



APEC-LSIF

APEC LSIF Update

by

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The ICH-Global Cooperation Group Meeting

Westin Hotel Michigan Avenue, Chicago, USA

8 November 2005



APEC-LSIF

Outcome

from
The APEC LSIF III Meeting
Sep.05, South Korea

APEC LSIF- GCG Chicago Nov. 05

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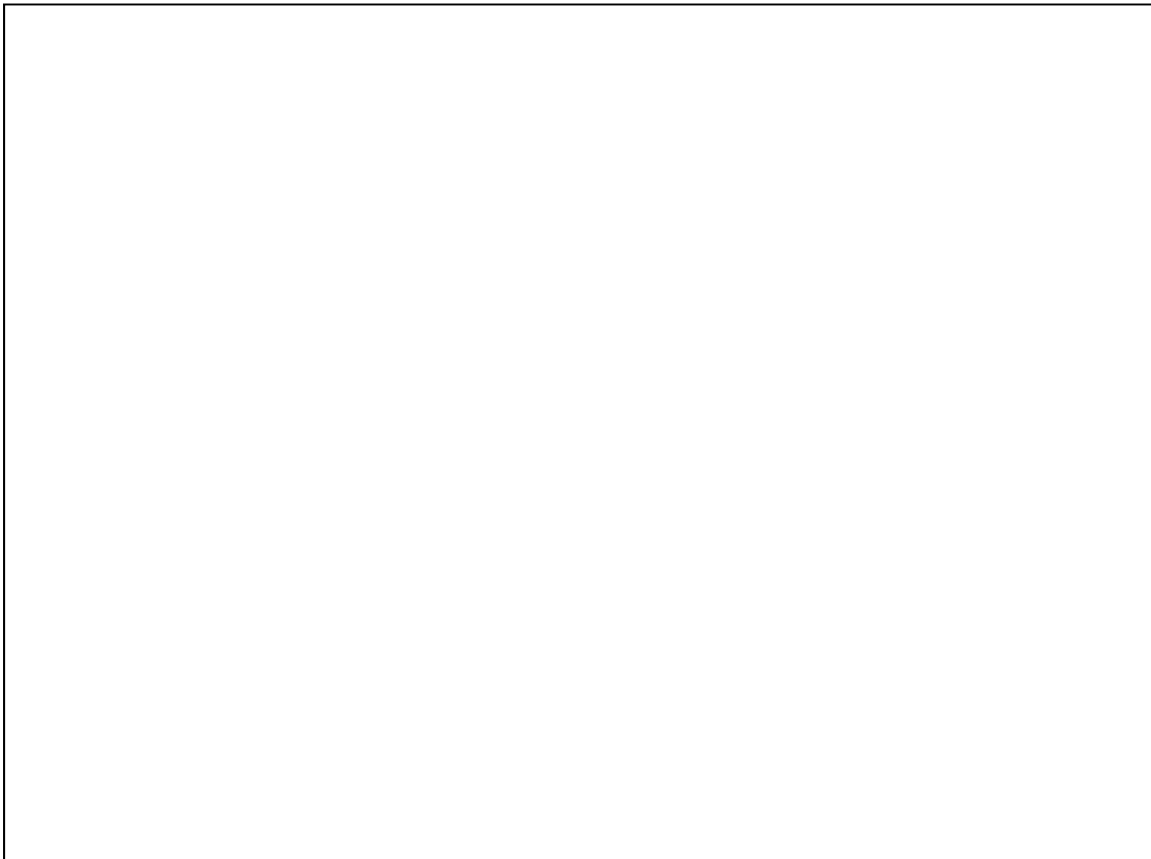
The Meeting

- **Date :-** September 8-9, 2005
- **Place :-** Gyeongju, Korea
- **Participants :-** ~ 280 from 15 economies
- **Host :-** Korean Ministry of Health and Welfare
- **Organizer :-** Korea Health Industry Development Institute(KHIDI)



APEC Key Challenges

- **Growing Risk of infectious disease pandemic**
- **the Rise in chronic diseases**
- **the Aging demographic trends**





Meeting's Objective

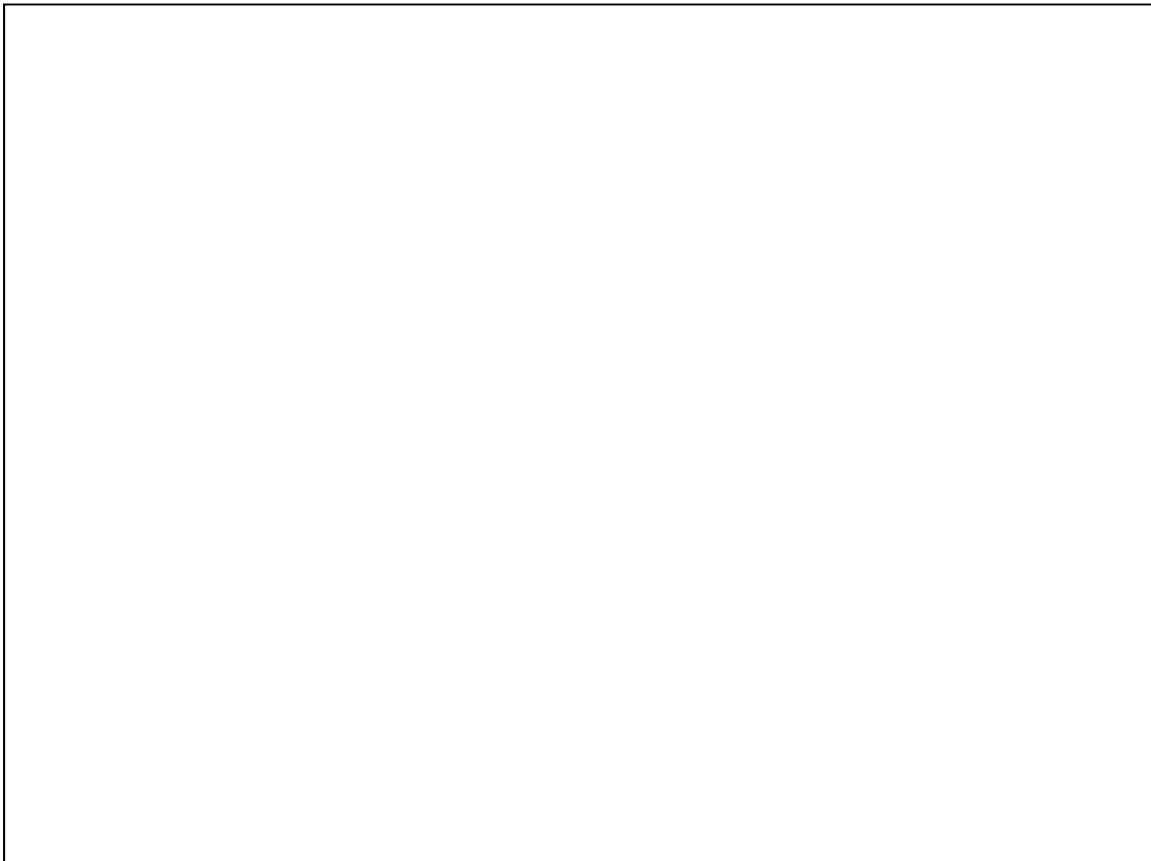
**“To identify and recommend
Priority Implementation projects
to give effect to the
endorsed APEC Strategic Plan for LSI”**





The Implementation Projects

- **developing an Environment**
that fosters innovation
- **providing Necessary Infrastructure**
for effective response and management of challenges
- **building Capacity /Resources**
to increase and attract investment in the sector in critical areas





Priority Areas of LSI

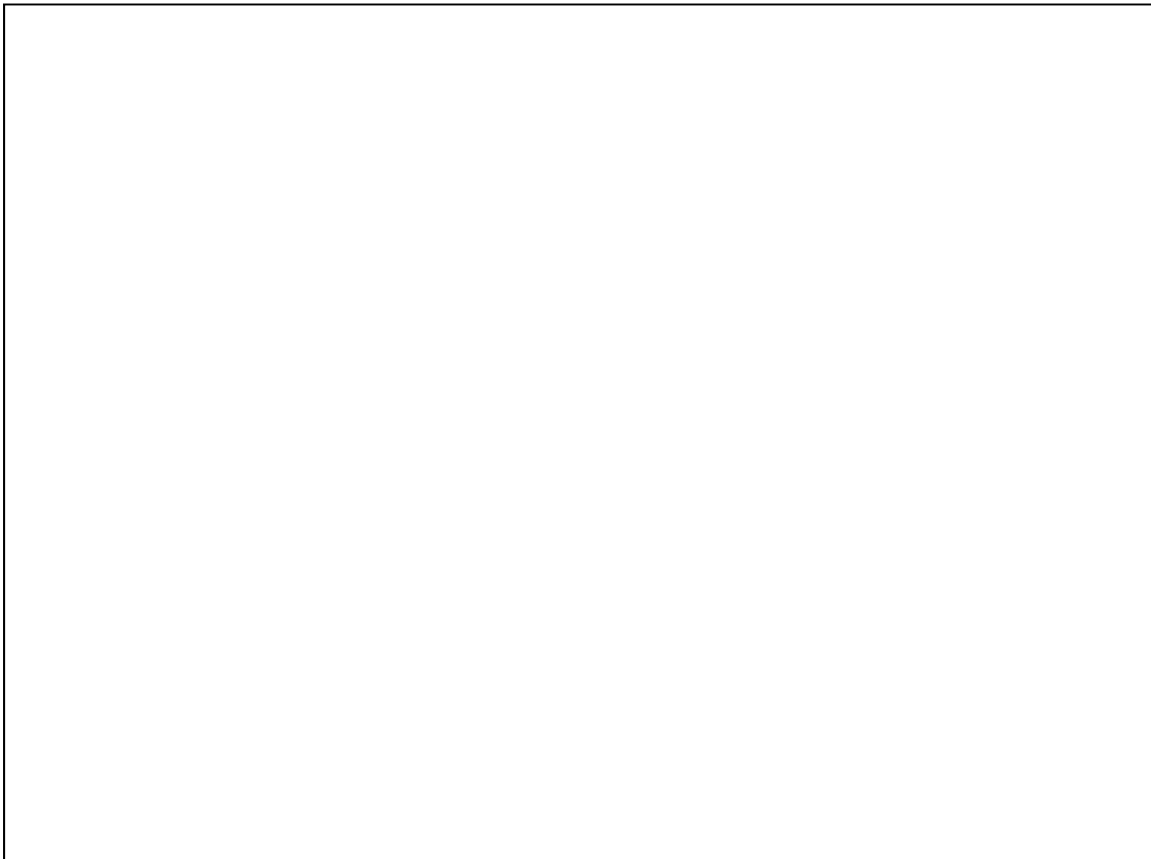
- **Research**
- **Regulatory harmonization**
- **Access to capital**
- **Health Services**





The Final Recommendations

- (1) the Extension in the region of a large-scale biomarker research collaboration and population study for the early Detection, Prevention, and Treatment of disease to *include a broad spectrum of diseases* of economic and health concern in the region





The Final Recommendations

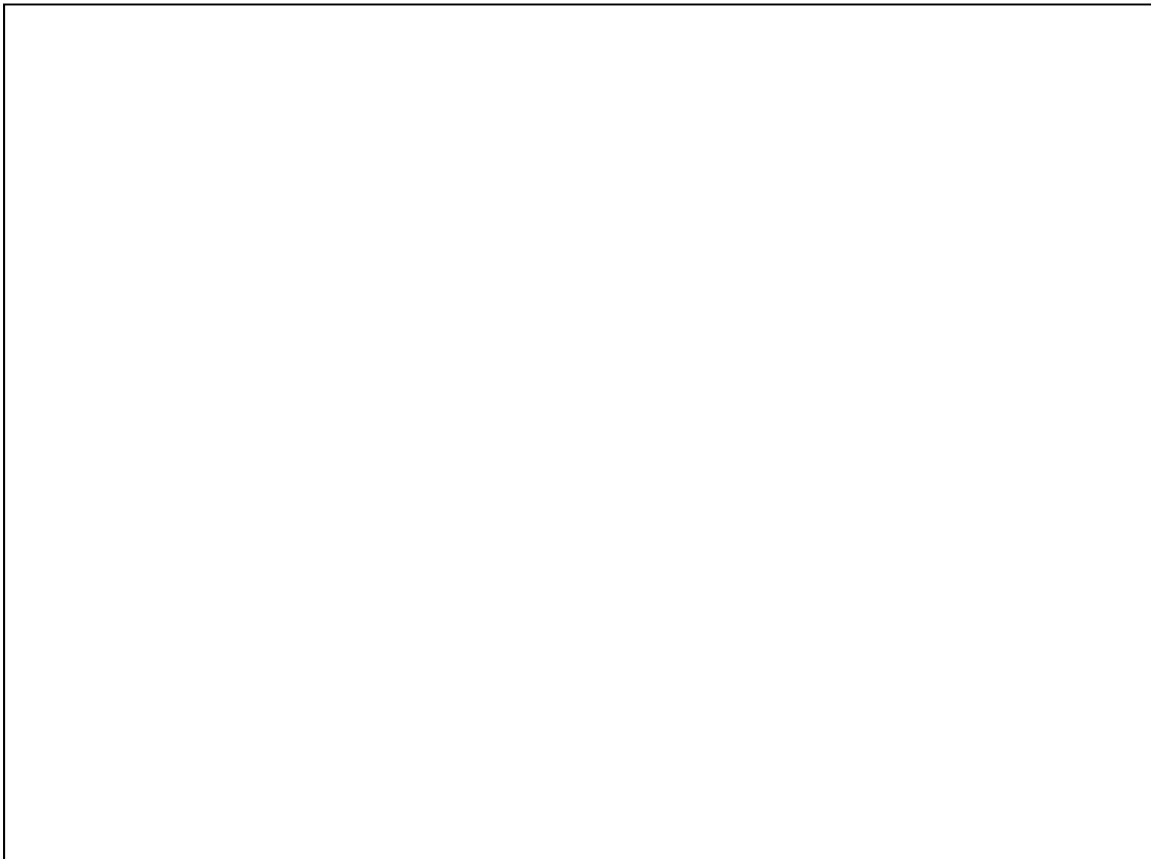
- (2) *Capacity building for the Harmonization of Standards and Regulatory Practices* for bio-medical products and services according to international best practices where the need is most pressing and obstacles are the greatest.**





The Final Recommendations

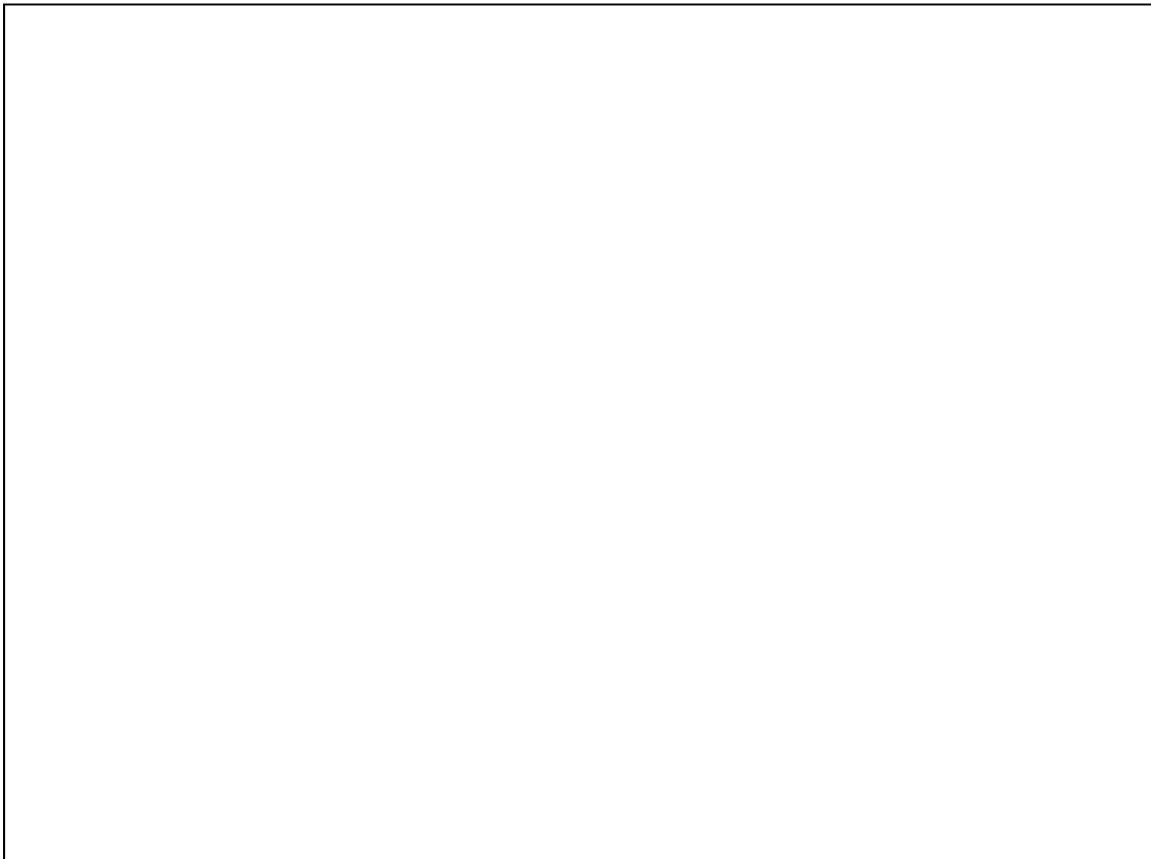
- (3) *Venture capital* to promote the development of LSI supporting industries in emerging economies. Example include Research infrastructure; CRO;, and Contract manufacturing organizations.





The Final Recommendations

- (4) The development of an *Early Health Index* to identify population needs and appropriate health service interventions, and a data collection exercise to better understand the current level of investment, distribution, and allocation of Resources in health systems**





Harmonization Initiative

- **The needs :-** *to ensure the addressing in Emerging Health and Economic Challenges*
- **Area of Harmonization :-**
 - *“Standard”, and “Regulatory Requirements & Practices”*
 - *“Product” and “Service”*
 - *“Pharmaceuticals”, “Medical Devices”, “Diagnostic”*



Recommendation on Harmonization (1)

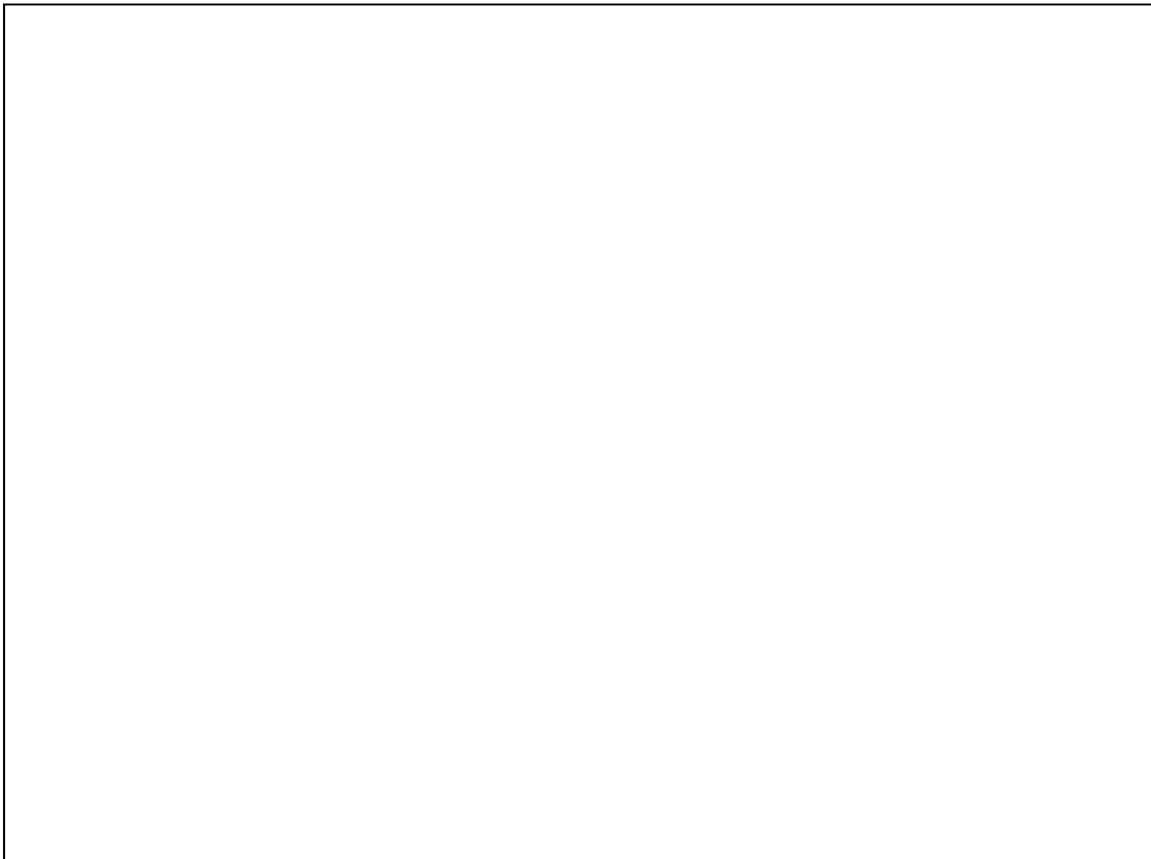
- **Identify all relevant Harmonization Initiatives**
in the region and forward to the APEC(or LSIF) Secretariat
- **Develop and Implement Harmonization Projects**
- **Implement existing Harmonization Guidelines**
with a focus on 1 or 2 areas for Training & Building
Infrastructure for GCP and/or GMP





Recommendation on Harmonization (2)

- **Develop Training's Guidelines and a Funding Strategy**
- **Promoting region-wide APEC regulatory harmonization activities** (pharmaceuticals, medical device, diagnostic)





Recommendation on Harmonization (3)

- **Form a Steering Committee to oversee 2 work groups**
 - Groups
 - Biomedical product
 - Medical device
 - Main activities
 - Roadmap Initiative
 - Harmonization project



