

APEC Harmonization Center

June 9, 2009

Dong Deuk Jang, Ph. D.
Yokohama, Japan



Contents

I. Background

II. Scope of Activities and Goals

III. 2009 Multi-Regional Clinical Trials

Seoul Workshop

IV. Future

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

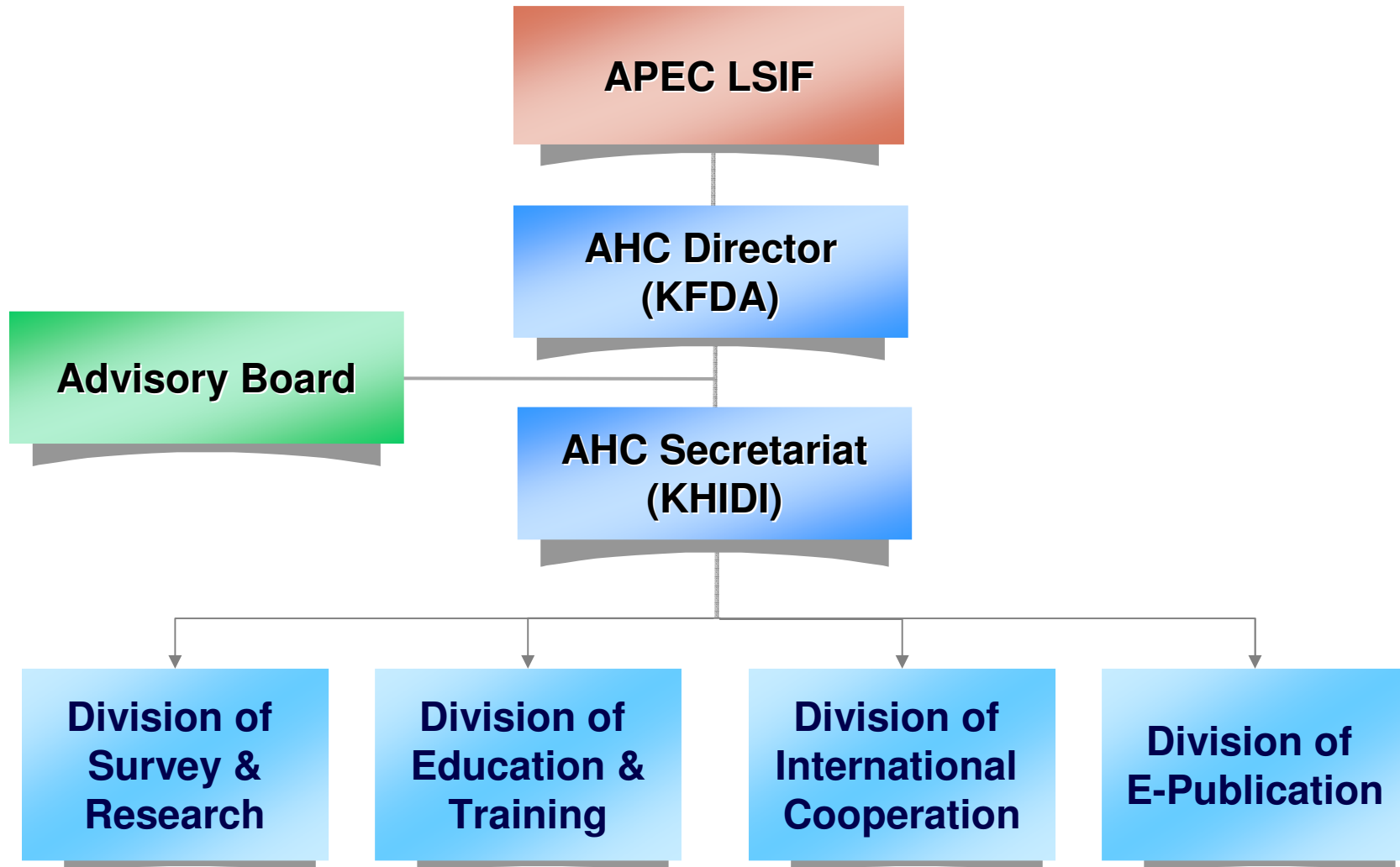
**November
2008**

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



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**

APEC Harmonization Center - website

The screenshot shows the website for the Multi-Regional Clinical Trials Seoul Workshop. At the top, there are logos for APEC (Asia-Pacific Economic Cooperation) and AHC (APEC Harmonization Center). The main header features the event title and dates: "Multi-Regional Clinical Trials Seoul Workshop, Inaugural workshop of the APEC Harmonization Center, June 15(Mon) ~ 18(Thu), 2009, Grand Hilton Hotel, Seoul, Korea". A navigation bar includes links for "About AHC", "1st Workshop", "Registration and Accommodation", "Archive", and "News and Bulletin".

On the left side, there are sections for "Upcoming Events" and "FAQ". The "Upcoming Events" section lists:

- Asian Medical Devices Regulatory Harmonization Delegation Visit to Australia (20 - 25 Sep)
- APEC Life Sciences Innovation Forum VII (03 - 04 Aug)
- Multi-Regional Clinical Trials Seoul Workshop (15 - 18 Jun)

 The "FAQ" section includes:

- Introduction to APEC:
- Who participates in APEC events?
- How does APEC differ from the World Trade ...

The central "Overview" section provides key details:

- 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
- Hosted by:** Korea Food and Drug Administration (KFDA)
- Organized by:** Korea Health Industry Development Institute (KHIDI)
- Supported by:** APEC LSIF
- Secretariat:** APEC Harmonization Center Secretariat

On the right side, there is an "On-line REGISTRATION" section with a "Registration" button and a note: "Participants are advised to register no later than June 5, 2009." Below this are logos for APEC, ICH, GHTF, World Health Organization, KFDA, and KHIDI. At the bottom right, there are utility links for "Weather", "Time", and "Exchange Rate".

At the bottom of the page, the AHC Secretariat contact information is provided:

APEC Harmonization Center Secretariat
 Tel: +82-2-2194-7323 / Fax: +82-2-822-8811 / Email: ahckorea@khidi.or.kr
 57-1 Noryangjin-Dong, Dongjak-Gu, Seoul, South Korea, 156-800
 COPYRIGHT 2009 APEC HARMONIZATION CENTER ALL RIGHTS RESERVED

www.apec-ahc.org

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

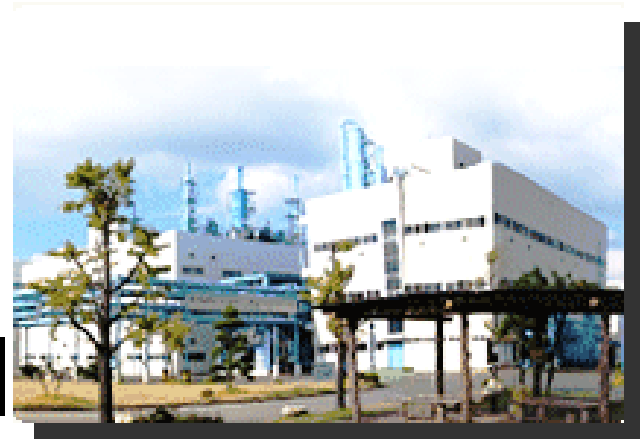
Main Topic

- 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

2009 Multi-Regional Clinical Trials Workshop

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

2009 Multi-Regional Clinical Trials Workshop



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*