel to Amsterdam.

The topics of the next conference are:

- Fed *vs.* fasted studies for immediate release dosage forms: relevance of excipients, disintegration/dissolution specificities, drug substance properties and physiological GI conditions
- Statistical considerations for BE assessment: replicate design for BE of highly variable drugs, two-stage design and PK modelling as supportive tools for BE assessment
- Topical products: scientifically-based approaches for a waiver of clinical endpoint trials
- Narrow therapeutic index drugs: study design and acceptance criteria