

FIP Symposium



International Symposium on BA/BE of Oral Drug Products

*More Science, Technology and
Better Regulatory Standards*

Co-sponsored with

The Pharmaceutical Society of Japan (PSJ)

The Academy of Pharmaceutical Science and Technology, Japan (APSTJ)

The Japanese Society for the Study of Xenobiotics (JSSX)

Asian Federation of Pharmaceutical Sciences (AFPS)

American Association of Pharmaceutical Scientists (AAPS)

European Federation for Pharmaceutical Sciences (EUFEPS)

German Pharmaceutical Society (DPhG)

The Swedish Academy of Pharmaceutical Sciences (SAPS)

Drug Delivery Foundation (DDF)

April 11– 13, 2011

National Center of Sciences,
Hitotsubashi Memorial Hall

2-1-2 Hitotsubashi, Chiyoda-ku,
Tokyo 101-8430, Japan

Get full program details and registration information at

<http://www.babe2011.org>

Co-Chairs:

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

International advisory board:

Tsuneji Nagai, Ph.D. (The Nagai Foundation Tokyo, Japan)
Yuichi Sugiyama, Ph.D. (University of Tokyo, Japan)
Ikumi Tamai, Ph.D. (Kanazawa University, Japan)
Leslie Z. Benet, Ph.D. (University of California, San Francisco, USA)
Dirk Barends, Ph.D. (National Institute of Public Health and the Environment, Netherlands)
Soo Youn Chung, Ph.D. (Korea Food and Drug Administration, Korea)
Jennifer Dressman, Ph.D. (Goethe University, Germany)
Peter Langguth, Ph.D. (University of Mainz, Germany)
Hans Lennernas, Ph.D. (Uppsala University, Sweden)
James Polli, Ph.D. (University of Maryland, USA)
Jan Welink, Ph.D. (European Medicines Evaluation Board, Netherlands)
Lawrence Yu, Ph.D. (Food and Drug Administration, USA)

Programming committee:

Shinji Sakuma, Ph.D. (Setsunan University, Japan)
Fumiyoshi Yamashita, Ph.D. (Kyoto University, Japan)
Kazutaka Higaki, Ph.D. (Okayama University, Japan)
Takuya Fujita, Ph.D. (Ritsumeikan University, Japan)
Kohsaku Kawakami, Ph.D. (National Institute of Material Science, Japan)
Noriyuki Muranushi, Ph.D. (Shionogi & Co. Ltd, Japan)
Ryusuke Takano, Ph.D. (Chugai Pharm. Co., Japan)
Bertil Abrahamsson, Ph.D. (AstraZeneca, Sweden)
Marival Bermejo, Ph.D. (Universidad de Valencia, Spain)
Michael B. Bolger, Ph.D. (University of Southern California, USA)
Jack A. Cook, Ph.D. (Pfizer, USA)
Ping Gao, Ph.D. (Abbott Laboratories, Inc, USA)
Kyung-Dall Lee, Ph.D. (University of Michigan, USA)

Program

Monday, April 11

9:20 am – 9:25 am

Opening remarks

Masatoshi Narita
Ministry of Health, Labour and
Welfare, Japan

9:25 am – 9:40 am

Welcome, introductions, and symposium overview

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

9:40 am – 10:20 am

Keynote address :

New era in BA/BE world

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

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

10:20 am – 11:00 am

Understanding the process of oral drug absorption *in vivo* in humans

Shinji Yamashita, Ph.D.
Setsunan University, Japan

11:00 am – 11:15 am

Short Break

11:15 am – 11:55 am

Drug absorption, first-pass extraction and bioavailability: experience from human *in vivo* studies

Hans Lennernas, Ph.D.
Uppsala University, Sweden

11:55 am – 12:35 pm

Physiology-based pharmacokinetic modeling of oral drug ADME and DDIs

Michael B. Bolger, Ph.D.
University of Southern California, USA

12:35 pm – 12:45 pm

Additional discussion

12:45 pm – 14:15 pm

Lunch & Poster presentation

14:15 pm – 14:55 pm

BDDCS for better understanding of DDI

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

14:55 pm – 15:35 pm

Role of absorptive transporter: Impact on oral BA and DDI

Ikumi Tamai, Ph.D.
Kanazawa University, Japan

15:35 pm – 16:15 pm

What's all the flux about? An industry perspective on the drug transporter whitepaper and recent regulatory guidances

Joseph W. Polli, Ph.D.
GlaxoSmithKline, USA

16:15 pm – 16:25 pm

Additional discussion

16:25 pm – 16:45 pm

Break

16:45 pm – 17:45 pm

Special lecture

Innovative strategies for drug development using microdose clinical study

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

18:00 pm – 19:30 pm

Welcome reception

Tuesday, April 12

Session 2: Improving oral BA of biopharmaceutical problem compounds

9:20 am – 9:55 am

Physical chemistry of API and its implication for formulation strategy

Kohsaku Kawakami, Ph.D.
National Institute of Material Science,
Japan

9:55 am – 10:30 am

Formulation design based on model and simulation

Ryusuke Takano, Ph.D.
Chugai Pharm. Co., Japan

10:30 am – 11:10 am

Design and development of conventional SEDDS and supersaturatable SEDDS formulations with improved oral absorption of poorly soluble drugs

Ping Gao, Ph.D.
Abbott Laboratories, Inc, USA

11:10 am – 11:25 am

Short Break

11:25 am – 12:05 pm

Delivery strategies to diminish intestinal metabolism and enhance bioavailability

Peter R. Langguth, Ph.D.
Johannes Gutenberg University-
Mainz, Germany

12:05 pm – 12:40 pm

Excipients modifying permeability to improve oral BA

Mariko Morishita, Ph.D.
Hoshi University, Japan

12:40 pm – 12:50 pm

Additional discussion

12:50 pm – 14:15 pm

Lunch & Poster presentation

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

14:15 pm – 14:55 pm

Predicting bioequivalence from in vitro dissolution tests

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

14:55 pm – 15:35 pm

Industrial perspective for evaluation of dissolution: Quality by Design

Bertil Abrahamsson, Ph.D.
AstraZeneca, Sweden

15:35 pm – 16:15 pm

IVIVC and BE for combination drug: Experiences in Pfizer

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

16:15 pm – 16:30 pm

Short Break

16:30 pm – 17:10 pm

Biowaivers for IR drug products - What have we learned since BCS?

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

17:10 pm – 17:50 pm

Future in BCS: Biowaiver Class 2 and Class 3 ?

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

17:50 pm – 18:00 pm

Additional discussion

18:30 pm – 21:00 pm

Banquet

Wednesday, April 13

Session 4: World wide standards for regulating oral drug products

9:20 am – 10:00 am

BE guidelines in EU: current status and future

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

10:00 am – 10:40 am

Japanese and global situations in regulating oral drug products

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

10:40 am – 11:20 am

Question based review of oral drug products

Lawrence Yu, Ph.D.
Food and Drug Administration, USA

11:20 am – 11:35 am

Short Break

11:35 am – 11:50 am

Bioequivalence guideline in Korea

Soo Youn Chung, Ph.D.
Korea Food and Drug Administration, Korea

11:50 am – 12:05 pm

Japanese draft guideline for BE studies for manufacturing Changes

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

12:05 pm – 12:40 pm

Panel discussion for world wide standards of BE guideline

12:40 pm – 12:55 m

Closing remarks

Mitsuru Hashida, Ph.D.
Kyoto University, Japan

Call for Posters

Submission deadline is December 11, 2010.

Please check the Submission Guideline at <http://babe2011.org/poster.html>.

Registration Fees

Registration opens mid September 2010 at

<http://babe2011.org/registration.html>

Early-bird deadline is March 15, 2011.

Registration type	Conference*		Banquet	
	On-line (3/15/2011)	On-site	On-line (3/15/2011)	On-site
Industry	JPY 50,000	JPY 60,000	JPY 10,000	JPY 12,000
Academia/ Government	JPY 35,000	JPY 45,000		
Student	JPY 5,000	JPY 8,000		

*Conference fee includes admission to all session with coffee break, welcome reception and symposium proceedings. Please note that the conference fee does NOT include meals or hotel accommodations.

Cancellation/Refund Policy

Cancellations will be accepted until March 15, 2011 with a refund of all prepaid fees less a handling fee. After this date no refunds will be given. Notice of cancellation should be submitted in writing to the conference office by e-mail or fax.

Symposium Secretariat

Secretariat of International Symposium on BA/BE of Oral Drug Products

c/o International Medical Information Center
Shinanomachi-Rengakan, 35 Shinanomachi
Shinjuku-ku, Tokyo 160-0016, Japan.

TEL: +81-3-5361-7370

FAX: +81-3-5361-7091

E-mail: office@babe2011.org