International Symposium on

BA/BE of Oral Drug Products:

More Science, Technology and Better Regulatory Standards

(BA/BE 2011)

Date: June 29 – July 1, 2011

Location: Kobe International Conference Center
6-9-1 Minatojima-nakamachi, Chuo-ku, Kobe 650-0046, Japan
(http://kobe-cc.jp/english/kaigi/index.html)

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Program

Wednesday, June 29

12:30 – 12:35 Opening remarks

Toshinari Mitsuoka (Ministry of Health, Labour and Welfare, Japan)

Opening Session

Session Chair: Mitsuru Hashida (Kyoto University, Japan)

12:35 – 13:00 Welcome, introductions, and symposium overview

Vinod P. Shah, Ph.D. (FIP, USA)

13:00 – 13:45 Keynote Lecture: New era in BA/BE world

Gordon L. Amidon, Ph.D. (University of Michigan, USA)

13:45– 14:00 Break

Session 1: Predicting oral BA and DDI to select better compounds

Session chairs: Fumiyoshi Yamashita (Kyoto University, Japan)
Takuya Fujita (Ritsumeikan University, Japan)

14:00 – 14:40 Physiology-based biopharmaceutical modeling

Kiyohiko Sugano, Ph.D. (Pfizer, UK)

14:40 – 15:20 Drug absorption, first-pass extraction and bioavailability: experience from human *in vivo* studies

Hans Lennernas, Ph.D. (Uppsala University, Sweden)

15:20 – 16:00 Role of absorptive transporter: Impact on oral BA and DDI

Ikumi Tamai, Ph.D. (Kanazawa University, Jap an)

16:00– 16:20 Break

16:20 – 17:00 Transporter mediated DDI in oral drug absorption (tentative)

Noriko Okudaira, Ph.D. (Daiichi Sankyo Co., Ltd.)

17:00 – 17:50 BDDCS for a better understanding of DDI

Leslie Z. Benet, Ph.D. (University of California, San Francisco, USA)

17:50– 18:10 Additional discussion

18:20 – 20:00 Welcome reception (at Poster Presentation & Exhibition Hall)

Thursday, June 30

Session 2: Improving oral BA of biopharmaceutical problem compounds

Session chairs: Kyung-Dall Lee (University of Michigan, USA)
Shinji Sakuma (Setsunan University, Japan)

9:00 – 9:35 **Physical chemistry of API and its implication for formulation strategy**
Kohsaku Kawakami, Ph.D. (National Institute of Material Science, Japan)

9:35 – 10:10 **Formulation design based on model and simulation**
Ryusuke Takano, Ph.D. (Chugai Pharm. Co., Japan)

10:10– 10:50 **Lipid Based Formulation - development of marketable products of poorly soluble drugs**
Ping Gao, Ph.D. (Abbott Laboratories, Inc, USA)

10:50– 11:10 Break

11:10 – 11:50 **Release-controlling mechanism of water-soluble and water-insoluble drugs in oral delivery**
Beom-Jin Lee, Ph.D. (Kangwon National University, Korea)

11:50 – 12:30 **Delivery strategies to enhance bioavailability and diminish intestinal metabolism**
Peter R. Langguth, Ph.D. (Johannes Gutenberg University-Mainz, Germany)

12:30 – 12:45 **Additional discussion**

12:45 – 14:15 **Lunch & Poster presentation**
(*Poster presentation 13:30-14:10*)

Special Lecture

Chair: Tsuneji Nagai (The Nagai Foundation Tokyo, Japan)

14:15– 15:15 **Innovative strategies for drug development using microdose clinical study**
Yuichi Sugiyama, Ph.D. (University of Tokyo, Japan)

15:15– 15:30 Short Break

Session 3-1: IVIVC and BCS for optimizing formulation and streamlining BE study

Session chairs: Kazutaka Higaki (Okayama University, Japan)

15:30 – 16:10 **IVIVC consideration based on the analysis of *in vivo* oral absorption process in human**
Shinji Yamashita, Ph.D. (Setsunan University, Japan)

16:10 – 16:50 **Predicting bioequivalence from *in vitro* dissolution tests**

Jennifer B. Dressman, Ph.D. (Goethe University, Frankfurt, Germany)

16:50 – 17:30 **Industrial perspective for evaluation of dissolution: Quality by Design**

Bertil Abrahamsson, Ph.D. (AstraZeneca, Sweden)

17:30 – 17:45 **Additional discussion**

17:45– 18:30 **Poster presentation**

19:00– 21:00 **Banquet** (at "Kobe Portopia Hotel")

(Banquet Hall will open at 18:45)

Friday, July 1

Session 3-2: IVIVC and BCS for optimizing formulation and streamlining BE study

Session chairs: Vincent H.L. Lee (Chinese University of Hong Kong, Hong Kong)
TBD

9:20 – 10:00 **Biowaivers for IR drug products - What have we learned since BCS?**

Dirk Barends, Ph.D. (National Institute of Public Health and the Environment, Netherlands)

10:00 – 10:40 **Future in BCS: Biowaiver Class 2 and Class 3?**

James E. Polli, Ph.D. (University of Maryland, USA)

10:40 – 11:00 Break

11:00 – 11:40 **IVIVC and BE for combination drug: Experiences in Pfizer**

Jack A. Cook, Ph.D. (Pfizer, USA)

11:40 – 12:20 **Quality by Design for modified release drug products**

Andre Raw, Ph.D. (Food and Drug Administration, USA)

12:20 – 12:35 **Additional discussion**

12:35 – 13:30 **Lunch**

Session 4: Worldwide standards for regulating oral drug products

Session chairs: Gordon L. Amidon (University of Michigan, USA)
Jennifer B. Dressman (Goethe University, Germany)

13:30– 14:10 BE guidelines in EU: current status and future
Jan Welink, Ph.D. (European Medicines Evaluation Board, Netherlands)

14:10 – 14:50 Japanese and global situations in regulating oral drug products
Chikako Yomota, Ph.D. (National Institute of Health Sciences, Japan)

14:50 – 15:15 Japanese draft guideline for BE studies for manufacturing changes
Noriyuki Muranushi, Ph.D. (Shionogi & Co. Ltd, Japan)

15:15 – 15:30 Short Break

15:30 – 16:10 Panel discussion for worldwide standards of BE guideline

16:10 – 16:20 Closing remarks
Mitsuru Hashida, Ph.D. (Kyoto University, Japan)