Regional Update – ASEAN PPWG

ICH-GCG Meeting
Cincinnati, Ohio, USA
June 2011

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Health Sciences Authority, Singapore
Scope

• Introduction

• Update on 18th PPWG Meeting

• Update on Q5C Training
Update on 18\textsuperscript{th} PPWG Meeting

• Held in Singapore from 7\textsuperscript{th} to 10\textsuperscript{th} 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**

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