

The APEC LSIF: Promoting a more effect approach to harmonization and cooperation

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Asia-Pacific
Economic Cooperation

APEC region: a 'hot bed' of regulatory harmonization

- APEC region spans a number of important regional harmonization initiatives, including ASEAN, AHWP, PANDRH
- 4/5 of GHTF and 2/3 of ICH parties founding members from APEC economies
- Efforts of individual APEC economies

Reflects importance placed on harmonization ...

...in promoting:

- a science based approach
- regulatory cooperation: common regulatory language
- more effective use of resources
- access to medical products and public health
- innovation and trade

Question

With all these harmonization efforts currently underway, what further role could APEC play in regional harmonization?

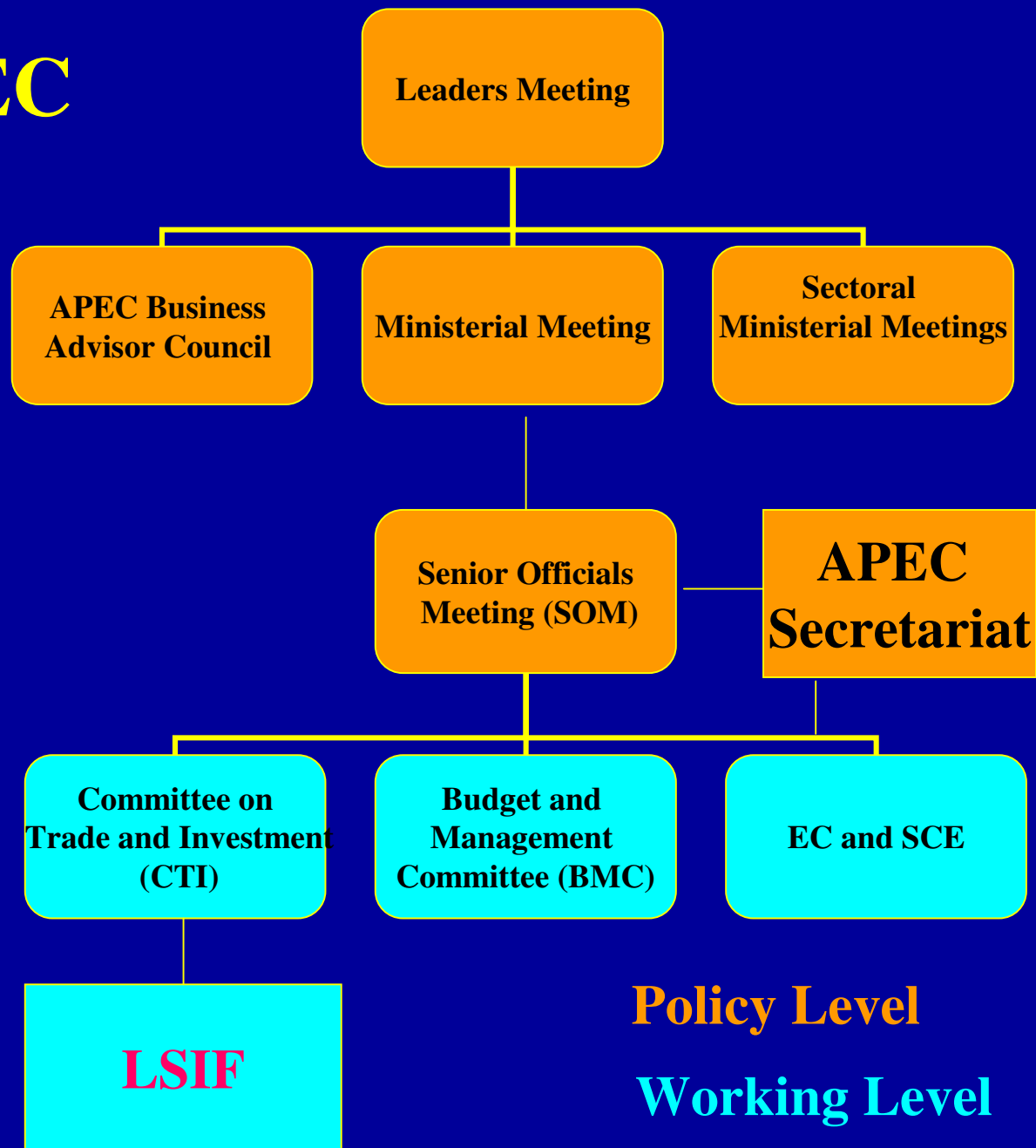
Overview of APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- Currently comprised of 21 member economies
- Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic and technical cooperation
- APEC agenda and annual work plan developed around SOMs culminating in Leaders declaration
- APEC Chair rotates annually – host economy (Singapore 2009, Japan 2010, US 2011, Russia 2012)

Member Economies

Australia, Brunei Darussalam, Canada,
Chile, China, Hong-Kong-China, Indonesia,
Japan, Republic of Korea, Malaysia,
Mexico, New Zealand, Papua New Guinea,
Peru, Philippines, Russia, Singapore,
Chinese Taipei, Thailand, United States,
Vietnam

APEC



Policy Level

Working Level

APEC Life Sciences Innovation Forum

- October 2002, Mexico: APEC leaders endorsed proposal to establish life sciences innovation forum
- Reflected belief that innovation in life sciences important in promoting public and economic health
- Annual forum serves to promote policy environment conducive to life sciences innovation
- From outset, harmonization seen as prerequisite to promoting innovation in life sciences...

Strategic Plan

- Leaders also endorsed development of strategic plan to address health challenges and economic development goals
- To include identifying factors critical to success in each segment of life sciences value chain
- Strategic plan endorsed in November 2004
- Current focus: implementation – in particular implementation projects in priority areas, including harmonization

LSIF well-positioned to serve as *enabler* of harmonization

Unique RHI in that doesn't *produce* harmonized guidances; rather, promotes use of *existing* international guidances:

- Ability to access APEC funds to advance projects
- Senior reporting level within APEC
- Linkages to international harmonization initiatives: since 2004 sits on the ICH Global Cooperation Group
- Tripartite structure: government, industry, academia
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation

APEC Principles on Harmonization

- Where international standards exist, these standards will form the basis for harmonization
- Where appropriate organizations exist for developing international standards, APEC economies will focus their coordinated efforts on promoting the development of international standards through these bodies
- Participation in harmonization activities is open to all APEC economies on a voluntary basis
- Decisions consensus-based

A word on harmonization

Simple in concept...

“the establishment, recognition and application of common standards and regulatory measures” (WTO)

...more difficult in execution.

Implementation Considerations

- Collateral guidance/policy work
- Regulatory implications
- Readiness of stakeholders
- Training
- Skill sets – right people/skills?
- System/infrastructure requirements
- Internal organizational/mandate issues
- Translation: equivalent terms/concepts?
- Resources

Training: a Key Focus of LSIF

- In recent years, the LSIF has contributed to regulatory harmonization and capacity building through the co-sponsorship and funding of workshops on clinical trial evaluation and GCP inspection, GHTF guidances and ICH quality guidances
- Workshops on CTA assessment and inspection have moved training beyond understanding of international guidances to their application from a regulatory perspective

However...

Despite progress made, recognition that LSIF has not been used to its full potential in promoting a more strategic and effective approach within the APEC region as a driver of regulatory harmonization and cooperation

Challenges

- Insufficient engagement of regulatory authorities in LSIF process
- Clear articulation of how LSIF can take best advantage of strengths to achieve stated objectives in a more strategic and coordinated fashion
- Effective engagement with international harmonization initiatives due in part to diversity of APEC region and lack of well-established network of subject matter experts (on pharmaceuticals side)

LSIF VI, August 08, Lima Peru: a turning point

Frank discussions on how to:

- Engage regulators and industry in identifying activities of greatest value to the region
- Promote greater synergies and coordination of effort: leveraging capacity by “connecting the dots”
- Optimize benefit derived from interactions with international harmonization bodies
- Develop mechanisms to sustain training and capacity-building work
- Better prioritize annual and longer term plans and projects

Outcomes

Series of recommendations, including two of strategic importance:

- Support for the establishment of the APEC Harmonization Center (AHC)
- Creation of a Regulatory Harmonization Steering Committee (RHSC)

Seoul, June 15-18, 2009: laying the foundation

- Inauguration of the AHC
- Workshop on MRCT which generated number of important recommendations
- Formation and first meeting of RHSC
- Events attracted over 600 participants, including officials, experts and interested parties from 17 economies

APEC Harmonization Center (AHC)

- APEC-wide resource to enhance and sustain harmonized and capacity building efforts by:
 - conducting research and surveys
 - providing educational programs
 - publishing and web posting
 - establishing networks and exchanges among participants and other international institutions
- Operate under aegis of LSIF, with direction from RHSC and an international advisory board

What AHC will do

Surveys & Research

Conduct research on harmonization policies and practices and identify best practices

Conduct surveys to define challenges and obstacles to harmonization and identify education needs

Providing Education

Provide symposiums, workshops, seminars and fellowship programs to regulators, policymakers and industry from interested APEC economies

Establish strong networks and exchange information among the participants

What AHC will do

e-Publication & Website

Develop and disseminate International Journal, AHC Newsletter, Seminar Compendium of the events and training programs

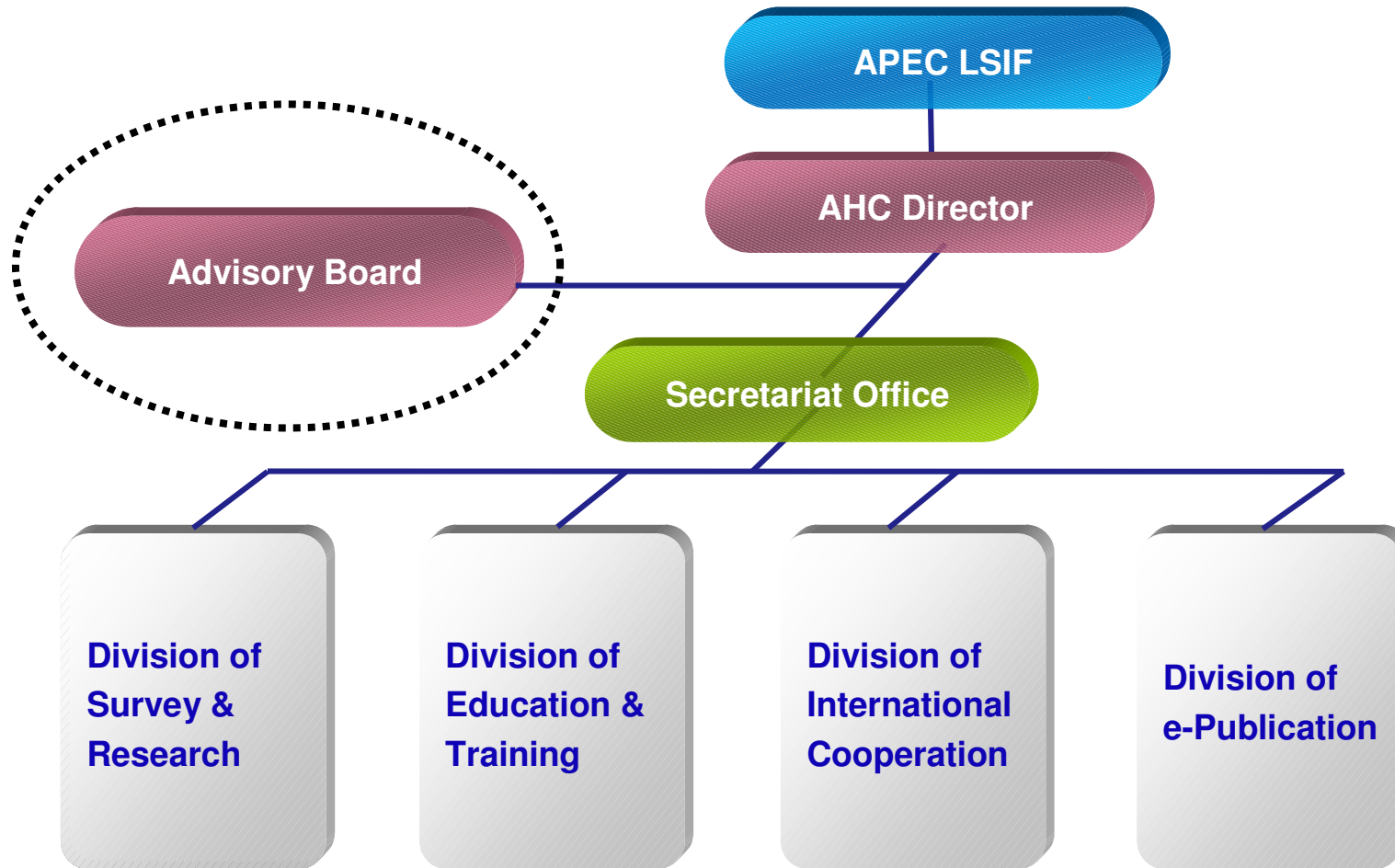
Run alumni board to support continuance in networking

International Cooperation

Organize Advisory Board of experts from international harmonization organizations, regulatory authorities

Develop cooperative networks with other international centres and institutions

Structure & Function



LSIF VII August 09, Singapore: solidifying work begun in Seoul

Accomplishments:

- Confirmed RHSC membership
- Finalized RHSC terms of reference
- Gained better understanding of APEC project approval process
- Reviewed series of project proposals
- Developed recommendations for endorsement by LSIF

Accomplishments (2)

Most importantly, recognized the need to move from individual effort to more collective, coordinated and effective action

RHSC sought endorsement of LSIF on:

- Terms of Reference for the RHSC
- Development of a multi-year strategic plan
- In principle, a number of project proposals:
 - multi-year proposal on best regulatory practices and exchange of review reports
 - development and submission in 2010 of an industry proposal on MRCTs

Outstanding Actions

- Conduct needs assessment as a means for identifying priorities related to harmonization and capacity-building activities
- Conduct a mapping exercise of existing and planned initiatives and key players in the area of harmonization and capacity building as a pre-requisite to adopting a more effective, coordinated approach

Outstanding Actions (2)

- Establish a permanent secretariat to support the RHSC
- Develop procedures document that will operationalize the work of the RHSC, to include:
 - Project assessment process and APEC funding approval guide
 - Formation of subcommittees and ad hoc working groups
 - Operations of a permanent secretariat
 - Etc.

RHSC Mandate and Goals

To promote a more *strategic, effective* and *sustainable* approach to harmonization by:

- *Proactively* identifying and prioritizing projects seen to be of greatest value
- Providing direction to the AHC on projects and activities that best meets these needs
- In partnership with AHC, **establish or strengthen linkages with harmonization initiatives**, training organizations and other key players in efforts to promote *complementary* actions and most effective use of resources

RHSC Mandate and Goals (2)

- Activities to be undertaken in accordance with a strategic plan to be developed by the SC
- Products within remit of SC: *medical products* (notably drugs and devices, but also other products determined to be within remit of RHSC)

RHSC Membership

- SC chaired by a regulatory authority from an APEC member economy and comprise up to 12 members representing a cross-section of LSIF expertise, including:
 - up to 7 from regulatory authorities (including the Chair)
 - Director of the AHC
 - 4 from industry
- Chair of the LSIF Planning Group serves as special advisor

Broader Participation and Input

- Observers and designated experts may participate in meetings at discretion of the Chair
- Annual Life Science Innovation Forum also provides opportunity for wider participation
- SC will consult with regional and international harmonization initiatives, Member Economies and additional representatives from industry, academia and governments, as appropriate
- SC may establish sub-committees to undertake certain activities, chaired by a member of the SC

RHSC Members

Regulators

Canada: Mike Ward (chair)

China: Ding Jianhua

(Zhang Wei)

Chinese Taipei: Li-Ling Liu

(Herng-Der Chern)

Rep of Korea: Tae Moo Yoo

(Kui Lea Park)

Peru: Victor Dongo

(Elizabeth Carmelino)

Thailand: Yuppadee Javroongrit

(Akanid Wapeewuttikorn)

USA: Michelle Limoli

(Joan Wilmarth Blair)

Industry

Hiroshi Ishikawa (Toshiba Medical)

GHTF SC

Lindsay Tao (J & J)

AHWP Secretariat

Peter Honig (Merck)

ICH SC

Wen Chang (Novartis)

PhRMA

Academia

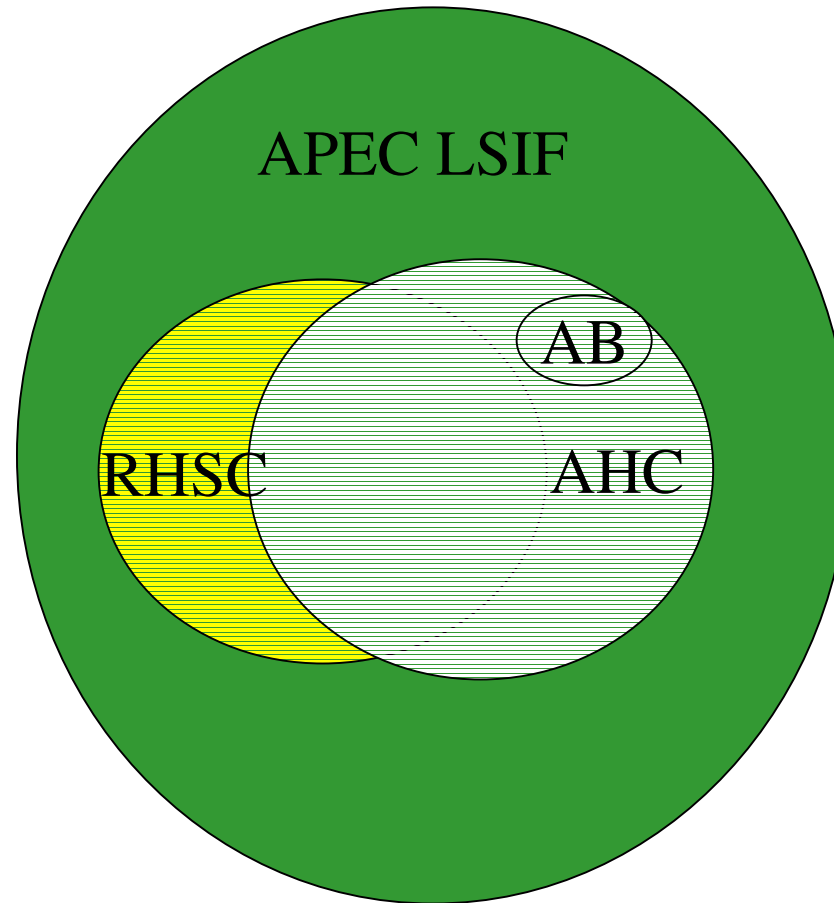
Seung-Hee Kim AHC Director

(Moo Young Yoo)

Relationship Between RHSC and AHC Advisory Board

- RHSC provides strategic direction to AHC based on established regulatory priorities
- AHC Advisory Board provides technical and scientific advice to the AHC Director on the organization of specific curriculum and projects

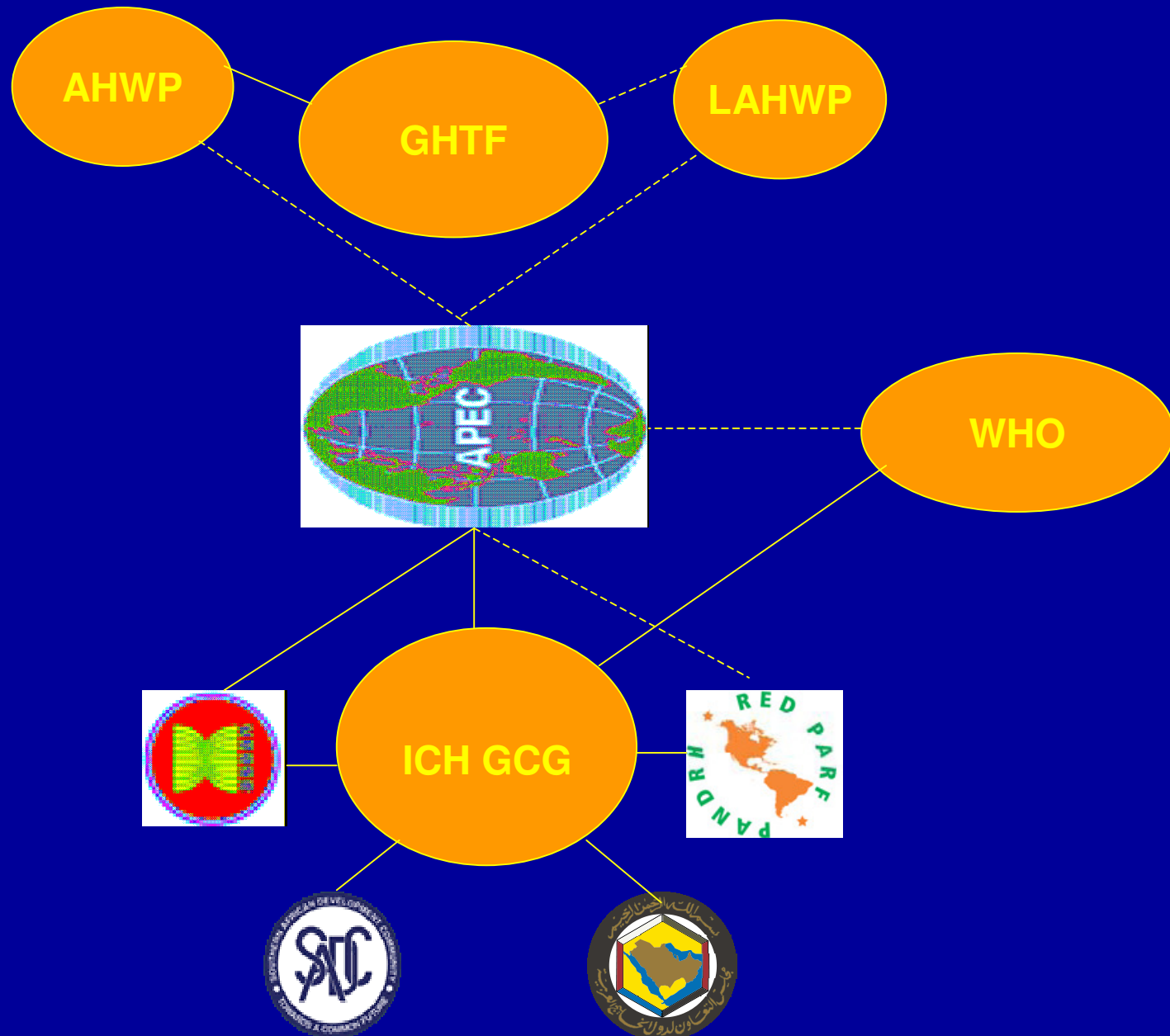
OPERATIONAL MODEL



Food for Thought

- Strategic approach to training activities
 - Coordination, planning within region: making best use of resources (regional/international)
 - Clearinghouse of relevant activities
 - Sustainability: centers of excellence/partners, e.g., AHC
- Mechanisms to promote more effective interactions with international harmonization initiatives
- Exchange and use of regulatory information
 - Reports, standards and processes
- Research Projects (AHC)
- Other?

A World of Possibilities



Building a Better Harmonization Model

**Development
(Stds, Guidances)**

Interface

Key Enabler:

APEC Harmonization Center + RHSC



+ DRAs: Australia, Brazil, China, Chinese Taipei, India, Korea, Russia, Singapore

Conclusion

- Exciting new developments within APEC that have implications beyond the region in advancing regulatory harmonization in a more strategic, sustainable and effective manner
- Directed towards concrete, complementary actions
- Key role as an enabler: building a better global harmonization model
- Great opportunities for AHWP and LSIF to cooperate to achieve common harmonization goals