aaps Workshops

AAPS/EUFEPS GLOBAL BIOEQUIVALENCE HARMONIZATION INITIATIVE: 4TH INTERNATIONAL WORKSHOP

DECEMBER 12-13, 2019 • BETHESDA, MD

Hosted by: EUFEPS European Federation for Pharmaceutical Sciences; aaps®

Co-sponsored by: FDA U.S. FOOD & DRUG ADMINISTRATION

Thursday, December 12, 2019

7:30 am – 9:30 am	AAPS Registration
7:30 am – 8:30 am	Continental Breakfast
8:30 am – 9:15 am	**Welcome and Introduction** Atilla Hincal, Ph.D., FAAPS, IDE Pharmaceutical Consultancy Mehul Mehta, Ph.D., FAAPS, U.S Food and Drug Administration Robert Lionberger, Ph.D., U.S. Food and Drug Administration
9:15 am – 12:00 pm	**Session I: Outcome Summary and Tying Up Loose Ends of GBHI Conference 2018 in Amsterdam** Moderator: Mehul Mehta, Ph.D., FAAPS, U.S Food and Drug Administration Moderator: Henning Blume, Ph.D., SocraTec C&S
9:15 am – 9:30 am	**Necessity of Multiple Dose Studies in BE Testing** Jan Welink, Ph.D., MEB
9:30 am – 9:45 am	**Suggestions for Further Harmonization of Remaining Open Issues** Nuno Silva, Ph.D., University of Lisbon
9:45 am – 10:10 am	**Discussion**
10:10 am – 10:25 am	Refreshment Break
10:25 am – 10:40 am	**Bioequivalence of Transdermal Delivery Systems** Markham Luke, Ph.D., U.S. Food and Drug Administration
10:40 am – 10: 55 am	**Suggestions for Further Harmonization of Remaining Open Issues**

	Charles E. DiLiberti, Montclair Bioequivalence Services, LLC
10:55 am – 11:20 am	**Discussion**
11:20 am – 11:30 am	**Liposomal Parenteral Preparations** Jan Welink, Ph.D., MEB
11:30 am – 11:40 am	**Scientific Approach to Suggestions for Harmonization** Peter Langguth, Ph.D., University of Mainz
11:40 am – 12:00 pm	**Discussion**
12:00 pm – 1:00 pm	Lunch
1:00 pm – 5:15 pm	**Session II: Evaluation of Bioequivalence for Long Acting Injectables and Implants** Moderator: Mehul Mehta, Ph.D., FAAPS, U.S. Food and Drug Administration Moderator: Jan Welink, Ph.D., MEB
1:00 pm – 1:20 pm	**Scientific Principles, and Similarities and Differences between International Guidelines** Gerald Beuerle, Ph.D., Teva
1:20 pm – 1:35 pm	**Justification of the Current Regulatory Approach by US FDA** Wenlei Jiang, Ph.D., U.S. Food and Drug Administration
1:35 pm – 1:50 pm	**Justification of the Current Regulatory Approach by EMA** Jan Welink, Ph.D., MEB
1:50 pm – 2:05 pm	**Justification of the Current Regulatory Approach by ANVISA: A case by case decision** Eduardo Fernandes, ANVISA
2:05 pm – 2:30 pm	**Discussion**

INVITED PRESENTATIONS:

2:30 pm – 2:50 pm	**PK Metrics for Evaluation of Bioequivalence of Long Acting Injectables and Implants, Including Assessment of Multiple Peaks** Bharat Damle, Ph.D., Pfizer
2:50 pm – 3:10 pm	**Discussion**

3:10 pm – 3:30 pm	Refreshment Break
3:30 pm – 3:50 pm	**Scientific Arguments in Favor and Against the Requirement to Perform Multiple Dose Studies for Long Acting Injectables and Implants** Jack Cook, Ph.D., Pfizer
3:50 pm – 4:10 pm	**Discussion**
4:10 pm – 4:30 pm	**In-Vitro Release Methodology of Long Acting Injectables and Implants for In-Vivo Relevance to Support Product Quality Assurance** Sandra Klein, Ph.D., University of Greifswald
4:30 pm – 5:15 pm	**Discussion**
5:30 pm – 6:30 pm	Networking Reception

Friday, December 13, 2019

7:30 am – 9:30 am	AAPS Registration
7:30 am – 8:30 am	Continental Breakfast
8:30 am – 9:20 am	**Keynote Lectures** Moderator: Vinod Shah, Ph.D., FAAPS Moderator: Atilla Hincal, Ph.D., FAAPS, IDE Pharmaceutical Consultancy
8:30 am – 8:40 am	**Road Map to an International BE Reference Product?** James Polli, University of Maryland
8:40 am – 8:50 am	**Road Map to an International BE Reference Product?** Susana Almeida, Medicines for Europe
8:50 am – 8:55 am	**Discussion**
8:55 am – 9:20 am	**Global Harmonization of Bioequivalence Requirements: Vision, Perspective or Illusion?** Henning Blume, Ph.D., SocraTec C&S
9:20 am – 12:35 pm	**Session III: Necessity of Assessing Bioequivalence for Immediate Release Dosage Forms in the Fed and/or Fasted State** Moderator: Nilufer Tampal, Ph.D. U.S. Food and Drug Administration

9:20 am – 9:35 am	**Where Do We Stand After the Discussions in Previous Conferences? Summary of outcome of GBHI-1 and GBHI-2** Jan Welink, Ph.D., MEB
9:35 am – 9:55 am	**Current Regulatory Approach by US FDA with Supporting Evidence from Case Studies** Nilufer Tampal, Ph.D. U.S. Food and Drug Administration
9:55 am – 10:10 am	**Justification of The Current Regulatory Approach by Japan** Ryosuke Kuribayashi, Ph.D., PMDA
10:10 am – 10:30 am	**Discussion**
10:30 am – 10:45 am	Refreshment Break

INVITED PRESENTATIONS:

10:45 am – 11:05 am	**Possibility to Identify Formulation/Excipient Effects Responsible for Failed Fed Studies of IR Products** Peter Langguth, Ph.D., University of Mainz
11:05 am – 11:20 am	**Discussion**
11:20 am – 11:40 am	**Situation When a Fed Study is More Sensitive to Detect Formulation Differences Between IR Products - examples from case studies** Elizabeth Rody, Ph.D., Teva
11:40 am – 11:55 am	**Discussion**
11:55 am – 12:15 pm	**Food interaction studies for determination of formulation related food effect: is the high-fat meal always the best choice?** Barbara Schug, Ph.D., SocraTec R&D
12:15 pm – 12:35 pm	**Discussion**
12:35 pm – 1:30 pm	Lunch
1:30 pm – 5:45 pm	**Session IV: Bioequivalence Assessment of Orally Inhaled Drug Products (OIDPs)** Moderator: Wenlei Jiang, Ph.D., U.S. Food and Drug Administration Moderator: Barbara Schug, Ph.D., SocraTec R&D

1:30 pm – 1:50 pm	**Introduction about different OIDP and overview about global regulatory approaches** Jennifer Wylie, Ph.D., Merck
1:50 pm – 2:05 pm	**Justification of The Current Regulatory Approach by EMA** Janet König, Ph.D., BfArM
2:05 pm – 2:20 pm	**Justification of The Current Regulatory Approach by US** Ke Ren, Ph.D., U.S. Food and Drug Administration
2:20 pm – 2:35 pm	**Justification of The Current Regulatory Approach by ANVISA** Eduardo Fernandes, ANVISA
2:35 pm – 3:00 pm	**Discussion**

INVITED PRESENTATIONS:

3:00 pm – 3:20 pm	**Systemic pharmacokinetic studies: design considerations for OIDPs** Barbara Schug, Ph.D., SocraTec R&D Andre Warnke, SocraTec R&D
3:20 pm – 3:40 pm	**In Vitro Testing - Predictive of in vivo performance of OIDPs?** Günther Hochhaus, Ph.D., University of Florida
3:40 pm – 3:55 pm	Refreshment Break
3:55 pm – 4:15 pm	**FEV1 Based Bioequivalence Study for Inhaled Corticosteroids** Liang Zhao, Ph.D., U.S. Food and Drug Administration
4:15 pm – 4:35 pm	**Alternative Thinking on Comparative Clinical Endpoint Study for OIDPs to Facilitate Harmonization** Yu Chung Tsang, Ph.D., Apotex
4:35 pm – 5:15 pm	**Discussion**
5:15 pm – 5:30 pm	**Conclusion and Future Perspective** Henning Blume, Ph.D., SocraTec C&S