APEC Harmonization Center - Update on Progress and Prospects for Future Work

Submitted by: APEC Harmonization Center (AHC)
AHC – An Overview

**Establishment of AHC**

**Benefits from harmonizing international standards**

- **Enhance** product quality
- **Improve** the transparency of a regulatory process
- **Reduce** regulatory burden to enhance trade facilitation

*Endorsed by APEC Leaders (Nov., 2008)*

“Recalling our commitment to promoting regulatory reform and harmonization, we welcomed and endorsed the establishment of the APEC LSIF Harmonization Centre in Seoul as a key step forward.”

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AHC – An Overview

**Vision and Goals of AHC**

“**Establishment of the Best Harmonization Model**”

1. Providing access to the **best practices and guidelines**
2. Promoting **collaborative actions & information-sharing activities**
3. Supporting clinical trials that meet **international standards**
4. Enhancing the **quality, safety, and efficacy** of therapeutic products
AHC – An Overview

Organization

- AHC Director (KFDA)
- Secretary General Secretariat Office (KHIDI)
- Advisory Board
- Division of Survey & Research
- Division of Education & Training
- Division of International Cooperation
- Division of e-Publication & Website

AHC – An Overview

Training Activities in 2009

**2009 1st Multi-Regional Clinical Trials (MRCT) Workshop**
- **Date:** June 15~18, 2009
- **Title:** Multi-Regional Clinical Trials (MRCT) Seoul Workshop
- **Participation:** About 600 Attendees including 17 speakers and delegates

**2009 2nd Biosimilar Workshop**
- **Date:** September 17 ~ 18, 2009
- **Title:** APEC Harmonization Center Biosimilar Workshop
- **Participation:** about 400 in attendance including 9 speakers and delegates

**2009 GMP Validation Workshop**
- **Date:** December 3, 2009
- **Title:** GMP Pharmaceutical Validation Workshop
- **Participation:** About 458 Attendees including 7 speakers
Overall Suggestions

- Need for Follow-up workshops with in-depth training programs
- Holding AHC workshops in other economies considering the accessibility of attendees from different zone
- Allocation of more time for Break-out sessions
  - Longer and In depth discussion on practical issues

Updates from SOM I in 2010

- Endorsed the revised AHC Guidelines and proposed AB candidates
- Education & Training: AHC Workshop plans in 2010
  - Workshop agenda were discussed and endorsed in principle

<table>
<thead>
<tr>
<th>Topic</th>
<th>Tentative Dates</th>
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<tbody>
<tr>
<td>Pharmaceuticals: Quality - Supply Chain &amp; Industry Awareness on LSIF RHSC/AHC</td>
<td>Late April</td>
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<tr>
<td>Clinical Development in East Asia &amp; MRCT</td>
<td>September</td>
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<td>Medical Devices - Clinical Trials</td>
<td>November</td>
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AHC 1st Workshops in 2010

• Date: May 12-14, 2010
• Title: Pharmaceutical Supply Chain
• 230 participants from 10 economies, including
  - 10 experts invited as speakers
  - 10 delegates from APEC travel-eligible economies

Program of Pharmaceutical Supply Chain Workshop

• Day 1
  - Supply Chain Challenges and Regulatory Approaches
  - Status of Pharmaceutical Supply Chain in various economies
  - Pilot Projects on Authentication & Serialization
  - Counterfeit drugs in the Asia-Pacific Region and the latest trends

• Day 2
  - Handling of Trial Materials for use in Multi-Regional Clinical Trials
  - DMF Regulation and Management in Korea
  - Regulatory Expectations for Manufacturers in Assuring Quality of Components

• Day 3
  - Pharmaceutical Facility Visit & Half-day Seoul tour
Suggestions

• Place links to RX360, ISPE and IPEC on the AHC website
  * Rx360 : An international Pharmaceutical Supply Chain Consortium
  * ISPE : International Society for Pharmaceutical Engineering
  * IPEC : International Pharmaceutical Excipients Council

• Organize additional workshops on supply chain with numerous break-out sessions

AHC 2nd Workshops in 2010

• Date : September 13-15, 2010
• Title : 2010 Multi-Regional Clinical Trials Seoul Workshop - highlighting Korea-China-Japan Tripartite Symposium
• 382 participants from APEC and Non-APEC region, including
  - More than 40 experts invited as speakers and panelists
  - 13 delegates from APEC travel-eligible economies
Program of MRCT Workshop

- **DAY 1**
  - session 1: Study Design of Multi-Regional Clinical Trials
  - session 2: Operational Aspects of MRCT

- **DAY 2**: Korea-China-Japan Tripartite Symposium
  - session 3: Korea-China-Japan Cooperative Research on Ethnic Factors
  - session 4: Korea-China-Japan Regulation & Expectations on MRCT

- **DAY 3**
  - session 5: Case Study: Oncology
  - session 6: Panel Discussion

Discussions and Recommendations

1. Ethnic Factors
   - **Intrinsic** (e.g. biological)
   - **Extrinsic** (medical practice and environment)

   - Panel members summarized and recommended that
     - it is imperative to carefully consider both intrinsic (ethnic) factors and extrinsic (medical practice) factors in the MRCT study design.
     - for successful MRCT study, it is important to collect sufficient PK/PD data during initial clinical trials.
Discussions and Recommendations

2. Issues discussed

- **Regional differences in data**
  - Regional differences in medical practice and statistical methods should be taken into account to improve data quality.

- **Data quality**
  - Template needs to be developed for providing points to be checked in MRCT protocols to those involved in MRCTs.

- **Ethnic factors**
  - Monitoring of ethnic factors in MRCTs is necessary.

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Discussions and Recommendations

2. Issues discussed

- **Regulators’ action**
  - Regulatory authorities are recommended to introduce experiences of exemplary clinical centers to support other centers.

- **Technical issues**
  - Participants emphasized the importance of reference drugs, appropriate trial endpoints and proper clinical study design in MRCTs.

- **Future cooperation**
  - Cooperation should be continued to address new scientific territories which require further studies of ethnic factors to develop personalized drugs and targeted therapy.
Other Activities

AHC Advisory Board

Countries of members of the AHC Advisory Board
(As of Sept. 2010)

<table>
<thead>
<tr>
<th>Seung-Hee Kim</th>
<th>Director General, National Institute of Food and Drug Safety Evaluation, KFDA</th>
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<tbody>
<tr>
<td>Yves Julien</td>
<td>Senior Advisor; LEEM/ Chair of Regulatory Policy and Technical Steering Committee, IFPMA</td>
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<tr>
<td>Michael B. Gropp</td>
<td>Vice President, Global Regulatory Strategy, Medtronic Co.</td>
</tr>
<tr>
<td>Hiroshi Ishikawa</td>
<td>Assistant to President, Toshiba Medical Systems Co./ GHTF Steering Committee</td>
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<tr>
<td>Kian Ming Lam</td>
<td>Division Director, Strategic Planning, Operations &amp; Communications Division, HSA</td>
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<tr>
<td>Mark Paxton</td>
<td>Advisory Board, RHI Associate VP, PhRMA</td>
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<tr>
<td>Nancy S. Travis</td>
<td>Vice President, Global Strategy and Analysis, Advamed</td>
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<td>William Wang</td>
<td>Head of Asia Pacific Operations, Department of Biostatistics and Research Decision Sciences(BARDS), Merck &amp; Co, Inc</td>
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<td>Heng-Der Chern</td>
<td>Executive Director, Center for Drug Evaluation, Chinese Taipei</td>
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<td>Florence Houn</td>
<td>Vice President, Regulatory Policy and Strategy, Celgene Co.</td>
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<tr>
<td>Rae Yuan</td>
<td>A.P. Head of PhRMA Development, Roche PhRMA</td>
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<td>Stuart Walker</td>
<td>Founder of Center for Medical Research(CMR)</td>
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<td>Heng Siew Christine Ngin</td>
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<td>Marie Vodicka</td>
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<td>Kyoschi Tadano</td>
<td>Director, Division of Planning and Coordination, PMDA, Japan</td>
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<td>Patricia Pineda</td>
<td>COFEPRIS (Mexico)</td>
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<tr>
<td>Hans Vasquez Solopuco</td>
<td>DIGEMID (Peru)</td>
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Other Activities

AHC Website Renewal

Future Plans for AHC Workshop

- **Workshop for 2010**
  - Workshop on medical devices - clinical trials
    on November 15-16 in Seoul

- **Workshop for 2011 and beyond**
  - Workshop co-hosted by KFDA, IFPMA and DIA in April
    * IFPMA: International Federation of Pharmaceutical Manufacturers and Associations
  - Workshop on ICH QbD
  - Workshop on stem cell and biosimilars
  - Workshop on pharmacovigilance

- **Long-term Plan for AHC Workshop**
THANK YOU FOR YOUR ATTENTION!

SEND YOUR ADDITIONAL COMMENTS OR QUESTIONS TO AHC SECRETARIAT AT AHCKOREA@KHIDI.ORG.KR

PLEASE VISIT OUR WEBSITE AT WWW.APEC-AHC.ORG