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2ND BIOEQUIVALENCE WORKSHOP

THE HOTEL, BRUSSELS | 26 APRIL 2023

#BIOEQ23

08.00 – 08.30 **Registration and welcome coffee**

08.30 – 08.40 **Welcome and opening address**
Adrian van den Hoven, Medicines for Europe

08.40 – 10.00 **Session 1 – International convergence and reliance**

Chair: Gerald Beuerle, Teva

Experience from the Generic Drug Cluster
Sarah Ibrahim, FDA

European views on international convergence and reliance in generic drug development
Kevin Blake, EMA

The role of IPRP and ICH in bioequivalence harmonization and convergence
Peter Bachmann, BfArM, Germany, Chair of IPRP

Single global development of generic medicines
Susana Almeida, Medicines for Europe

Panel Discussion

10.00 – 10.20 **Networking coffee break**

10.20 – 12.20 **Session 2 – ICH M13 - Bioequivalence for IR solid oral dosage forms**

Chair: Russ Rackley, Viatris

M13 guideline series
Lei Zhang, FDA

Impact of M13A from a European perspective
Jan Welink, MEB/EMA

Industry's perspective on the M13A
Gerald Beuerle, Teva

Statistical challenges and opportunities in ICH M13A
Helmut Schütz, University of Vienna

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An originators' perspective on ICH M13
Talia Flanagan, UCB

Panel Discussion

12.20 – 13.20 **Networking buffet lunch**

13.20 – 14.05 **Rapid session 3 – Model informed drug development and model-based BE**

Chair: Pavel Farkas, Teva

M15 and model-based BE
Pavel Farkas, Teva

Regulatory views on M15 and model-based BE
Kristin Karlsson, Swedish Medical Products and Vice chair of the EMA MWP

Panel Discussion

14.05 – 14.50 **Rapid session 4 – Implementation of ICH M10: Bioanalytical Method Validation**

Chair: Pavel Farkas, Teva

Impact of M10 on new studies and existing studies

Implementation of M10 in Europe
Jan Welink, MEB

Impact of M10 on new studies and existing studies
Pradeep Rawat, Sandoz Hyderabad
Indravadan Bhoir, Teva

Panel Discussion

14.50 – 15.10 **Networking coffee break**

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15.10 16.30 — **Session 5 – Compliance and oversight in BE**

Chair: Janja Luksa, Sandoz Int., GmbH

European insight on compliance and oversight of BE trials
Peter Twomey, EMA

US perspective on compliance and oversight in BE trials
Nilufer Tampal, FDA

Sponsor oversight: challenges and opportunities
Janja Luksa, Sandoz Int., GmbH

Panel Discussion

16.30 16.45 — **Closure of the workshop**
Susana Almeida, Medicines for Europe

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