



Asia-Pacific
Economic Cooperation

Report to ICH: GCG Activities in the Life Sciences Innovation Forum

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Background

- Life Sciences Innovation Forum in APEC
 - A tripartite mechanism
 - Working to address key health challenges in the APEC (21 economies) region
 - Striving for a more holistic approach to life sciences development

Timeline

- October 2002: Ministers & Leaders launched LSIF in Los Cabos, Mexico
- August 2003: Inauguration of the First Life Sciences Innovation Forum, Thailand
- November 2004: Ministers & Leaders approve Strategic Plan in Santiago, Chile
- Annual LSIF meeting

Regulatory authorities, industry, academia effort to:

- Engage key players in identifying strategies, roles, mechanisms and projects of greatest value to the region
- Promote synergies and coordination of effort
- Optimize benefit derived from interactions with international harmonization initiatives
- Develop mechanisms to sustain training and capacity-building work
- Better prioritize annual and longer term plans and projects

LSIF VI August 14-15 2008, Lima, Peru Report

- *Study on the Benefits of Investment in Health Innovations*
- *Enablers of Investment Checklist*
- *Research and Innovation Contribution*
- *Regulatory Harmonization*

LSIF VI – August 14-15 2008, Lima, Peru Report

- Regulatory Harmonization
- Breakout session over two days
- KOREA APEC Harmonization Center (AHC) proposal.
- Korean Food and Drug Administration (KFDA) and the Korea Health Industry Development Institute (KHIDI)

LSIF VI – August 14-15 2008, Lima, Peru Report.

- Additional harmonization actions be taken:
 - member economies work towards the adoption of harmonized application and review formats, promoting a common regulatory language that supports the sharing of information, good review practices and the leveraging of regulatory resources.
 - a feasibility study be conducted on the confidential exchange and use of regulatory information.
- APEC support the establishment, as proposed by LSIF, of a regulatory steering committee within the LSIF structure

LSIF for harmonization and enhanced regulatory performance include:

- The ability to apply for project funds and seek endorsement from senior officials, ministers and leaders on recommended actions
- The complementary roles played by government, industry and academia
- Linkages to international harmonization initiatives and between the various harmonization efforts within the APEC region
- The APEC principle of voluntary engagement, which ensures the participation of those economies interested and committed to cooperative activities.

APEC Harmonization Center Korea

- Launch 15-18 June in Seoul
- June 17-18 with the ***LSIF Regulatory Harmonization Steering Committee*** (LSIF RHSC) meeting.
- Workshop : Advancing the Regional Economic Integration Agenda through Regulatory Harmonization: Series I: Multi-Regional Clinical Trials (MRCT)

Proposals and papers

- Stakeholder Perceptions on Vaccines as an Investment in Health Innovation
- The APEC Harmonization Center Guidelines

Proposals and papers

- Stem Cell Quality Assurance and Quality Control (QA/QC)
- Enablers of Investment Checklist
- The Impact of Environmental Change on Disease Patterns
- Returns to Investment in Health Innovation
- Health Information Technology (Health IT)

Seminars and reports

- seminars held in Mexico City February 17-19, 2009: Anti-counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: Building International Cooperation to Protect Patients

LSIF VII : August 3-4, 2009

Singapore

- R& D financing in an economic downturn
- Health Information Technology
- The Value of Innovation
- The Impact of Environmental Change on Disease Patterns
- Driving the Regulatory Process

Thank you for your attentions

