

1st MOPI Bioequivalence Workshop



Gateway to
Excellence



The National Pharmaceuticals Control Bureau (NPCB) launched its '1st Bioequivalence List' in 1999 with 3 compounds; Nifedipine, Cyclosporin and Captopril. Now, 10 years on with 7th Bioequivalence Lists covering a total of 97 compounds, are we equipped with the right skill, knowledge and strategy in the development of our products?

As ASEAN gravitates towards harmonization, Malaysian companies will be faced with a new challenge to remain competitive. A natural response would be to enter new markets. Beside PIC/S, the advancement in bioequivalences studies can be another competitive advantage to enter into regulated markets.

Why you should attend

Through this workshop, we can sharpen our skills and increase our knowledge with regards to Bioequivalence. The modules provide a good understanding of GCP requirements and clinical quality assurance for clinical trials.

The modules are carefully selected to address the many questions, myths, misconceptions as well as to provide a deeper insight into the science behind Bioequivalence.

What you will learn

- gain real-time experience in techniques for detecting, correcting and preventing clinical study deficiencies at the trial site.
- Practical examples are included.
- how to ensure that their data and supporting documentation are accurate, factual and in the appropriated format for the company and regulatory authorities.

Organised by:



Malaysian Organisation of
Pharmaceutical Industries

Endorsed by:



National Pharmaceutical
Control Bureau

Facilitated by:



Info Kinetics
Sdn Bhd



MONITORING MODULE

29 - 30 June 2009

- Principals of pharmacokinetics, bioavailability (BA) and bioequivalence (BE)
- Understanding BE protocols and the different regulatory standards governing the study design
- Interpretation of BE reports and pharmacostatistics
- Statistical analysis of comparative BA data
- BE report requirements
- Updates on the new draft BA/BE guidelines 2009

Topics Covered

Those involved in:

- evaluation of BE reports and regulatory submissions.
- reviewing BE dossier submitted for market authorisation (including regulators).

Who Should Attend

Learning objectives

Upon completion, participants will be able to:

- Identify and define the principles and requirements for GCP and ensure compliance
- Understand the importance of qualification and monitoring program, putting them into practice
- Understand the roles and responsibilities of the sponsor & monitor
- Comply with informed consent requirements
- Put into practice the regulatory, source documentation and record-keeping requirements
- Ensure that data and supporting documentation are accurate and complete for inspection
- Manage a GCP inspection
- Detect and prevent fraud and

Learning objectives

Upon completion, participants will be able to:

- Identify and define the principles and requirements for GCP
- Understand the various regulatory requirements and standards for BE study
- Understand the BE study protocol and report content / format (ICH)
- Ensure that data and supporting documentation are accurate and complete for regulatory submission
- Able to respond to enquiries from regulatory authority pertaining to study design, statistical analysis & report interpretation
- Get updates on the New Draft BA/BE Guideline 2009 (EMA)

Who Should Attend

Those involved in:

- monitoring and/or QA of bioequivalence (BE) studies.
- supervision or oversight of clinical trial practices and policies will find this course beneficial.

Topics Covered

- GCP requirements
- Informed consent requirements
- Role of a SMART clinical trial monitor
- The 'what', 'when' and 'how' in site monitoring
- Evaluating a study protocol and Case Report Forms
- Preventing fraud and scientific misconduct
- Statistical Analysis for the Non-Statistician
- Managing and reporting of adverse events
- GLP for GCP Trials

BIOEQUIVALENCE REPORT MODULE

11 - 12 August 2009

BIOANALYTICAL MODULE

29 September 2009

Learning objectives

Upon completion, participants will be able to:

- Identify and define the principles and requirements for GCP and ensure compliance
- Understand the importance of GLP and ensure compliance
- Put into practice the regulatory, source documentation and record-keeping requirements
- Ensure that data and supporting documentation are accurate and complete for regulatory submission
- Able to respond to enquiries from regulatory authority pertaining to analytical methodology and validation data
- Able to detect and prevent fraud and misconduct in

Who Should Attend

Those involved in:

- clinical trial site selection.
- evaluation of .BE reports, and
- regulatory submission.

Topics Covered

- Defining the basic requirements of GCP
- Updates on Putting GLP into perspective for GCP Trials
- Understanding FDA Guidance for Industry: Bioanalytical Method Validation
- Evaluation of a Validation Report, Analytical Report and Chromatogram
- Preventing fraud and scientific misconduct in bioanalysis

The Facilitator

Dr. Lee Toong Chow, B.Pharm(PG Hons), MACPP, Ph.D.

Dr Lee, a graduate from University of Queensland had over 18 years of hands-on experience in the clinical research arena. Dr Lee worked as a senior scientist as well as a medical manager for generic and transnational pharmaceutical company in Malaysia. Responsibilities held by Dr Lee include as investigator, associate professor, centre director, consultant and trainer in areas of analytical laboratory, animal PK study, clinical trial, BA/BE, consultant in setting up GLP lab in GMP, ISO17025 facilities, including facility OQ/PQ.

Dr Lee was also the chairperson in the drafting committee for the "Malaysian Guidelines on BA & BE Studies", as well as advisor/ technical expert to National Pharmaceutical Control Bureau, ASEAN ACCSQ PPWG on BE matters. He maintains close communication with EMEA, TGA and WHO representative in the development of the ASEAN BA/BE guide, training of Regulators and implementing the requirement of GCP and GLP in ASEAN.

Dr Lee is currently the Managing Director of Info Kinetics Sdn Bhd, a premier contract research organization (CRO) in the Asian & Australasian region, focusing on Bioavailability & Bioequivalence Studies. Dr Lee still holds academic positions in University Malaya, Penang Medical College, University of Queensland and Murdoch University.

Mr. Kenneth Ho, B.Pharm(Hons), MMPS.

Kenneth is a home grown pharmacist from the School of Pharmaceutical Sciences, Universiti Sains Malaysia. From his undergraduate days, he has been an active member of the Pharmaceutical Student's Society, and continued on to be a member of the Malaysian Pharmaceutical Society. Upon his completion of his pupillage in Ipoh General Hospital, he was registered with the Malaysian Pharmacy Board in 2002. Kenneth is currently the Business Development Manager of the company.

Being GCP qualified and accustomed to ISO 9001, ISO 17025 and GLP requirements, Kenneth's research interest areas are in bioequivalence and clinical trials. He has had experience as a Project Manager for conducting clinical trials in Malaysia. Besides that, Kenneth also has a keen interest in investigating traditional / complementary medicine for adulterated substances and forensic investigation of drugs of abuse in urine.

**TO REGISTER: Fax 603-7956 0018 Call 603-7957 3070, 03-7957 1004
Email: mike@mopi.org.my**

REGISTRATION FORM

Course Details

Training Grant is available under HRDF SBL Scheme

3 Easy ways to Register:

Fax
603-7956 0018

Email
mike@mopi.org.my

Tel
603-7957 3070
603-7957 1004

Course Dates:

Monitoring Module

29 – 30 June 2009 (Mon – Tue)

Bioequivalence Report Module

11 – 12 August 2009 (Tue – Wed)

Bioanalytical Module

29 September 2009 (Tue)

Venue:

Crystal Crown Hotel
12, Lorong Utara A, Off Jalan Utara, 46200
Petaling Jaya
Selangor Darul Ehsan
Tel: 603 – 7958 4422

Time:

9.00 am – 5.00 pm

Delegate Name 1	
Dr/Mr/Mrs/Ms	
Position	
Email	
Delegate Name 2	
Dr/Mr/Mrs/Ms	
Position	
Email	
Registration Contact	
Dr/Mr/Mrs/Ms	
Position	
Email	
DID Tel	Fax
Full Company Name (For Billing)	
Billing Address	

Fee per participant per course:

(The fee includes course materials, lunch and refreshments)

Module Selection	Course Dates	Book 30 days before commencement of course	Save	Book 29-14 days before commencement of course	Save	Book within 13-7 days before commencement of course
<input type="checkbox"/> Monitoring	29-30 June 2009	<input type="checkbox"/> RM 1300	200	<input type="checkbox"/> RM 1400	100	<input type="checkbox"/> RM 1500
<input type="checkbox"/> Bioequivalence Study Report	11-12 August 2009	<input type="checkbox"/> RM 1300	200	<input type="checkbox"/> RM 1400	100	<input type="checkbox"/> RM 1500
<input type="checkbox"/> Bioanalytical	29 September 2009	<input type="checkbox"/> RM 650	100	<input type="checkbox"/> RM 700	50	<input type="checkbox"/> RM 750

Payment Method

Cheque No.

All payments to be made payable to **Malaysian Organisation of Pharmaceutical Industries.**

Payment is required with registration and must be received 2 weeks prior to the start of the relevant module to guarantee your place. Registration will be treated as confirmed only upon receipt of payment in full. Walk-in participants will only be admitted on the basis of space availability at the course and with immediate full payment by company cheque in favour of the "Malaysian Organisation of Pharmaceutical Industries".

CANCELLATIONS AND REPLACEMENTS:

A full refund less 10% administrative charge will be made for cancellation received in writing (fax/email) 14 days before commencement of each module. Substitutions are welcome at no extra course. **Regrettably, no refund can be made for cancellations received less than 7 working days prior to the commencement of each module. However a complete set of documentation will be sent to you.**

Important Note

It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that a module is cancelled MOPI is not liable for any costs incurred by delegates in relation to their attendance.

BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:

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