

# Day 1

8:00–9:00

Registration

**9:00–10:30**

**Morning session 1 (2 × 45 min)**

**Topic 1: ICH M9 – BCS**

- ICH M9 – BCS Guideline – overview of comments/final version  
*Henrike Potthast (BfArM, PKWP)*
- ICH M9 – BCS Guideline – industry perspective  
*Martina Nora Odložilíková (Consultant)*

10:30–11:00

Coffee Break ☕

**11:00–12:30**

**Morning session 2 (2 × 45 min)**

**Topic 2: EMA Scientific Advices**

- Biosimilar PK trials and an Agency's perspective to EMA Scientific Advice  
*René Anour (AGES)*
- EMA Scientific Advices – industry perspective  
*Nathalie Masson (Unither Pharmaceuticals)*

12:30–13:30

Lunch 🍴

**13:30–15:00**

**Afternoon session 1 (2 × 45 min)**

**Topic 3: ICH M10 – Bioanalytical Method Validation**

- ICH M10 – Feedback and comments from the European Bioanalysis Forum  
*Philip Timmerman (EBF)*
- ICH M10 – Bioanalytical Method Validation – industry case studies  
*Maria Caturla (Anapharm Bioanalytics)*

15:00–15:30

Coffee Break ☕

**15:30–17:30**

**Afternoon session 2 (2 × 45 min)**

**Topic 4: WEU**

- Well-established use - principles, requirements and case-studies  
*Jana Klimasová (SUKL)*
- WEU procedures – reflection of reality  
*Marina Feřtek (Consultant)*

**Topic 5: Future trends**

- Panafrican agency  
*Alassane Ba (Centre Humanitaire des Métiers de la Pharmacie)*



## Day 2

9:00–10:30

**Morning session 1 (2 × 45 min)**

**Topic 6: LALA topicals**

- Draft guideline on quality and equivalence of topical products  
*Flavian Radulescu (Universitatea de Medicina si Farmacie „Carol Davila“)*
- Draft guideline on quality and equivalence of topical products – case study  
*Volodymyr Stus (Polpharma)*

10:30–11:00

Coffee Break ☕

11:00–12:30

**Morning session 2 (3 × 30 min)**

**Topic 7: Dissolution/development**

- Dissolution for specific products e.g. vaginal rings, IVIVC, suspensions  
*Jean-Michel Cardot (Université d’Auvergne)*
- Simulations – bootstrapping, Q and A  
*Jiří Hofmann (Zentiva)*
- Dissolution profile comparison using different statistical approaches –  $f_2$  bootstrapping  
*Paulo Paixão (Universidade de Lisboa)*

12:30–13:30

Lunch 🍴

13:30–15:30

**Afternoon session 1 (2 × 45 min plus 1 x 30 min)**

**Topic 8: Product specific guidelines / BE**

- Harmonization of BE requirements – harmonization of reference products  
*Susana Almeida (Medicines for Europe)*
- EMA product specific guidelines  
*Paola Coppola (MHRA)*
- BioBridges 2019 – concluding remarks  
*BB team*

15:30

Coffee Break / End of meeting ☕