## 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:00 - 8:30 AM</td>
<td><strong>CHECK-IN/BREAKFAST</strong></td>
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</table>
| 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

<table>
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<tr>
<th>Time</th>
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| 9:00 - 9:05 AM| Summary of Preceding GBHI Discussions on ICH M13 Related Topics  
Nilufer Tampal (FDA), US                                                                 |

#### Part 1: Oral PBPK

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<thead>
<tr>
<th>Time</th>
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| 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)

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>10:30 – 10:50 AM</td>
<td><strong>BE Study Design for NTI Drugs and Control of Type I Error</strong></td>
<td>Paulo Paixão (Infarmed), Portugal</td>
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<tr>
<td>10:50 - 11:10 AM</td>
<td><strong>Alternative BE Criteria/Approaches for NTI Products</strong></td>
<td>Wanjie Sun (FDA), US</td>
</tr>
<tr>
<td>11:10 – 11:30 AM</td>
<td><strong>Deep Dive into Generic Drug Applications to Seek Data-Driven Harmonization of BE Criteria</strong></td>
<td>Wenlei Jiang (FDA), US</td>
</tr>
<tr>
<td>11:30 – 11:50 AM</td>
<td><strong>HVD and Type I Error</strong></td>
<td>Helmut Schütz (BEBAC), Austria</td>
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<tr>
<td>11:50 AM - 12:10 PM</td>
<td><strong>Two-stage Designs and their Acceptability in the EC Area</strong></td>
<td>Susanne Urach (AGES), Austria</td>
</tr>
<tr>
<td>12:10 - 12:40 PM</td>
<td><strong>PANEL DISCUSSION</strong></td>
<td>Paulo Paixão, Wanjie Sun, Wenlei Jiang, Helmut Schütz, Susanne Urach, Junya Makino (PMDA), Japan</td>
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<tr>
<td>12:40 - 1:30 PM</td>
<td><strong>LUNCH</strong></td>
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### 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

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<tr>
<td>1:30 – 1:45 PM</td>
<td><strong>Summary of Preceding GBHI Discussions on MR Drug Products including Solid Oral MR Products, Transdermal Therapeutic Systems and Long-Acting Injectables (LAI)</strong></td>
<td>Barbara Schug (SocraTec R&amp;D GmbH), Germany</td>
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<tr>
<td>1:45 – 1:55 PM</td>
<td><strong>Why Are Multiple-Dose Studies Considered Necessary for MR Drug Products at Risk for Accumulation – Background Information on the EMA Requirement</strong></td>
<td>Carolien Versantvoort (MEB), The Netherlands</td>
</tr>
<tr>
<td>2:25 - 2:45 PM</td>
<td><strong>Considerations and Challenges of Pharmacokinetics BE Studies for LAIs and the Application of Model-Integrated Evidence (MIE) Approaches</strong></td>
<td>Yuqing Gong (FDA), US</td>
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<td>2:45 - 3:10 PM</td>
<td><strong>PANEL DISCUSSION</strong></td>
<td>Carolien Versantvoort, Vivek Purohit, Yuqing Gong, Helmut Schütz, and Eduardo Agostinho Freitas Fernandes (Anvisa), Brazil</td>
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<td>3:10 - 3:30 PM</td>
<td><strong>COFFEE BREAK</strong></td>
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### Part 2: Studies Needed for BE Demonstration of Additional Strengths in Solid Oral MR Products

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<td><strong>European Specificities of MR Drug Products Strength Waiver – Differentiation Between Single and Multiple Unit Dosage Forms</strong></td>
<td>Carolien Versantvoort (MEB), The Netherlands</td>
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<tr>
<td>3:45 - 4:00 PM</td>
<td><strong>BE Demonstration for Additional Strengths in Solid Oral MR Products</strong></td>
<td>Rong Wang (FDA), US</td>
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<td>Time</td>
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<td>Presenter and Details</td>
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<td>4:00 - 4:25 PM</td>
<td><strong>Understanding In Vitro-In Vivo Relationships between Different Strengths of Oral MR Products</strong> Yihong Qiu (QPD Solutions LLC), US</td>
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<td>4:25 - 4:50 PM</td>
<td><strong>PANEL DISCUSSION</strong> Carolien Versantvoort, Rong Wang, Yihong Qiu, Eduardo Agostinho Freitas Fernandes, and Heather Boyce (FDA), USA</td>
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<td><strong>ADJOURN DAY 1</strong></td>
<td><strong>Workshop Closing</strong> Chaitanya Koduri (USP), US</td>
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</table>
| 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**

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<td>8:00 - 8:15 AM</td>
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| 8:15 - 8:35 AM | 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               |
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| 12:50 - 12:55 PM | **Summary of Preceding GBHI Discussion on OIDPs**  
Gerald Beuerle (Teva), Germany |
| 12:55 - 1:10 PM | **EMA Current Practices for BE Evaluation of OIDPs**  
Alfredo Garcia 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** |
| 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 Pharmacopoeia (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
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
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
Nilufer Tampal, Ph.D., Associate Director for Scientific Quality, Office of Bioequivalence (OB), OGD | CDER | US FDA
Yu Chung Tsang, B.Sc., 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 (DB I), 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
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, YCT Scientific Inc.
Ralph-Steven Wedemeyer, PhD, SocraMetrics, Germany
Jan Welink, PhD, Medicines Evaluation Board (MEB), Netherlands