APEC Harmonization Center - Updates -

June 8, 2010

Sun Hee Lee, Ph.D.
Director of Drug Evaluation Department
Korea Food & Drug Administration
I. AHC- A Brief Overview
II. Activities in 2009
III. Activities in 2010
IV. Next Steps
V. Conclusion
AHC – A Brief Overview

Establishment of the Best Harmonization Model in the Asia-Pacific Region through achieving goals:

- Supporting access to the best practices and guidelines
- Promoting collaborative actions and wide information exchanging activities among participants
- Promoting the conduct of clinical trials
- Enhancing the quality, safety, and efficacy of therapeutic products
I. Inauguration Ceremony of AHC (June 15, 2009)
II. 1st Workshop (June 15~18, 2009)
   - AHC Multi-Regional Clinical Trial (MRCT) Seoul Workshop
III. 2nd Workshop (September 17~18, 2009)
   - AHC Biosimilar Workshop
IV. 3rd Workshop (December 3, 2009)
   - AHC GMP Validation Workshop (Pharmaceuticals)
GMP Validation Workshop

- **Date:** December 3, 2009
- **Title:** GMP Pharmaceutical Validation Workshop
- **Participation:** 458 in attendance
  - 7 Speakers
  - **Participants** (Government, Industry and Academia)

- Held as a domestic workshop due to H1N1 influenza and time constraint
GMP Workshop – Program

- **Program**: 2 Sessions

- **Session 1**: Utilities Validation
  - Water Validation
  - Air Utilities Validation

- **Session 2**: Process Validation
  - Sterile Pharmaceutical Products Process Validation
  - Solid Dosage Process Validation
  - Process for Liquid and Other Dosage
AHC GMP validation workshop provided practical and informative training session to Korean stakeholders.

Workshop provided a forum to discuss the needs of Korean industry in preparing for cGMP validation:
- Sharing experience on utility and process validation from cGMP-approved companies.

Workshop provided an opportunity of discussion in order to enhance the Public-Private Partnership for the pharmaceutical industry development.
Overall Suggestions-2009

- **Follow-up workshops and training programs**
  - Follow-up workshops and in-depth training programs on three topics of 2009 AHC workshops
  - Provide a forum for sharing the different regulations among APEC economies in order to achieve harmonization

- **AHC Workshops in different economies within APEC regions**
  - Holding AHC workshops in different APEC economies considering the accessibility of attendees from different zones.

- **Allocation of more time to Break-out sessions**
  - Longer and in-depth discussion on practical issues
## Activities in 2010

### Education & Training: AHC Workshop plans in 2010

<table>
<thead>
<tr>
<th>Topic</th>
<th>Tentative Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals: Quality - Supply Chain &amp; Industry Awareness on LSIF RHSC/AHC</td>
<td>May 12~14</td>
</tr>
<tr>
<td>Clinical Development in East Asia &amp; MRCT</td>
<td>September</td>
</tr>
<tr>
<td>Medical Devices - Clinical Trials</td>
<td>November</td>
</tr>
</tbody>
</table>
Activities in 2010- Supply Chain

- **Date:** May 12~14, 2010
- **Title:** Globalization in the Pharmaceutical Supply Chain
- **Participation:** 287 in attendance
  - 9 Speakers
    (Asia, North America, Europe)
  - AHC Supported Trainees from Indonesia, Malaysia, Peru, Thailand, Vietnam
Session 1: Challenges in the Globalization of Drug Development, Approvals, and Distribution and the Need for Greater Harmonization

- Counterfeits and other Adulterated Drugs in the Global Supply Chain and Regulatory Responses
- Overview of Distribution Channels of Approved Products in the US
- EFPIA Pilot Project on Authentication
- INTERFARMA Pilot Project on Serialization
- Supply Chain Management in the US and Impending Changes: Serialization and California Requirements
- Panel Discussion
Supply Chain Workshop - Programs

Session 2 : Special Topics in Distribution Channels and Related Regulatory Concerns

- Controlled Substances: A Special Supply Chain Requirement
- Regulatory Expectations for Manufacturers in Assuring Quality of Components
- DMF Regulation and Management in Korea
- Handling of Trial Materials for use in Multi-Regional Clinical Trials
- Enhancing APEC's role in Advancing Regulatory Science
- Panel Discussion

GMP ware visit (Day 3)

- Pharmaceutical Ware: Hanmi Fine Chemicals. Co., Ltd.
Next Steps

Survey & Research

- Conduct survey in order to assess the training needs and current situation of the APEC economies.

E-Publication & Website

- Post training materials on the AHC website
- Develop new website for Repository of Information, Database, and Training Activities; provide Members Only Page to RHSC

International Cooperation

- Strengthen cooperation with governments, industry and academia (both APEC and non-APEC)
- Confirm members of the Advisory Board experts from international harmonization organizations including ICH, GHTF, WHO, and others
Concluding Remarks

- **AHC Welcomes** other interested governments, institutions, corporations and foundations **to cooperatively work with AHC** in the future events

- **AHC Welcomes suggestions on AHC activities**

- **AHC will work with LSIF RHSC** in various harmonization activities mapping out existing harmonization models and capacity building
Thank You