EUFEPS
Global BE Harmonization Initiative
- intention and perspective -

3rd symposium on bioequivalence requirements
Amman/Jordan, May 2/3, 2018
History …

- starting point: series of BIO-international Conferences
  - BIO '89 Toronto Airport/Canada
  - BIO '92 Bad Homburg/Germany
  - BIO '94 Munich/Germany
  - BIO '96 Tokyo/Japan
  - BIO 2000 Montreal/Canada
  - BIO '03/'05/'08 in London/U.K.

- Goals:
  - improve regulatory requirements ("science-driven regulations")
  - suggestions for unresolved issues …
  - … based on experimental findings
  - some kind of "consensus" conferences
The EUFEPS initiative

- 2006: Network on Bioavailability & Biopharmaceutics
- several conferences & Open Fora on CHMP Draft Guidelines
- since 2013: start of preparation of GBHI
  - significant support by CHMP (Tomas Salmonson & PK-WP)
  - FDA accepted to join the process (Mein-Ling Chen, Mehul Mehta)
  - EUFEPS invited AAPS, FIP, WHO as co-sponsors

The main conferences

- 2015: 1\textsuperscript{st} conference in Amsterdam/The Netherlands
  (contributing Agencies: EMA, US-FDA, CFDA, NIHS, ANVISA)
- 2016: 2\textsuperscript{nd} conference in Rockville/USA
  (additional Agencies: Mexico, Chile, Health Canada, …)
- 2018: 3\textsuperscript{rd} conference in Amsterdam/The Netherlands
3rd EUFEPS GBHf Conference
April 11-13, 2018

More than 100 scientists attended and contributed
GBHI - 3 conference in Amsterdam 2018

Scientific Planning Committee:
chair: Henning Blume, SocraTec C&S ● co-chair: Mehul Mehta, US-FDA

- Gerald Beuerle, ratiopharm/DE
- Mei-ling Chen, ex-FDA/USA
- Barbara Davit, ex-FDA/USA
- Wenlei Jiang, FDA/USA
- Andreas Kovar, Sanofi/DE
- Henrike Potthast, BfArM/DE
- Tomas Salmonson, MPA/S
- Barbara Schug, SocraTec R&D/DE
- Nilufer Tempal, US-FDA
- Yu-Chung Tsang, Apothex/CAN
- Jan Welink, MEB/The Netherlands
- Clive Wilson, Glasgow University/UK

Topics for harmonization
- Necessity of multiple dose studies in BE assessment
- BE of Transdermal Delivery Systems
- Liposomal parenteral preparations
Regional Harmonization Conferences

- our intention/goal:
  - extension of the activity to global horizon
  - involvement of regulatory authorities outside EU, USA, Japan
  - attracting scientists all over the world to contribute

- ACDIMA took the initiative ...

3rd HBR Conference 2018 in Amman/Jordan
3rd Amman conference

- reflecting the outcome of previous GBHI conference ...
  - BCS-based biowaiver (update and beyond ...)
  - doxorubicin liposomal parenterals
- ... but adding additional topics to the agenda
  - importance of BE in developing fixed-dose combination products
  - conditions for designing and developing value-added medicines

Perspective for MENA/GCC region

- harmonization of regulatory requirements essential
- essential goal: "science-driven" regulations
- suggestion for pharmaceutical scientists: learn & confirm ...
  - share your experience and let us learn from it
  - don't insist in your own perspective/existing position ...
  - ... be open minded (even if this might be more difficult)