08.00 – 09.00 **Registration and welcome coffee**

09.00 – 09.15 **Welcome and opening address - Susana Almeida,** IGBA

09.15 – 10.40 **Session 1 – Single global development of generic medicines: enabling patient access and share your views on the topic**

Chair: Susana Almeida, IGBA

- Regulatory barriers to global access to generic and biosimilar medicines: preliminary research findings
  University of Maryland and University of Michigan
- Regulatory reliance: perspective from an international coalition of regulators
  Matthias Roost, Clinical Pharmacology Assessor, Division Clinical Assessment, Swissmedic
- Harmonization and Global Access to Generic Drugs
  Sarah Ibrahim, FDA (invited)
- How can the EU regulatory framework and new Pharmaceutical legislation support single global development?
  TBC, EC

Panel discussion

10.40 – 10.50 **Networking coffee break**

10.50 – 12.25 **Session 2 – Model informed approaches supporting bioequivalence in generic medicines development and share your views on the topic**

Chair: Pavel Farkas, Teva (invited)

- ICH introduces M15 guideline: a milestone in model-informed BE
  Pavel Farkas, Teva (invited)
- Regulatory views on M15 and model-informed BE
  Kristin Karlsson, Swedish Medical Products and Vice Chair of the EMA MWP (invited)
- Application of model informed drug development in generic medicines: Bioequivalence risk assessment steady state exposure and evaluation of food effect.
  Carlos Walter Bertoncini, Biopharmaceutics & Clinical Science Manager, Chemo Group
- Application of physiologically-based biopharmaceutics modeling (PBBM) in BE risk assessment
  Talia Flanagan, UCB
- Opportunities and observations about utility of modeling to support BE
  James E. Polli, University of Maryland

Panel discussion

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12.25 – 13.15 **Networking buffet lunch**

13.15 – 15.15 **Session 3 – International harmonisation of bioequivalence: current status and next steps (ICH M13A implementation and hot topics for M13C)**

Co-Chairs: Lei Zhang, FDA (invited) and **Russ Rackley**, Viatris

- M13 guideline series
  Lei Zhang, FDA (invited)
- Impact of M13A from a European perspective
  Jan Welink, MEB/EMA
- Challenges and opportunities of M13A guideline for generic industry
  Irmela Gabriel, Teva
- M13A implementation plan in the EU
  Kevin Blake, EMA
- Statistical challenges and opportunities in ICH M13C
  Helmut Schütz, University of Vienna
- M13C an opportunity to harmonise bioequivalence requirements for (NTI) drugs
  Paulo Paixão, University of Lisbon Faculty of Pharmacy

Panel discussion

15.15 – 15.30 **Networking coffee break**

15.30 – 16.30 **Rapid session 4 – Compliance and oversight in BE**

Chair: Janja Luksa, Sandoz

- Regulatory expectations for data integrity
  Peter Twomey, EMA (invited)
- FDA's perspective
  Nilufer Tampal, FDA (invited)
- Data integrity in BE: sponsor's perspective
  Janja Luksa, Sandoz

Panel discussion

16.30 – 16.45 **Closure of the conference - Susana Almeida,** IGBA

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