Bioavailability and Bioequivalence:
The Language of Drug Product Quality

Venue: Lo Kwee-Seong Integrated Biomedical Sciences Building, Area 39, The Chinese University of Hong Kong.

Date: 12 May 2012 (Saturday)

Time: 9:00am — 5:30pm

Main Topics

1. BA/BE: From Generics to Biosimilars
2. BCS from Theory and Applications
3. Predicting bioequivalence from in vitro dissolution tests
4. Factors affect equivalence in human BE study
5. Bioequivalence of highly variable drugs
6. Simulation in BA/BE assessment
7. Application of BCS theory in Japan and Hong Kong
8. Significance of solid state properties in drug product development
9. Closing the gap between in vitro and in vivo data in BA/BE studies

Speakers

- Prof. Gordon Amidon, University of Michigan
- Dr. Michael Bolger, Simulations Plus, Inc.
- Prof. Albert Chow, CUHK School of Pharmacy
- Prof. Vincent H. L. Lee, CUHK School of Pharmacy
- Prof. Brian Tomlinson, CUHK Department of Medicine and Therapeutics
- Prof. Fumiyoshi Yamashita, Kyoto University
- Prof. Shinji Yamashita, Setsunan University
- Prof. Joan Zuo, CUHK School of Pharmacy

Organizer

School of Pharmacy
Faculty of Medicine
The Chinese University of Hong Kong
Tel: (852) 3943-6831
Fax:(852) 2603-5295
Email: pharmacy@cuhk.edu.hk
Website: www.pharmacy.cuhk.edu.hk/babe

Organized by:

School of Pharmacy CUHK
Expanding the pharmaceutical universe, Creating opportunities for life

Professional Advancement Clinical Excellence 1992-2012 Anniversary
SCHOOL OF PHARMACY, CUHK

Sponsored by:

Jacobson Jacobson Pharma Group

simulations plus, inc.
integrating science and software

Bioavailability and Bioequivalence:

The Language of Drug Product Quality

Lo Kwee-Seong Integrated Biomedical Sciences
Building, Area 39, The Chinese University of Hong Kong
Saturday, May 12, 2012

Bioavailability (BA) and bioequivalence (BE) studies are required of new as well as generic drug products. BA/BE are parameters with practical and public health value for drug manufacturers, for regulatory agencies, and ultimately for patients. From a drug product performance perspective, BA studies also benchmark the performance of the formulation(s) used in the clinical trials. The performance of further reformulation of this product and subsequently its generic equivalent is expected to be linked to the benchmark performance of the clinical trial dosage form.

The objective of this one-day workshop is to provide a broad perspective on the theory and practice of BA/BE, with a special emphasis on the utility of the Biopharmaceutic Classification System (BCS) as an important decision making tool for assessing drug product quality. As examples, generic drug products in Hong Kong and in Japan will be profiled according to the BCS. In addition to introducing quality-by-design (QbD) as a proactive strategy for incorporating critical quality attributes into drug formulation design, the workshop will conclude with an open forum on the way forward for BA/BE as the language of drug product quality in Hong Kong.

Programme

May 12, 2012 Morning (9:00am – 12:30pm)

9:00am – 9:20am	Opening remarks	
9:30am – 10:00am	BA/BE: From generics to biosimilars	Prof. Vincent H. L. Lee
10:00am – 10:30am	BCS: From Theory to Applications in Pharmaceutical Product Development and Quality Control	Prof. Gordon Amidon
10:30am – 11:00am	Predicting bioequivalence from in vitro dissolution tests	Prof. Gordon Amidon
11:00am – 11:30am	***Tea Break***	
11: 30am –12:00nn	BCS based analysis on the factors which incur bio-in–equivalence in human BE study	Prof. Shinji Yamashita
12:00nn – 12:30pm	Evaluation of bioequivalence of highly variable drugs/narrow therapeutic index drugs and drug products–experience from Hong Kong	Prof. Brian Tomlinson
12:30pm – 2:30pm	***Lunch Break***	

May 12, 2012 Afternoon (2:30pm – 5:30pm)

2:30pm – 3:00pm	Role of mechanistic oral absorption modeling and simulation in BA/BE assessment	Dr. Michael Bolger
3:00pm – 3:30pm	Application of BCS theory in Japanese pharmaceutical industry and regulatory agency	Prof. Shinji Yamashita
3:30pm – 4:00pm	Application of BCS in local generic products	Prof. Joan Zuo
4:00pm – 4:30pm	Significance of solid state properties in drug product development	Prof. Albert Chow
4:30pm – 5:00pm	Closing the gap between in vitro and in vivo data in BA/BE studies	Prof. Fumiyoshi Yamashita
5:00pm – 5:30pm	Open forum	

Bioavailability and Bioequivalence:

The Language of Drug Product Quality

Lo Kwee-Seong Integrated Biomedical Sciences Building,
Area 39, The Chinese University of Hong Kong
Saturday, May 12, 2012

REGISTRATION FORM

Please complete all sections

Name of Company / Organization:

Address:

(Prof./ Dr./ Mr./ Mrs./ Ms/ Miss)

	Title	Name	Position	Tel.	E-mail
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Registration Fee: HKD 750 / Per Participant X No. of Participants _____ = Total Amount HKD _____

I enclose a cheque in the amount of HKD _____ Cheque no.: _____

Payable to "The Chinese University of Hong Kong"

Name: _____

Signature: _____ Date: _____

Please send the completed form with payment to Ms. Kate Cheung **Address: School of Pharmacy, 8/F, Lo Kwee-Seong Integrated Biomedical Sciences Building, Area 39, The Chinese University of Hong Kong. Email:** pharmacy@cuhk.edu.hk **Tel: 3943-6831 Fax:2603-5295**