

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>)

Main Sponsor:
International Pharmaceutical Federation (FIP)

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European Federation for Pharmaceutical Sciences (EUFEPS)
German Pharmaceutical Society (DPhG)
The Swedish Academy of Pharmaceutical Sciences (SAPS)
The Nagai Foundation Tokyo
Drug Delivery Foundation (DDF)

Organization

Co-Chairs:
Gordon L. Amidon, Ph.D. (University of Michigan, USA)
Mitsuru Hashida, Ph.D. (Kyoto University, Japan)
Masatoshi Narita (Ministry of Health, Labour and Welfare, Japan)
Vinod P. Shah, Ph.D. (International Pharmaceutical Federation, USA)
Shinji Yamashita, Ph.D. (Setsunan University, Japan)
Chikako Yomota, Ph.D. (National Institute of Health Sciences, Japan)

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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, Japan)

16:00– 16:20

Break

16:20 – 17:00 The Challenge and Strategy to Study Transporters in Drug Development

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 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 – 14:10 Lunch & Poster presentation

(Poster presentation 13:30-14:10)

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

Session chairs: Kazutaka Higaki (Okayama University, Japan)

- 14:10 – 14:50 IVIVC consideration based on the analysis of *in vivo* oral absorption process in human**
Shinji Yamashita, Ph.D. (Setsunan University, Japan)
- 14:50 – 15:30 Predicting bioequivalence from *in vitro* dissolution tests**
Jennifer B. Dressman, Ph.D. (Goethe University, Frankfurt, Germany)
- 15:30 – 16:10 Industrial perspective for evaluation of dissolution: Quality by Design**
Bertil Abrahamsson, Ph.D. (AstraZeneca, Sweden)
- 16:10 – 16:25 Additional discussion**

16:25– 16:45 Break

Special Lecture

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

16:45– 17:45 **Innovative strategies for drug development using microdose clinical study**

Yuichi Sugiyama, Ph.D. (University of Tokyo, Japan)

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 – 13:40 **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)

13:40– 14:20 BE guidelines in EU: current status and future

Jan Welink, Ph.D. (European Medicines Evaluation Board, Netherlands)

14:20 – 15:00 Japanese and global situations in regulating oral drug products

Chikako Yomota, Ph.D. (National Institute of Health Sciences, Japan)

15: 00– 15:25 Japanese draft guideline for BE studies for manufacturing changes

Noriyuki Muranushi, Ph.D. (Shionogi & Co. Ltd, Japan)

15:25 – 15:40

Short Break

15:40 – 16:20 Panel discussion for worldwide standards of BE guideline

16:20 – 16:30 Closing remarks

Mitsuru Hashida, Ph.D. (Kyoto University, Japan)

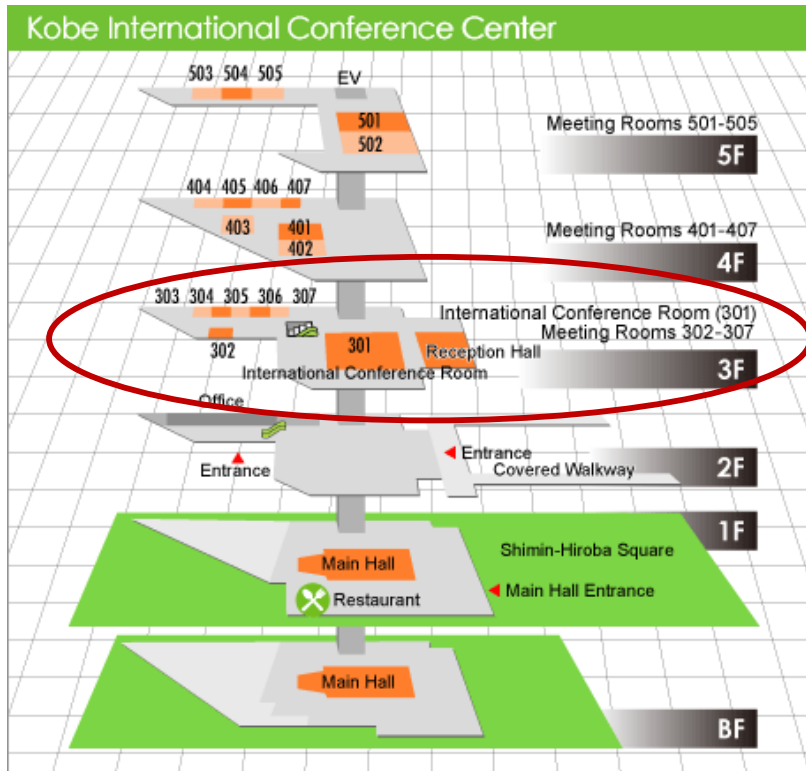
General Information

Venue: 3F of Kobe International Conference Center, 3F

Main Hall: International Conference Rom

Poster presentation: Lounge area

Exhibition: Reception Hall



Registration Hours:

Registration desk will be located on 3F of Kobe International Conference Center. All participants should pick up the badges and meeting materials during the following times. On-site registration is also accepted.

Wednesday, June 29 : 11:30 - 17:00

Thursday, June 30 : 8:45 -17:00

Friday, July 1 : 9:00 -12:00

Certificate of Attendance:

A certificate of attendance will be given to registered participants upon request.

Language:

The official language of BA/BE 2011 symposium is English. No simultaneous translation will be provided

Social Events:

Wednesday, June 29: 18:20 – 20:00,

- **Welcome Reception** at Poster Presentation & Exhibition Hall (complimentary for all participants)

Join the reception and enjoy complimentary beverages and meals, visit with poster presenters and exhibitors.

Thursday, June 30 : 19:00– 21:00

- **Banquet** at “Kobe Portopia Hotel” (South Wing 16F : Sky Banquet Room “Rainbow”)

(<http://www.portopia.co.jp/index.html>)

Enjoy dinner and attractions. “Kobe Portopia Hotel” is connecting to the Conference venue. Additional fee is required (10,000 JP Yen).

Poster Presentation:

All posters will be displayed in the Poster Presentation hall both June 29 and 30.

June 29: 12:30 to 18:10

June 30: 9:00 to 18:30 (presentation time, 13:30 -14:10, 17:45 - 18:30)

Authors are required to be at the poster during the presentation time (June 30 : 13:30-14:10, 17:45-18:30) to answer questions and/or participate in discussions.

Exhibition:

A commercial exhibition is arranged in the Exhibition hall for 3 days.

Exhibition time: June 29 : 12:30 to 18:10

June 30 : 9:00 to 18:30

July 1 : 9:20 to 13:30

Recess and Coffee Break Place:

All participants can take a recess in the Exhibition hall. For invited speakers, Guest room is also available.

Cloakroom:

Cloakroom is available at 3F of Kobe International Conference Center.

BA/BE 2011 Office:

During the conference, office of the symposium will be located at small conference rooms 303 and 304 at 3F of Kobe International Conference Center.