**PROGRAM**

**EUFEPS Open Forum: ICH M13 Draft Guideline**

**May 15, 2023 Frankfurt**

**Conference Co-chairs: Erem Bilensoy and Sandra Klein**

**Moderator: Henning Blume and Leslie Z. Benet**

**Scientific Planning and Organisational Committee:**

* Erem Bilensoy (chair), *Hacettepe University, Turkey*
* Sandra Klein (chair), *University Greifswald, Germany*
* Gerald Beuerle, *Teva, Germany*
* Henning Blume, *FFQM, Germany*
* Anne Seidlitz, *University Düsseldorf, Germany*
* Ralph-Steven Wedemeyer, *SocraTec R&D GmbH, Germany*
* Jennifer Dressman, *Fraunhofer ITMP, Germany*
* Sandra Häberle, *EUFEPS, Germany*
* Georg Hempel, *University of Münster, Germany*
* Andreas Kovar, *Sanofi Aventis, Germany*
* Barbara Schug, *SocraTec R&D GmbH, Germany*
* Peter Stopfer, *Boehringer Ingelheim, Germany*

**Special guest and co-moderator:** Leslie Z. Benet, University of California, USA

**Drafting group panel members:**

* Jan Welink, *Dutch Medicines Evaluation Board CBG-MEB, The Netherlands*
* Susana Almeida, *Medicines for Europe, Belgium*
* Paolo Paixao, *INFARMED, Portugal*
* Talia Flanagan, *UCB Pharma S.A., Belgium*
* Sebastian Haertter, *Boehringer Ingelheim, Germany*

**PROGRAMME SCHEDULE**

10:00-16.30

**Welcome and introduction**

Erem Bilensoy: *Goals, objectives and structure of the conference*

Sandra Klein: *How the input from stakeholders were collected and presented*

Jan Welink: *Regulatory considerations of the ICH bioequivalence guideline*

**Session I: Study design aspects and evaluation**

**Lines 59-305 of the draft M13A Guideline**

**Chair:** Gerald Beuerle

N.N. (Drafting group): Regulatory considerations

Gerald Beuerle: Presentation of the comments

**Session II: Data Analysis and Investigational Products**

**Lines 306-481 of the draft M13A Guideline**

**Chair:** Anne Seidlitz

N.N. (Drafting group): Regulatory considerations

Anne Seidlitz: Presentation of the comments

***13:00-13:45 Lunch break***

**Session III: Endogenous compounds, Special IR products & pH dependent solubility**

**Lines 482-581 of the draft M13A Guideline**

**Chair:** Erem Bilensoy

N.N. (Drafting group): Regulatory considerations

Erem Bilensoy: Presentation of the comments

**Session IV: Introduction, Documentation and Glossary**

**Lines 1-58 and 582-705 of the draft M13A Guideline**

**Chair:** Ralph-Steven Wedemeyer

N.N. (Drafting group): Regulatory considerations

N.N.: Presentation of the comments

**Session V: Upcoming ICH draft guidelines: When to expect what?**

**Chair:** Jan Welink

**Award Ceremony**

**Lifetime Achievement Award 2023**

**of the Frankfurt Foundation Quality of Medicines (FFQM)**

Awardee:

Prof. Leslie Z. Benet, PhD

Schools of Pharmacy & Medicine

University of California San Francisco

***16:30: End of conference and closing remarks (conference chairs)***