Draft Program as of 1/11/2024: Presentation Titles and Speakers subject to change

Organized By: EUFEPS Bioavailability & Biopharmaceutics Network; PQRI Product Quality Research Institute

The Global Bioequivalence Harmonisation Initiative

In Collaboration with: U.S. FOOD & DRUG ADMINISTRATION

Hosted by: USP

PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative 6th International Workshop – GBHI 2024

April 16-17, 2024 - Rockville, MD

GBHI 2024 In-Person Event

Tuesday – Wednesday, April 16 - 17, 2024

United States Pharmacopeia (USP) Meeting Center

12601 Twinbrook Pkwy, Rockville, MD 20852

Wenlei Jiang, Food and Drug Administration (FDA), US (Co-Chair)
Barbara S. Schug (SocraTec R&D), Germany (Co-Chair)

Day 1 – Tuesday, April 16, 2024 8:00 AM – 5:00 PM US EDT All times are in US Eastern Daylight Savings Time	
8:00 - 8:30 AM	***CHECK-IN/BREAKFAST***
8:30 - 8:35 AM	***Workshop Opening*** Wenlei Jiang, Food and Drug Administration (FDA), US (Co-Chair)
8:35 - 8:40 AM	***Welcome and Introduction*** PQRI Board Chair (Invited)
8:40 - 9:00 AM	***Opening Remarks*** Lei Zhang (FDA), US
SESSION 1: MOVING THE NEEDLE TOWARDS CONVERGENCE ON ICH M13 TOPICS Session Chairs: Nilufer Tampal (FDA), US & Paulo Paixão (Infarmed), Portugal	
9:00 - 9:05 AM	***Summary of Preceding GBHI Discussions on ICH M13 Related Topics*** Nilufer Tampal (FDA), US
Part 1: Oral PBPK	
9:05 – 9:20 AM	***Physiological Based Pharmacokinetics (PBPK) Fasted/Fed Bioequivalence (BE) – Generic Industry Perspective*** Rebeka Jereb (Sandoz)
9:20 – 9:35 AM	***Industry Perspective on the Utility of Model-Based Approaches in BE*** Filippos Kesisoglou (Merck), US
9:35 – 9:50 AM	***PBPK Modeling for Waiving Fed BE Study*** Rodrigo Cristofoletti (University of Florida), US
9:50 – 10:10 AM	***PANEL DISCUSSION*** Rebeka Jereb, Filippos Kesisoglou, Rodrigo Cristofoletti, Paulo Paixão, Fang Wu (FDA), US

10:10 – 10:30 AM	***COFFEE* BREAK**
Part 2: Narrow Therapeutic Index (NTI) Drugs And Highly Variable Drugs (HVDs)	
10:30 – 10:50 AM	***BE Study Design for NTI Drugs and Control of Type I Error*** Paulo Paixão (Infarmed), Portugal
10:50 - 11:10 AM	***Alternative BE Criteria/Approaches for NTI Products*** Wanjie Sun (FDA), US
11:10 – 11:30 AM	***Deep Dive into Generic Drug Applications to Seek Data-Driven Harmonization of BE Criteria for NTI drugs*** Wenlei Jiang (FDA), US
11:30 – 11:50 AM	***HVD and Type I Error*** Helmut Schutz (BEBAC) Austria
11:50 AM - 12:10 PM	***Two-stage Designs and their Acceptability in the EC Area*** Susanne Urach, European Medicines Agency (EMA), Austria
12:10 - 12:40 PM	***PANEL DISCUSSION*** Paulo Paixão, Wanjie Sun, Wenlei Jiang, Helmut Schutz, Susann Urach
12:40 - 1:30 PM	***LUNCH***
SESSION 2: BE CONSIDERATIONS FOR MODIFIED RELEASE (MR) DRUG PRODUCTS: SINGLE DOSE VS MULTIPLE DOSE STUDIES AND STRENGTH WAIVERS **Session Chairs: Barbara Schug (SocraTec R&D), Germany & John Gordon (Health Canada), Canada**	
1:30 – 1:45 PM	***Summary of Preceding GBHI Discussions on MR Drug Products including Solid Oral MR Products, Transdermal Therapeutic Systems and Long-Acting Injectables (LAI)*** Barbara Schug, (SocraTec R&D), Germany
Part I: Single Dose vs. Multiple Dose for BE Demonstration of MR Products	
1:45 – 1:55 PM	***Why Are Multiple-Dose Studies Considered Necessary for MR Drug Products at Risk for Accumulation – Background Information on the EMA Requirement*** Carolien Versantvoort, Medicine Evaluation Board (MEB), The Netherlands
1:55 – 2:25 PM	***How PopPK Modeling Could Help Avoid Multiple Dose Studies: Industry Perspective*** Vivek Purohit (Pfizer), US
2:25 - 2:45 PM	***Model-Integrated Evidence (MIE) to Demonstrate BE for LAI and Implantables*** Yuqing Gong (FDA), US
2:45 - 3:10 PM	***PANEL DISCUSSION*** Carolien Versantvoort, Vivek Purohit, Yuqing Gong, Other Panelists TBD
3:10 - 3:30 PM	***COFFEE BREAK***
Part 2: Studies Needed for BE Demonstration of Additional Strengths in Solid Oral MR Products	
3:30 - 3:45 PM	***European Specificities of MR Drug Products Strength Waiver – Differentiation Between Single and Multiple Unit Dosage Forms*** Carolien Versantvoort (MEB), The Netherlands

3:45 - 4:00 PM	***Current FDA Consideration and Practices for BE Demonstration of Additional Strengths in Solid Oral MR Products*** Rong Wang (FDA), US
4:00 - 4:25 PM	***Industry Examples on BE Demonstration of Additional Strengths in Solid Oral MR Products*** Yihong Qiu (QPD Solutions LLC), US
4:25 - 4:50 PM	***PANEL DISCUSSION*** Carolien Versantvoort, Rong Wang, Yihong Qiu, Heather Boyce (FDA), USA; other panelists TBD
ADJOURN DAY 1	***Workshop Closing*** USP Representative
6:00 – 7:30 PM	**Networking Reception** Hilton Washington DC/Rockville Hotel & Executive Meeting Center 1750 Rockville Pike, Rockville, MD

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GBHI 2024

Tuesday – Wednesday, April 16-17, 2024

Day 2 – Wednesday, April 17, 2024 8:00 AM – 5:00 PM US EDT All Times in US Eastern Daylight Savings Time	
8:00 - 8:15 AM	***BREAKFAST***
SESSION 3: Partial AUC (pAUC) for Bioequivalence Demonstration **Session Leads: Mehul Mehta (FDA), US & Jan Welink (MEB), The Netherlands**	
Part 1: Regulatory Overview	
8:15 - 8:35 AM	***FDA Current Rationales to Recommend pAUC and Practice for Product Evaluation*** Lucy Fang (FDA), US
8:35 - 8:50 AM	***EMA Current Practice*** Jan Welink, (MEB), Netherlands
8:50 - 9:00 AM	***Health Canada Current Practice*** John Gordon (Health Canada), Canada
9:00 - 9:15 AM	***ANVISA Current Practice*** Eduardo Agostinho Freitas Fernandes (ANVISA), Brazil
Part 2.: Academic Overview	
9:15 - 9:50 AM	***Advantages and Challenges of Partial AUC: Insights from GI Physiology, Pharmacokinetics, and Drug Dissolution in the GI Tract*** Duxin Sun (University of Michigan), US
Part 3: Industry Viewpoint	
9:50 - 10:05 AM	***Innovator Industry Experiences on pAUC*** Jack Cook (A2-Ai), US
10:05 - 10:20 AM	***Application of pAUC for Evaluation of MR Products: Generic Perspectives*** Russell Rackley, Viatris, US
10:20 - 10:35 AM	***Early Exposure in IR Products: pAUC and Alternative Approaches – View from the Generic Industry*** Susana Almeida (IGBA), Switzerland
10:35 - 10:55 AM	***COFFEE BREAK***
10:55 - 11:50 AM	***PANEL DISCUSSION*** Lucy Fang, Jan Welink, John Gordon, Duxin Sun, Jack Cook, Russell Rackley, Susana Almeida, Eduardo Agostinho Freitas Fernandes, Hao Zhu (FDA), USA, Junya Makino (PMDA), Japan
11:50 AM- 12:50 PM	***LUNCH***

SESSION 4: BE STUDY CONSIDERATION FOR ORALLY INHALED DRUG PRODUCTS (OIDPs) **Session leads: Wenlei Jiang (FDA), US & Gerald Beuerle (Teva), Germany**	
12:50 - 12:55 PM	***Summary of Preceding GBHI Discussion on OIDPs*** Gerald Beuerle (Teva), Germany
Part 1: Regulatory Session	
12:55 - 1:10 PM	***EMA Current Practices for BE Evaluation of OIDPs*** Alfredo García Arieta (AEMPS), Spain
1:10 - 1:25 PM	***PMDA Current Practices for BE Evaluation of OIDPs*** Junya Makino (PMDA), Japan
1:25 - 1:40 PM	***FDA Current Practices for BE Evaluation of OIDPs*** Ke Ren (FDA), US
1:40 - 2:00 PM	***PANEL DISCUSSION*** Alfredo García Arieta, Junya Makino, Ke Ren, Eduardo Agostinho Freitas Fernandes
2:00 - 2:20 PM	***COFFEE BREAK***
Part 2: Scientific Session	
2:20 - 2:45 PM	***Progress Made in Alternatives to Comparative Pharmacodynamic and Clinical Endpoints for BE Demonstration of OIDPs*** Bryan Newman (FDA), US
2:45 - 3:10 PM	***Identify Key in vitro Comparative Tests & Propose Optimal Data Analysis Method for in vitro Tests*** Anthony Hickey (Research Triangle Institute), US
3:10 - 3:35 PM	***Systemic Pharmacokinetic BE studies With and Without Blocked GI Absorption to Predict Regional Lung Exposure*** Barbara Schug (SocraTec R&D), Germany
3:35 - 4:00 PM	***Recommended Studies to Support Different Levels of Post Approval Changes of OIDPs*** Xian-Ming Zeng (TranspireBio), US
4:00 - 4:40 PM	***PANEL DISCUSSION*** Bryan Newman, Barbara Schug, Xian-Ming Zeng, Anthony Hickey
4:40 - 4:50 PM	***Day 2 Closing Remarks*** Barbara S. Schug (SocraTec R&D), Germany (Co-Chair)

Workshop Planning Committee

Wenlei Jiang, PhD, Food and Drug Administration, (FDA), US (Co-chair)
Barbara S. Schug, PhD, SocraTec R&D, Germany (Co-chair)
Susana Almeida, PhD, International Generic and Biosimilar Medicine Association (IGBA), Switzerland
Gerald Beuerle, PhD, Teva, Germany
Erem Bilensoy, PhD, Hacettepe University, Turkey
David Brown, PhD, Medicines and Healthcare products Regulatory Agency, (MHRA), UK
Jack Cook, PhD, A2-Ai, US
Eduardo Agostinho Freitas Fernandes, MSc, Agência Nacional de Vigilância Sanitária (ANVISA), Brazil
Dede Godstrey, Product Quality Research Institute (PQRI), US
John Gordon, PhD, Health Canada, Canada
Sandra Häberle, the European Federation for Pharmaceutical Sciences (EUFEPS)
Sebastian Haertter, PhD, Boehringer Ingelheim, Germany
Georg Hempel, PhD, University of Münster, Germany
Evangelos Kotzagiorgis, PhD, European Medicines Agency (EMA), Netherlands
Ryosuke Kuribayashi, PhD, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Mehul Mehta, PhD, FDA, US
Andreas Kovar, PhD, Sanofi, Germany
Katalina Mettke, PhD, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany
Paulo Paixão, PhD, Lisbon University, Member of the Medicines Evaluation Board at Infarmed, Portugal
Anne Seidlitz, PhD, Heinrich Heine University Düsseldorf, Germany
Nilufer Tampal, PhD, FDA, US
Yu-Chung Tsang, PhD, Apotex, Canada
Ralph-Steven Wedemeyer, PhD, SocraMetrics, Germany
Jan Welink, PhD, Medicines Evaluation Board (MEB), Netherlands