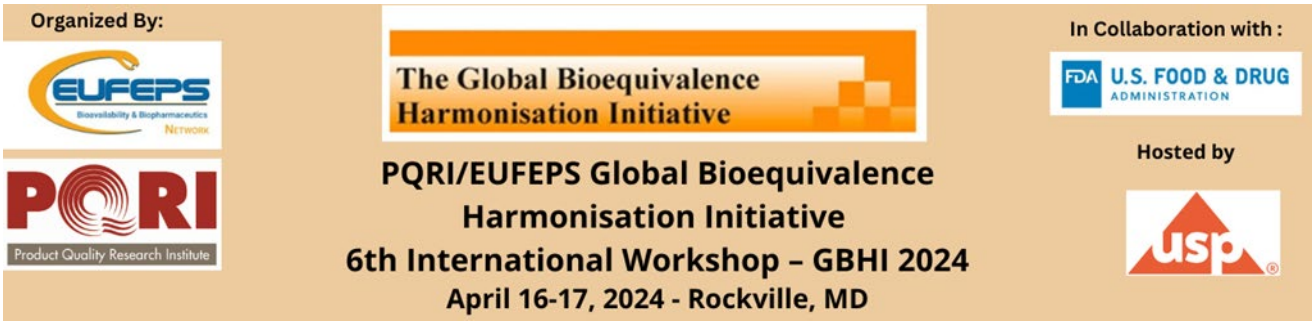
Final Program



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*** Diane Paskiet (PQRI), US
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, 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, Junya Makino (PMDA), Japan
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, Helmut Schütz, and Eduardo Agostinho Freitas Fernandes (Anvisa), Brazil
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, Eduardo Agostinho Freitas Fernandes, and Heather Boyce (FDA), USA
ADJOURN DAY 1	***Workshop Closing*** Chaitanya Koduri (USP), US
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.

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 Chairs: 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*** Lanyan "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*** Mehul Mehta, Lucy Fang, Jan Welink, Eduardo Agostinho Freitas Fernandes, Duxin Sun, Jack Cook, Mark Liu, Susana Almeida, Junya Makino, and Hao Zhu (FDA), US
11:50 AM- 12:50 PM	***LUNCH***

SESSION 4: BE Study Consideration for Orally Inhaled Drug Products (OIDPs) **Session Chairs: 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	***A Scientifically Rationalized Approach for Instituting Requirements to Support Post Approval Changes in OIDPs*** Gur Jai Pal Singh (BBSG Pharm Associates), US
4:00 - 4:40 PM	***PANEL DISCUSSION*** Elizabeth Bielski , Anthony Hickey, Barbara Schug, Gur Jai Pal Singh, 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 J. 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
Lanyan "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
John Gordon, Ph.D., Assessment Officer, Health Canada
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.
Dr. Chaitanya Koduri, Director for International Government and Regulatory Engagement, United States Pharmacopeia (USP)
Mark Liu, M.S., Head of Statistics and Data Management (early phase), Viatris Inc.
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
Diane Paskiet, M.Sc., PQRI Chair, Board of Directors
Vivek S. Purohit, Ph.D., Senior Director, Pfizer
Yihong Qiu, Ph.D., Founder, QPD Solutions LLC
Ke Ren, Ph.D., Deputy Division Director, DB III | OB | OGD | CDER | US FDA
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Helmut Schütz, B.Eng., Owner/Lecturer, BEBAC Vienna/Center for Medical Data Science of the Medical University of Vienna
Gur Jai Pal Singh, Ph.D., Chief Scientific Advisor, BBSG Pharm Associates
Duxin Sun, Ph.D., Associate Dean for Research, Charles Walgreen Jr. Professor of Pharmacy, University of Michigan
Wanjie Sun, Ph.D., Master Scientist, DB VIII | OB | OTS | CDER | US FDA
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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)
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Hao Zhu, Ph.D., Division Director, Division of Pharmacometrics, OCP | CDER | US FDA

Workshop Planning Committee

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