APEC Harmonization Center
update on progress and future work

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Contents

I. AHC - A Brief Overview
II. 2010 AHC Training Programs
III. AHC Workshops in 2011
IV. Future Plan
AHC – A Brief Overview

**Vision & Activity**

**Vision**
- Providing access to the **best practices and guidelines**
- Promoting **collaborative actions** & **information-sharing activities**
- Supporting clinical trials that meet **international standards**
- Enhancing the **quality, safety, and efficacy** of therapeutic products

**Activity**
- Conducting Surveys and Research
- Providing Education
- Establishing Strong Networks
- Maintaining an e-Publication and Website
- Developing and Disseminating harmonization models
- Supporting International Cooperation
## AHC Training Programs 2009-2010

<table>
<thead>
<tr>
<th>Year</th>
<th>Main Topics</th>
<th># of Participants</th>
<th># of Economies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Multi-Regional Clinical Trials</td>
<td>562</td>
<td>17</td>
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<tr>
<td></td>
<td>Biosimilar</td>
<td>434</td>
<td>13</td>
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<td></td>
<td>GMP Validation (Pharmaceuticals)</td>
<td>458</td>
<td>Korea</td>
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<td>2010</td>
<td>Pharmaceutical Supply Chain</td>
<td>287</td>
<td>10</td>
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<tr>
<td></td>
<td>Multi-Regional Clinical Trials (Tripartite Symposium)</td>
<td>415</td>
<td>15</td>
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<td>Medical Devices</td>
<td>150</td>
<td>8</td>
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</table>
Date: November 15-16, 2010

Title: 2010 AHC Workshop on Medical Devices

- Use of Clinical Evidence in the Medical Device Premarket Conformity Assessment Process

- 150 participants from 8 economies

- 15 experts invited as speakers

Key Agenda Items

- Understanding and implementation of GHTF guidance on clinical evidence for premarket conformity assessment

- Understanding the infrastructure needed to ensure a clinical trial is designed and conducted ethically and scientifically when it is required for premarket conformity assessment
**AHC in 2011**

Workshop Agendas were discussed at RHSC meeting & endorsed in principle

<table>
<thead>
<tr>
<th>Topics</th>
<th>Sponsors</th>
<th>Proposed Dates</th>
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</thead>
<tbody>
<tr>
<td>Asia’s Role in Global Drug Development</td>
<td>AHC, DIA, IFPMA</td>
<td>APR 26-28</td>
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<tr>
<td>Medical Devices: GHTF Implementation</td>
<td>AHC, AHWP</td>
<td>JUL 4-5</td>
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<td>Pharmaceutical Quality: QbD</td>
<td>AHC</td>
<td>OCT 4-5</td>
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<td>Multi-regional Clinical Trial</td>
<td>Japan, AHC</td>
<td>NOV</td>
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<td>Pharmacovigilance</td>
<td>AHC</td>
<td>2012</td>
</tr>
</tbody>
</table>
2011 AHC 1st Co-sponsoring Workshop
AHC/DIA/IFPMA Asia Regulatory Conference

Date: April 26-28, 2011
Title: Asia’s Role in Global Drug Development

730 participants from 24 economies including
- 55 experts invited as speakers and chairs,
- 64 AHC supported trainees, etc.
2011 AHC 1st Co-sponsoring Workshop
AHC/DIA/IFPMA Asia Regulatory Conference

Update on ICH activities, focus on New Activities

- 20 Years of ICH: Learning and Accomplishments (Justina A. Molzon)
- Expanding Participation in ICH Technical Working Groups (Mike Ward)
- Japan’s Experience with ICH and the Implementation of Guidelines (Shinobu Uzu)
- KFDA’s Perspectives on the Implementation of ICH Guidelines (Sun Hee Lee)
Regional Harmonization Initiatives

<Parallel tracks on Day 1>

- Fighting counterfeit medicines in emerging countries
  - Addressing infrastructure and capacity gaps
- Ensuring quality - Enhance the approach of quality driven by ICH Q8, Q9, Q10, and Q11: What about practical implementation?
Asia’s Regulatory Harmonization Initiatives

<Parallel tracks on Day 1>

- Practical uses of CTDs in Asia

<Plenary sessions on Day 2>

- Similar biotherapeutic products (SBPs) in Asia
  : Opportunities and challenges in regulatory evaluation

<Parallel tracks on Day 2>

- Ensuring quality – Harmonizing and optimizing inspection approach in the global environment
2011 AHC 1st Co-sponsoring Workshop
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Regulatory Trends on Clinical trials in Asia

<Plenary sessions on Day 2>

- Early and late clinical development in Asia

<Parallel tracks on Day 2>

- Establishing the Asia Pacific Region as an important partner in global pediatric development
- Ethical business practices: Towards better marketing compliance

GCP tour after closing a workshop
: Seoul National University Hospital
Cooperation between Regulatory Authorities & Industries

<Plenary sessions on Day 3>

- **Electronic submissions and eCTD** as vehicle to reconcile differences in technical regulatory requirements
- **Pharmacovigilance**: How do regulatory agencies and industry work together to protect patients?
- **Good regulatory practices**, including assessment report, efficient use of certificate of pharmaceutical product (CPPs) and transparency
Future Plans

AHC is planning to ...

- Make long-term plans for AHC Workshops
  - to provide good training programs in the APEC region

- Expand the list of AHC Advisory Board members

- Add new features to AHC website
  - to better promote AHC activities and disseminate harmonization models
Thank You for Your Attention!

Send your additional comments or questions to AHC secretariat at ahckorea@khidi.or.kr

Please visit our website at www.apec-ahc.org