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
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• 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)
• 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.
• 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