

ICH-GCG ASEAN Training Workshop

ICH Q5C : Stability Testing for Biotechnological/Biological Products

30th – 31st May 2011, Kuala Lumpur, Malaysia

Introduction

The training for ICH Quality Guideline ICH Q5C: Stability Testing for Biotechnological/Biological Products is an activity under the ICH-Global Cooperation Group (GCG) Initiative. This training workshop provides a great opportunity for up skilling of knowledge and sharing of experiences between regulators and industries from ASEAN countries.

Objectives

- To understand the scientific basis of stability guidelines
- To update and enhance technical and practical knowledge on stability testing requirements for biotechnological/biological products (ICH Q5C), comparability (ICH Q5E) and specifications (ICH Q6B).
- To better understand how to design, conduct stability studies for biotech products.

Who Should Attend

NRA regulators and industry representatives from ASEAN countries and everyone interested in ICH Q5C guideline and its practical implementation.

Training Highlights

Speakers :

Dr. Brigitte Brake Federal Institute for Drugs and Medical Devices (BfArM), Germany.

Dr. Alberto Ganan Jimenez European Medicines Agency, United Kingdom.

The training will focus on:

- Stability studies: protocol, design, specifications etc.
- Relevant quality aspects of stability evaluation.
- Comparability of products subjected to changes in manufacturing process.
- Update on latest regulatory and EU experience on Biosimilars and Advanced Therapy Medicinal Products (ATMPs).

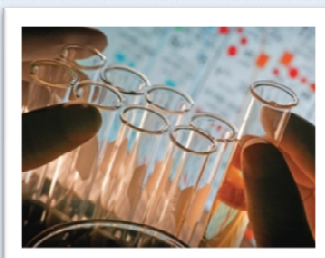
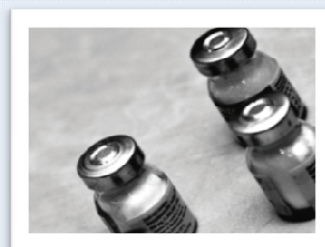
Venue

ONE WORLD HOTEL

FIRST AVENUE, BANDAR UTAMA,
47800 PETALING JAYA, SELANGOR,
MALAYSIA.

Contact

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Organised by :



National Pharmaceutical Control Bureau
Ministry of Health Malaysia
www.bpfk.gov.my



International Conference
on Harmonisation
www.ich.org



Association of
Southeast Asian Nations
www.aseansec.org

Program: ICH-GCG ASEAN Training Workshop
ICH Q5C: Stability Testing for Biotechnological/Biological Products
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Day 1 : Quality of biological products

Time	Topic	Speaker
0800 – 0900	- Registration	
0910 – 0925	- Opening remarks	NPCB
0930 – 0950	- Overview of International Conference on Harmonisation Global Cooperation Group (ICH-GCG)	Dr. Alberto Ganan
Session I: Characterisation and Stability of Biologicals		
0950 – 1040	- Scope of ICHQ5C guideline/terminology - Batch selection	Representative of EMA
1040 – 1100	- Coffee break	
1100 – 1200	- Stability indicating profile - Storage conditions - Testing frequency - Specifications and labelling	
1200 – 1245	- “Case study on stability”	
1245 – 1300	- Discussion	
1300 – 1415	- Lunch	
Session II : Comparability and Development of Biologicals		
1415 – 1515	- General principles on comparability - Quality considerations	Representative of EMA
1515 – 1530	- Coffee break	
1530 – 1615	- Manufacturing process considerations - Comparability during development	
1615 – 1630	- Discussion	

Day 2 : Specifications

Time	Topic	Speaker
Session III : Specifications : Test Procedures and Acceptance Criteria		
0900 – 0945	- Principles in setting specifications	Representative of EMA
0945 – 1030	- Drug substance and drug product - Justifications of specifications	
1030 – 1100	- Coffee break	
Session IV : European Experience and Challenges On Biologicals		
1100 – 1230	- Biosimilars and issues related	Representative of EMA
1230 – 1300	- Discussion	
1300 – 1430	- Lunch	
1430 – 1530	- Advanced therapy medicinal products	
1530 – 1600	- Discussion	
1600 – 1630	- Workshop Outcomes & Concluding remarks	

REGISTRATION FORM

ICH-GCG ASEAN Training Workshop: ICH Q5C
30 – 31 May 2011, Kuala Lumpur, Malaysia

REGISTRATION FEE please (✓)

- | | |
|---|------------|
| ☐ INTERNATIONAL PARTICIPANTS | USD 300.00 |
| ☐ LOCAL PARTICIPANTS | RM 900.00 |

**LIMITED PLACES FOR FIRST
100 PARTICIPANTS ONLY!**

HOW TO REGISTER

-  MAIL the completed registration form with your proof of payment to:
**Biotechnology Section,
National Pharmaceutical Control Bureau,
Ministry of Health Malaysia
Lot 36, Jalan Universiti, 46200 Petaling Jaya,
Selangor, Malaysia.**
-  FAX **+(60)3 7958 1312**
-  EMAIL shahrizan@bpfk.gov.my OR khlee@bpfk.gov.my
-  For any enquiries, please contact:
Mr. Shahrizan/Mr. Lee **+(60)3 7883 5400 ext. 5527/5519**

PARTICIPANT DETAILS

[illegible]

SIGNATURE _____ DATE _____

MODE OF PAYMENT please (✓)

- ☐
- Bankdraft
- ☐
- LPO No |

For the sum of RM / USD _____
 Payment should be made payable to "NRC 2008"

- ☐ Visa ☐ Master Card ☐ American Express ☐ Diners Club

For Amex, please provide 4 digits I/D No | _____ |
 For Visa / Master Card/Diners Club, please provide 3 digits (behind credit card) I/D No | _____ |
 Card number | _____ | Valid till | _____ |
 Date | _____ | Signature | _____ |

- By direct bank transfer / ATM into the conference bank account **“NRC 2008“**. **A/C No: 5-142713-37523** (Swiftcode:MBBEMYKL).
Address: Maybank, 2 Lorong Rahim Kajai 14, Taman Tun Dr Ismail, 60000 Kuala Lumpur, Malaysia.
Please send the bank receipt (or a scan copy) to MPS to confirm your registration

For enquiries on payment of fees: Please contact:
Malaysian Pharmaceutical Society (MPS), 5B, Lorong Rahim Kajai 13, Taman Tun Dr Ismail, 60000 Kuala Lumpur
Tel: (60) 3 77291409 / Fax: (60) 3 77263749 / Email: mspharm@po.jaring.my

TERMS & CONDITIONS

- Registration fee includes course materials, refreshments and lunch. Accommodation is not included.
- Registration will be closed on **10th of May 2011**. Registration is on a first come first serve basis for the first 100 confirmed registration only.
- Upon receipt of payment, a confirmation letter will be sent within 2 weeks via email.
- Registration fees will not be returned on cancellation. Replacement is allowed.