

APEC's role in advancing regulatory convergence

**2012 APEC Advanced Good Review Practices
Workshop**

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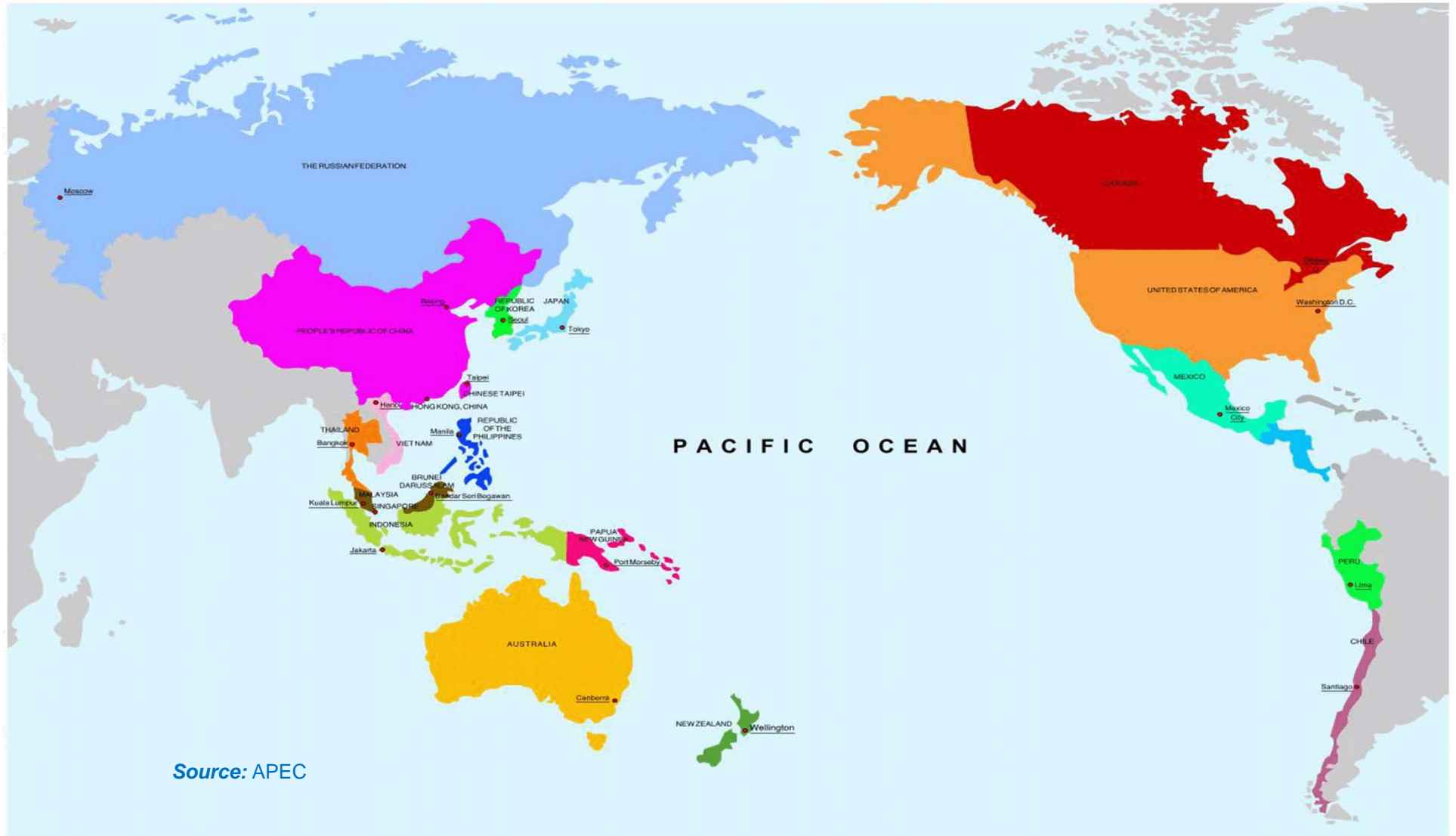


Asia-Pacific
Economic Cooperation

APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- 21 member economies account for 40 % of world population, 54% of GDP and 44% of world trade
- 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 (US 2011, Russia 2012, Indonesia 2013)

APEC MEMBER ECONOMIES



Life Sciences Innovation Forum

- Created following endorsement by APEC Leaders in 2002
- Recognized importance of *life sciences innovation* in promoting public and economic health
- From outset, harmonization seen as prerequisite to fostering innovation

Unique role

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

- Ability to access APEC funds to advance projects
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation
- Tripartite structure / complementary roles: government, industry, academia

RHSC Mandate

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

- ***Proactively*** identifying and prioritizing projects seen to be of greatest value
- Strengthening linkages with harmonization initiatives, training organizations and other key players to promote ***complementary*** actions and most effective use of resources
- Products of interest: *medical products*

Members

- Regulators from 10 APEC Economies:
Canada, China, Chinese Taipei, Japan, Korea,
Mexico, Peru, Singapore, Thailand, US
- Industry representatives
- Director of APEC Harmonization Center

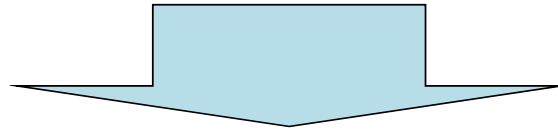
APEC Harmonization Center

- APEC-wide resource to enhance and sustain regulatory convergence and capacity building efforts
- Operates under the authority of LSIF, with direction from RHSC and an international advisory board
- Key enabling role in operationalizing RHSC objectives , having hosted numerous international workshops

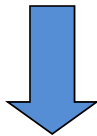
Strategic Framework

- Framework outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
- Describes guiding principles and general multi-step approach
- Voluntary action: each economy proceeds at own pace
- Includes definition of regulatory convergence
- Includes appendices for pharmaceuticals and medical devices and suggested indicators of success
- Endorsed by APEC Ministers in November 2011

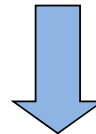
Strategic Framework
Coordinated approach
to promote regulatory convergence



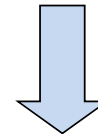
Priority Work Areas
Needs assessment from diagnostic workshops
and a roadmap for promoting best practices



Project



Project



Project

Individual projects are part of strategy & contribute to goals
Move away from Ad Hoc/Individual Proposals

Priority Work Areas (PWAs)

- Roadmap to be developed by champion economy for each PWA
- Champions/PWAs identified to date:
 - MRCTs (Japan: completed)
 - Supply chain integrity (US: completed)
 - Good Review Practices and **Combination Products** (Chinese Taipei)
 - Biotech Products and Pharmacovigilance (Korea)
 - Cellular Therapies (Singapore)

Regulatory Convergence

- “Regulatory convergence” represents process whereby regulatory requirements across economies become more aligned over time as a result of the adoption of internationally recognized technical guidances, standards and best practices
- Does not require the harmonization of laws and regulations
- Broader concept than “harmonization”
 - Example: Good Review Practices

Equivalence

- Two or more systems are said to be “equivalent” if, despite differences, they are expected to produce the same outcomes
- Should be established through objective means and documented
- Example: Mutual Recognition Agreements relating to conformity assessment of GMPs

In Summary

- International regulatory cooperation has become an essential part of dealing effectively with the challenges of an increasingly complex and global environment
- Cooperation should lead to tangible, meaningful results
- Despite challenges, some encouraging developments and trends taking place
- Maximum benefit will come from more strategic discussions, planning and action
- APEC serves as a recent model of success