Harmonization for a Healthier World
- Establishing an APEC Harmonization Center in Seoul

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APEC support harmonization efforts of International Harmonization Organizations such as ICH & GHTF

Essential Action toward Harmonization requires more practical experience and information sharing between industry-regulator and between regulators needs to provide more information and education to regulators and industry experts in more systematic way with best practices and advanced guidelines

Therefore, at APEC LSIF VI, Korea proposed to member economies of APEC to establish an **APEC Harmonization Center (AHC)**
Definition of AHC

International in status, non-profit in management Center organized and operated to enhance the harmonization level of therapeutic products to the advanced standards and regulatory practices under the aegis of APEC LSIF.

Develop and disseminate Harmonization Models across the Asia-Pacific Region.

Establish cooperative networks for Harmonization by linking regulators, industry experts, institutions, investors and policy makers.
What AHC will do

Survey & Research
Conduct research and survey to define challenges and opportunities of harmonization / identify education demands

Providing Education
Provide education programs to regulators, policymakers and industry from interested APEC economies

e-Publication & Website
Develop and disseminate journals and reports of AHC

International Cooperation
Develop cooperative networks with other international organizations, countries and fora
Structure & Function

- Advisory Board
- APEC LSIF
- AHC Director
- Secretariat Office
- Division of Survey & Research
- Division of Education & Training
- Division of International Cooperation
- Division of e-Publication
Advisory Board

- Int’l Organ.
- AHC
- Member Economies
- KFDA KHIDI
- Developed Regulators
- Experts from APEC member economies
- Experts from developed regulatory countries
- Experts from:
  - ICH
  - GHTF
  - APEC LSIF
  - WHO
  - PIC/S
The government of Republic of Korea has committed to serving as “Foundation Sponsor” of AHC in 2009.

KFDA and KHIDI also affirm their commitment to making significant, continued contribution annually to support AHC.

AHC will ask to APEC funds for travel eligible economies to attend the inaugural workshop of AHC on coming June.

AHC welcomes and will recognize other interested governments, institutions, corporations and foundations who provide financial support for its program as sponsors.
Announced establishment plan of AHC (Aug. 08, APEC LSIF)

Organizing an early stage Advisory Board (Nov. 08)

H.E. Myung-bak Lee, the President of Republic of Korea, will announce Korea’s willingness to support AHC (Nov. 08, APEC Leaders Meeting)

Inauguration Ceremony and Symposium (June, 2009)

Consecutively after ICH Yokohama Meeting June 6-11
Venue will be wonderful place in Seoul
AHC will provide a platform to address and solve priority concerns of APEC member economies on regulatory harmonization by supporting access to the best practices and guidelines, resulting improvement of quality, safety and efficacy of therapeutic products.

Promotes the collaborative actions and wide information exchanging activities among participants.

Facilitates international trade of therapeutic products.

Contribute to enhance health status of APEC economies.
Thank you for your attention