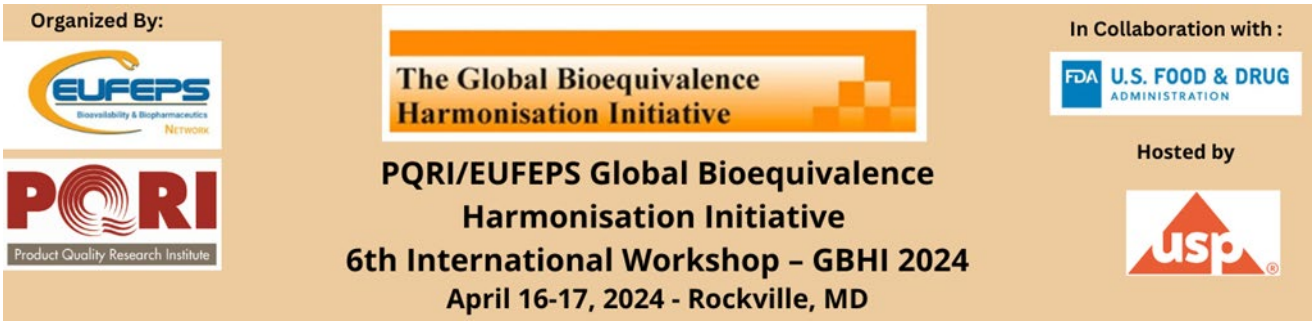
Draft Program as of 3/21/2024: Presentation Titles and Speakers subject to change



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, US Food and Drug Administration (FDA), US (Co-Chair)
Barbara S. Schug (SocraTec R&D GmbH), 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, (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	***Physiologically Based Pharmacokinetic (PBPK) Modeling of Fasted/Fed Bioequivalence (BE) – Generic Industry Perspective*** Rebeka Jereb (Lek, Sandoz) Slovenia
9:20 – 9:35 AM	***Industry Perspective on the Utility of Model-Based Approaches in BE*** Filippos Kesisoglou (Merck & Co., Inc.), 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*** Wenlei Jiang (FDA), US
11:30 – 11:50 AM	***HVD and Type I Error*** Helmut Schütz (BEBAC) Austria
11:50 AM - 12:10 PM	***Two-stage Designs and their Acceptability in the EC Area*** Susanne Urach (AGES), Austria
12:10 - 12:40 PM	***PANEL DISCUSSION*** Paulo Paixão, Wanjie Sun, Wenlei Jiang, Helmut Schütz, Susanne 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 & Yu Chung Tsang (YCT Scientific Inc.) 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 GmbH), 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 (MEB), The Netherlands
1:55 – 2:25 PM	***How Model Informed Drug Development (MIDD) Approaches Could Help Avoid Multiple Dose Studies: Industry Perspective*** Vivek Purohit (Pfizer), US
2:25 - 2:45 PM	***Considerations and Challenges of Pharmacokinetics BE Studies for LAIs and the Application of Model-Integrated Evidence (MIE) Approaches*** 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	***BE Demonstration for Additional Strengths in Solid Oral MR Products*** Rong Wang (FDA), US
4:00 - 4:25 PM	***Understanding In Vitro-In Vivo Relationships between Different Strengths of 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
5:30 – 7:00 PM	**Networking Reception** Hilton Washington DC/Rockville Hotel & Executive Meeting Center 1750 Rockville Pike, Rockville, MD **Pearls of Bioequivalence Award** At the networking reception, The Frankfurt Foundation Quality of Medicines and the EUFEPS Network Bioavailability and Biopharmaceutics will present the 2024 Pearls of Bioequivalence Award. This award recognizes senior scientists, who contribute significantly to the development of advanced concepts for bioequivalence assessment.

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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	***pAUC for BE Demonstration: 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 on pAUC for BE Demonstration of Prolonged Release Products*** 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	***pAUC for BE Demonstration – An Innovator Company Viewpoint*** Jack Cook (A2-Ai), US
10:05 - 10:20 AM	***Application of pAUC for Evaluation of MR Products: Generic Perspectives*** Mark Liu (Viatris Inc.), 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, Mark Liu, Susana Almeida, Eduardo Agostinho Freitas Fernandes, Hao Zhu (FDA), US, Junya Makino (PMDA), Japan
11:50 AM- 12:50 PM	***LUNCH***

SESSION 4: BE Study Consideration for Orally Inhaled Drug Products (OIPs) **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	***Recent Updates for the Use of Alternative Approaches for Demonstrating BE with OIDPs*** Elizabeth Bielski (FDA), US
2:45 - 3:10 PM	***Identify Key in vitro Comparative Tests & Optimal Data Analysis Methods for in vitro Tests*** Anthony Hickey (Astartein LLC), 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 GmbH), Germany
3:35 - 4:00 PM	***Recommended Studies to Support Different Levels of Post Approval Changes of OIDPs*** Speaker TBC
4:00 - 4:40 PM	***PANEL DISCUSSION*** Elizabeth Bielski , Barbara Schug, Anthony Hickey and Yu Chung Tsang
4:40 - 4:50 PM	***Day 2 Closing Remarks*** Barbara S. Schug (SocraTec R&D GmbH), Germany (Co-Chair)

Workshop Faculty

Susana Almeida, Ph.D., Secretary General, International Generic and Biosimilar Medicines Association (IGBA)
Alfredo García Arieta, Ph.D., Head of Area on Pharmacokinetics and Generic Medicines, The Spanish Agency for Medicines and Health Products (AEMPS)
Gerald Beuerle, Ph.D., Senior Director, Teva
Elizabeth Bielski, M.S., Ph.D., Senior Pharmacologist, DTP-I | ORS | OGD | CDER | US FDA
Heather Boyce, Ph.D., Lead Pharmacokineticist, DTP II | ORS | OGD | CDER | US FDA
Rodrigo Cristofoletti, Ph.D., Assistant Professor, University of Florida.
Jack Cook, Ph.D., Senior Vice President, A2-Ai, LLC
Lucy Fang, Ph.D., Deputy Director, DQMM | ORS | OGD | CDER | US FDA
Eduardo Agostinho Freitas Fernandes, MSc, Therapeutic Equivalence Coordinator, Brazilian Health Regulatory Agency (Anvisa)
Yuqing Gong, Ph.D., Pharmacologist, DQMM | ORS | OGD | CDER | US FDA
Anthony J. Hickey, Ph.D., CEO, Astartein, LLC
Rebeka Jereb, Ph.D., Senior Scientist, Lek (Sandoz)
Wenlei Jiang, Ph.D., Senior Advisor for Innovation and Strategic Outreach, ORS | OGD | CDER | US FDA
Filippos Kesisoglou, Ph.D., FAAPS, Distinguished Scientist, Merck & Co., Inc.
Mark Liu, Viatris
Junya Makino, Ph.D., Reviewer, Pharmaceuticals and Medical Devices Agency (PMDA)
Mehul U. Mehta, Ph.D., Director, Division of Neuropsychiatric Pharmacology (DNP) OCP | CDER | US FDA
Paulo Paixão, Ph.D., Clinical Pharmacology Assessor, INFARMED; Methodological Working Party Member, EMA
Vivek S. Purohit, Ph.D., Senior Director, Pfizer
Yihong Qiu, Ph.D., Founder, QPD Solutions LLC
Ke Ren, Ph.D., Deputy Division Director, DBIII | OB | OGD | CDER | US FDA
Barbara Schug, Ph.D., Managing Director, SocraTec R&D GmbH
Helmut Schütz, B.Eng., Owner/Lecturer, BEBAC Vienna/Center for Medical Data Science of the Medical University of Vienna
Duxin Sun, Ph.D., Associate Dean for Research, Charles Walgreen Jr. Professor of Pharmacy, University of Michigan
Wanjie Sun, Ph.D., Master Scientist, DBVIII | OB | OTS | CDER | US FDA
Nilufer Tampal, Ph.D., Associate Director for Scientific Quality, Office of Bioequivalence (OB), OGD | CDER | US FDA
Yu Chung Tsang, B.Sc., Ph.M., Ph.D., President, YCT Scientific Inc.
Susanne Urach, Ph.D., Statistical Assessor, Austrian Agency for Health and Food Safety (AGES)
Carolien Versantvoort, Ph.D., Senior Clinical Pharmacokinetic Assessor, Medicine Evaluation Board (MEB), The Netherlands
Rong Wang, Ph.D, Pharm.D., Associate Director, Division of Bioequivalence I (DBI), OB | OGD | CDER | US FDA
Jan Welink, Ph.D., Senior Clinical Assessor, Medicines Evaluation Board (MEB), The Netherlands
Fang Wu, Ph.D., Senior Pharmacologist, DQMM | ORS | OGD | CDER | US FDA
Lei Zhang, Ph.D., Deputy Director, Office of Research and Standards (ORS), OGD | CDER | US FDA
Hao Zhu, Ph.D., Division Director, Division of Pharmacometrics, OCP | CDER | US FDA

Workshop Planning Committee

Wenlei Jiang, PhD, Food and Drug Administration, (FDA), US (Co-chair)
Barbara S. Schug, PhD, SocraTec R&D GmbH, 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
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Ralph-Steven Wedemeyer, PhD, SocraMetrics, Germany
Jan Welink, PhD, Medicines Evaluation Board (MEB), Netherlands