

BioBridges 2022 – Program

Thursday, September 22

8:30–9:00 Registration

9:00–10:30 Morning session 1

Biosimilars and orphan medicinal product development
Rene Anour (AGES) 45 min

Improvement of PK drug properties – development and regulatory perspective
Tomáš Hauser (Zentiva) 45 min

10:30–11:00 Coffee break

11:00–12:30 Morning session 2

ICH M13 BES harmonization – basic prerequisites
Susana Almeida (Medicines for Europe) 45 min

EMA News in dissolution 2020–2022
Jean-Michel Cardot (Consultant) 45 min

12:30–14:00 Lunch

14:00–15:30 Afternoon session 1

Untangling absorption mechanisms and variability in bioequivalence studies using population analysis
Nuno Silva (Universidade de Lisboa) 45 min

Locally applied Locally acting in GIT – biowaivers
Jean-Michel Cardot (Consultant) 45 min

15:30–16:00 Coffee break

16:00–17:00 Afternoon session 2

Locally applied, locally acting products
Flavian Radulescu (University of Medicine and Pharmacy) 60 min

19:00–? 😊 Dinner at Altány Kampa Restaurant

Friday, September 23

9:00–10:30 Morning session 1

Product specific guidelines – Tmax criteria
Graham Pennick (Reckitt Benckiser)

45 min

Tmax evaluation – where do we go...
Helmut Schütz (BEBAC)

45 min

10:30–11:00 Coffee break

11:00–12:30 Morning session 2

Partial AUCs – tool for development vs regulation
Vít Perlík (BioBridges, Consultant)

45 min

Product specific guidelines
Loice Kikwai (Consultant)

45 min

End of meeting

12:30–13:30 Lunch