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Towards the AHC Establishment

2005
APEC LSIF III
“Capacity building for the harmonization of standards and regulatory practices for bio-medical products and services…”

August 2008
APEC LSIF VI (Lima, Peru)
Proposal for the APEC Harmonization Center

November 2008
20th APEC Ministerial Meeting (Lima, Peru)
Endorsement of AHC by APEC Ministers

“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.”
Organization

APEC LSIF

AHC Director (KFDA)

AHC Secretariat (KHIDI)

Advisory Board

Division of Survey & Research
Division of Education & Training
Division of International Cooperation
Division of E-Publication
Goals

- **Supporting** access to the best practices and guidelines for regulatory harmonization
- **Promoting** collaborative actions and wide information exchanging activities among participants
- **Promoting** the conduct of clinical trials that meet international standards
- **Enhancing** the quality, safety, and efficacy of therapeutic products
Scope of Activities

- Conduct Surveys & Research
- Provide Education
- Establish Strong Networks
- e-Publication & Website
- Develop and Disseminate Harmonization Models
- Support International Cooperation
2009 Multi-Regional Clinical Trials Workshop

Title: MULTI-REGIONAL CLINICAL TRIALS SEOUL WORKSHOP- Inaugural Workshop of the APEC Harmonization Center

Date: 15 (Mon) - 18 (Thu) June 2009

Venue: Grand Hilton Seoul Hotel, Seoul, Korea

Main Topic
- The Values and Challenges of Multi-Regional Clinical Trials
- Intra-Regional Efforts to Streamline the Conduct of Clinical Trials
- ICH Overview
- Multi-Regional Clinical Trial Design Issues
- Operational Aspects
- Regulatory Guidance / Perspectives / Issues
- Breakout Sessions
GMP Pharmaceutical Ware Visit

- Day 4: June 18th
- Location: Yuhan Corporation(Ochang Plant)
- cGMP System
Future AHC Activities

Current Program Developments:

- 2nd AHC Workshop: September 16-18, 2009 (BIO KOREA)
- 3rd AHC Workshop: November, 2009

Next Workshop Agenda
Grand Hilton Seoul Hotel

201-1 Hongeun-dong, Seodaemun-Ku, Seoul, South Korea
Thank You!

For more information please visit our website at: www.apec-ahc.org