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**EUFEPS/AAPS GLOBAL BIOEQUIVALENCE HARMONISATION
INITIATIVE: 5th International Workshop – GBHI 2021
September 28 - 29 • 2022 • Amsterdam, The Netherlands**



**The Global Bioequivalence
Harmonisation Initiative**

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 harmonization.

The Organising 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 conference have been fixed:

- Fed *versus* fasted studies for immediate release dosage forms: relevance of excipients, disintegration/dissolution specificities, drug substance properties and physiological GI conditions - new findings shall help achieve harmonisation
- 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

9th BBBB International Conference on Pharmaceutical Sciences

Pharma sciences of tomorrow

15th to 17th September 2022, Ljubljana, Slovenia

The 9th BBBB Conference on Pharmaceutical Sciences “Pharma sciences of tomorrow” is to be held on-site in Ljubljana, Slovenia, from 15th to 17th September 2022, following COVID-secure guidelines to facilitate face-to-face networking and learning.

The 2022 BBBB Conference will feature focused panels in all areas of pharmaceutical sciences to establish an informative and successful BBBB Congress with the goal of bringing the community together and strengthening the BBBB scientific network.

The program consists of plenary and keynote lectures by well-known experts in various fields of pharmaceutical sciences, from all BBBB partners and the wider scientific community. There will also be ample opportunities for younger researchers to present their findings in the form of oral presentations and posters in an international setting. The conference will provide an opportunity for the exchange of scientific ideas between young and established scientists and professionals, as well as between people from academia, industry and regulatory authorities.

Main topics of the 9th BBBB Conference:

✓ Pharmaceutical Technology & Nanotechnology: towards digital, sustainable and continuous processing of user-friendly (biotech) medicines

✓ Pharmaceutical Chemistry: new molecules for treating neurodegenerative diseases, and bacterial/ viral infections

✓ Pharmaceutical Biology: peptides as therapeutics and biorecognition elements, and m-RNA vaccines

✓ Clinical Pharmacy and Laboratory Medicine: therapeutic drug monitoring (TDM) & pharmacogenomics in personalised medicine

✓ Pharmaceutical Analytics: emerging contaminants in environmental samples and pharmaceutical products

Further information on registration and contribution requirements are available on the symposium website: <http://bbbb2022.sfd.si/>