



Regional Update – ASEAN PPWG

**ICH-GCG Meeting
Cincinnati, Ohio, USA
June 2011**

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Scope

- **Introduction**
- **Update on 18th PPWG Meeting**
- **Update on Q5C Training**

Update on 18th PPWG Meeting



- Held in Singapore from 7th to 10th June 2011
- > 260 participants from ASEAN regulatory agencies and industry
- Ongoing discussions by Technical Working Groups and Implementation Working Group on quality, safety and efficacy guidelines, variation guidelines, and implementation of ASEAN Common Technical Dossier (ACTD).
- Established TOR of new Technical Working Group for Biologics
- To surface revised TOR of PPWG and Joint Sectoral Committee for GMP MRA implementation to ACCSQ for adoption.



Update on 18th PPWG Meeting

- Updates of GCG activities
 - GCG webinar is opened to all ASEAN member states
 - Announcement of training modules are posted on GCG website
- ASEAN member states are asked to suggest guidelines for future webinar



Update on Q5C Training

Title	ICH-GCG ASEAN Training Workshop on ICH Guidelines Q5C: Stability Testing for Biotechnological/Biological Products
Date	30 th – 31 st May 2011
Venue	Kuala Lumpur, Malaysia
Trainers	<p>Dr. Alberto Ganan Jimenez Scientific Administrator, Quality of Medicines Sector – Biologicals at Human Medicines Development and Evaluation Unit, European Medicines Agency (EMA), London, United Kingdom</p> <p>Dr. Brigitte Brake Head of Unit Pharmaceutical, Biotechnology and Inspections at the Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany.</p> <p>Both speakers are also members of CHMP Biologics Working Party (BWP)</p>
Participants	117 participants, from ASEAN Member States & Korea



Update on Q5C Training

- **Activity under ICH-GCG ASEAN Collaboration Scheme.**
- **Focus of training was to provide better understanding of several key elements of stability testings/profile and relevant elements of ICH Q5E and ICH Q6B.**
- **Training also highlighted data and studies required to establish product storage conditions and shelf life, including several practical case studies on stability of drug substances and drug products.**
- **Workshop also included a general discussion and updates on the ICH and EU regulatory guidelines and sharing on EU regulatory framework on Advanced Therapy Medicinal Products (ATMPs) and biosimilars.**



Update on Q5C Training

Feedback on Workshop

- The workshop was successful and met the objectives.
- The participants agreed it was timely and in fact requested more of such training programs in this region.
- The case studies were excellent towards better understanding.
- The speakers were very good, knowledgeable, were very willing to share their expertise and experiences. This has certainly contributed to the high quality of the training.
- In conclusion - It was a truly insightful workshop and enjoyable learning experience for everyone.



ASEAN Training Needs

- **Advanced training on Q8/9/10 guidelines with case studies**
- **Quality by Design (QbD) with case-studies covering the following areas:**
 - **To understand how a good Design of Experiments (DoE) is established**
 - **To learn about the appropriate or acceptable approach to validate/verify a design space in production scale**
 - **To understand how to assess a risk management system**
 - **To know about the appropriate sampling plan, size or protocol as well as acceptance criteria for a PAT**
 - **To gain the knowledge on importance of a control strategy throughout the product lifecycle and how its change could impact QbD**
 - **FDA's and EMA's latest Guidance on Process Validation adopting the QbD approach**



Acknowledgement

- ASEAN PPWG will like record our sincere appreciation to GCG for
 - Supporting training programme of ICH guidelines in ASEAN
 - Opportunities to participate in Webinar/ICH related training



Thank You