

Updates
APEC Life Science and Innovation Forum
Regulatory Harmonization Steering Committee
(APEC LSIF-RHSC)
BRISBANE – AUSTRALIA,
22-24 August, 2018

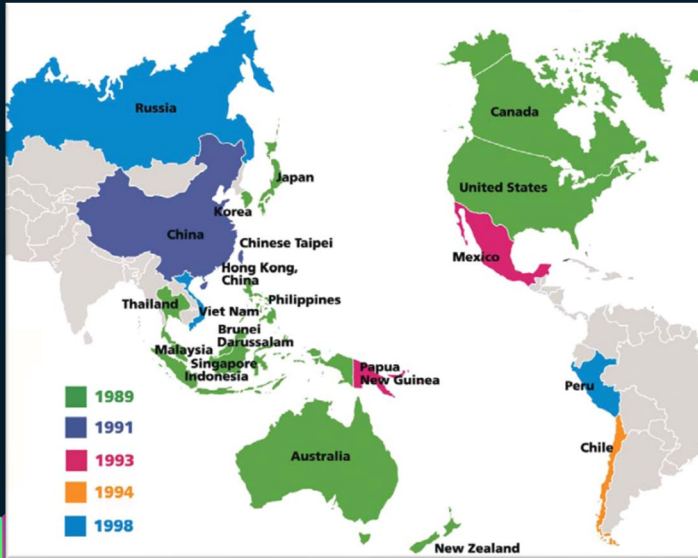


ARIANTI ANAYA
Secretary
Directorate General of
Pharmaceutical and Medical Devices
Ministry of Health, Republic Indonesia



Asia-Pacific
Economic Cooperation

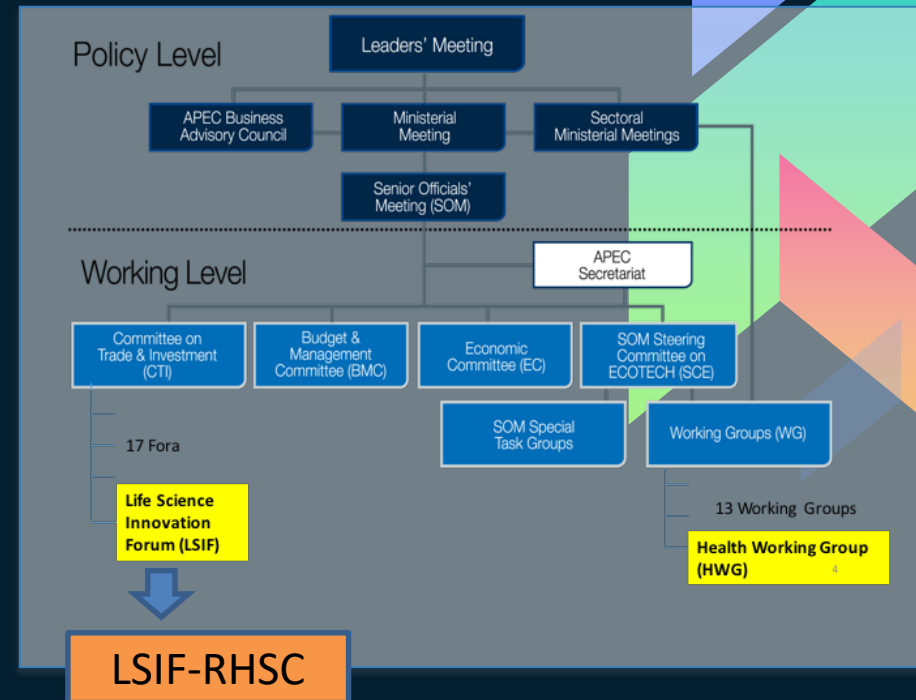
APEC



APEC aim to create **greater prosperity** for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration

APEC Member Economies : 21 Members

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, and Vietnam



APEC LSIF - RHSC

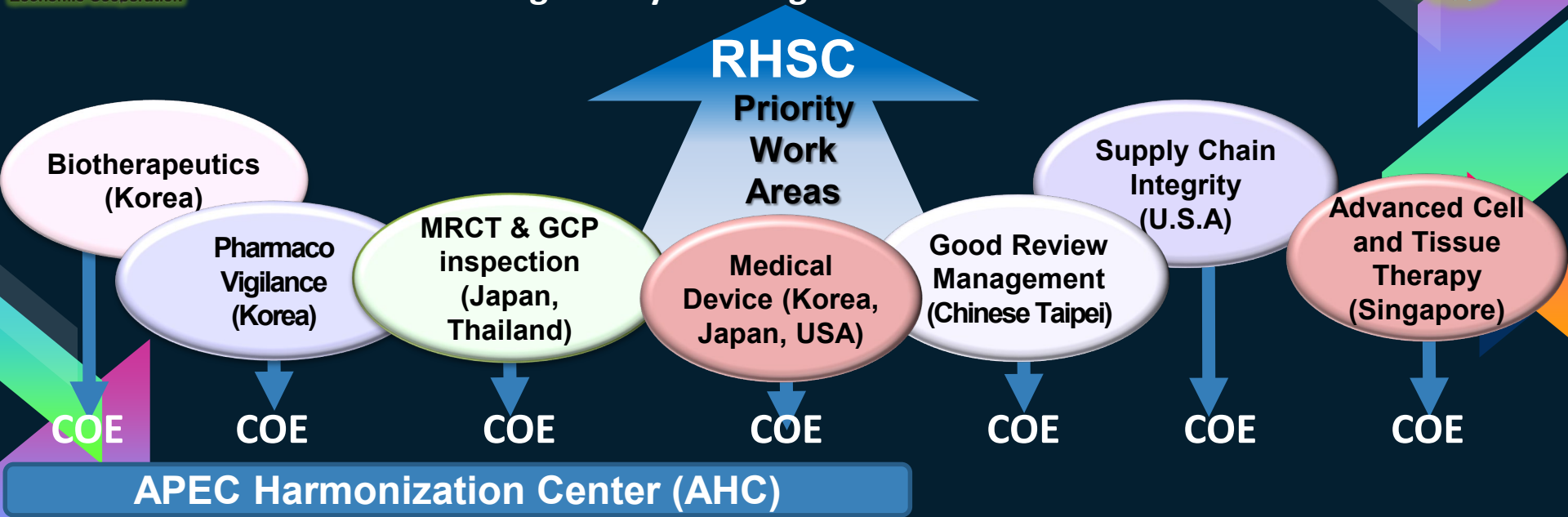
Mandate:

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

- › Proactively identifying and prioritizing projects seen to be of greatest value
- › Strengthen linkages with harmonization initiatives, training organizations and other key players to promote complementary actions and most effective use of resources
- › Leverage work with other harmonization initiatives – avoid duplication of work
- › Ensuring sustained efforts
- › Products of interest: **medical products**

VISION

Regulatory Convergence in the APEC

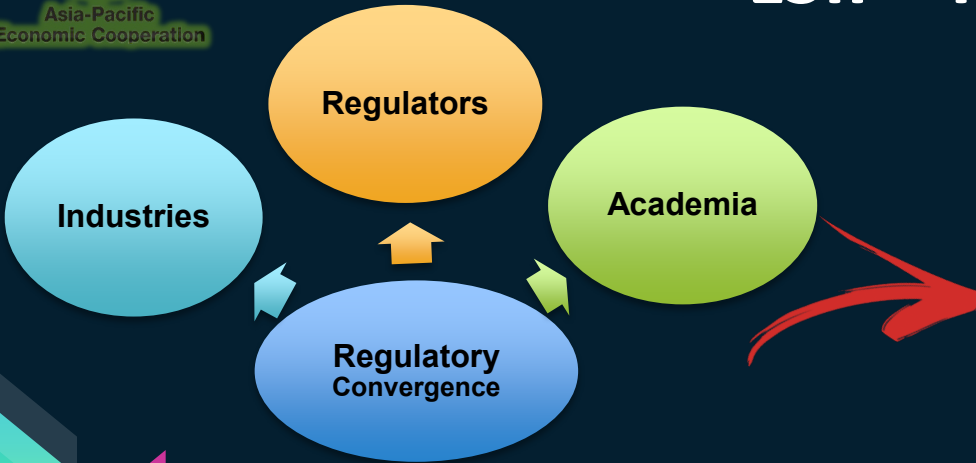


1. To facilitate **regulatory convergence** in the region and beyond
2. To support access to **best practices** and **international guidelines**
3. To promote **collaborative actions** and **information sharing**
4. To enhance **quality, safety and efficacy** of medicinal products
5. To oversee the **performance of COE**



Asia-Pacific Economic Cooperation

LSIF - RHSC



Center of Excellence (CoE)

- ✓ Partnership of academia, regulators and industry to deliver and maintain educational programs
- ✓ Benefit must be realized by all 3 partners

› Building a Better Harmonization Model

Development Organizations
(Standards, Guidance, Tools)

Key Enabler:
RHSC + APEC Harmonization Center



Key role played by WHO



Asia-Pacific
Economic Cooperation

APEC Harmonization Centre Trainings



Since 2009 | Total **38** Workshops | **9200** Participants | Supported **320** Trainees

- MRCT
- Biosimilar
- GMP Validation
- Medical Devices
- Supply Chain
- QbD

2009 - 2011

2012 - 2014

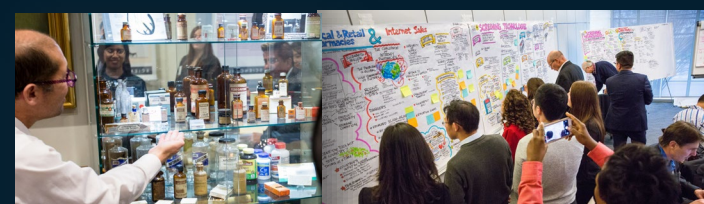
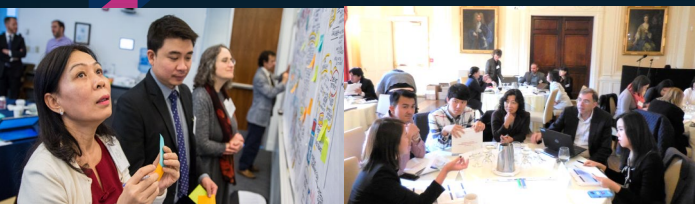
2015 - 2017

2018

- Pharmacovigilance
- Biotherapeutics
- GMP Validation
- Supply Chain Integrity
- CTT
- MRCT & GCP Inspection

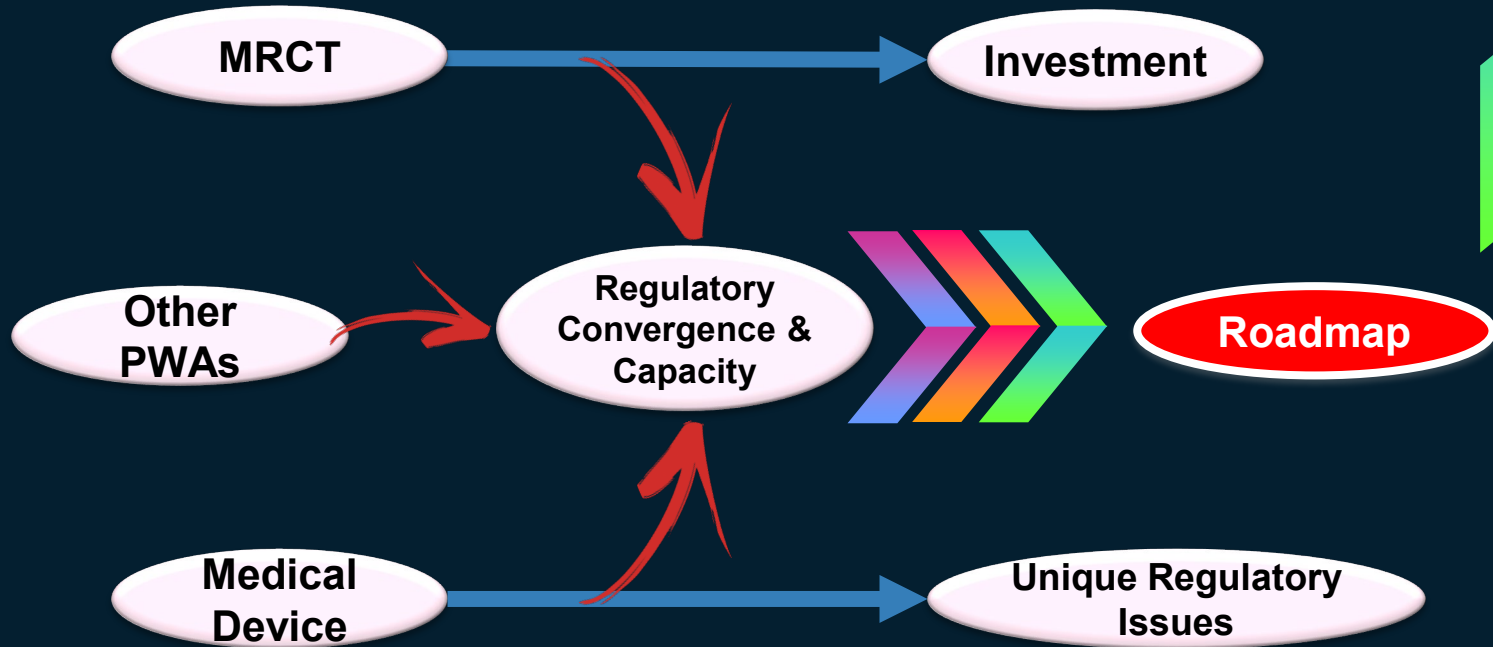
- Pharmacovigilance
- Biotherapeutics
- Generic Drug
- Supply Chain Integrity
- MRCT & GCP
- CTT

- MRCT
- Supply Chain Integrity
- Medical Device
- Biotherapeutics



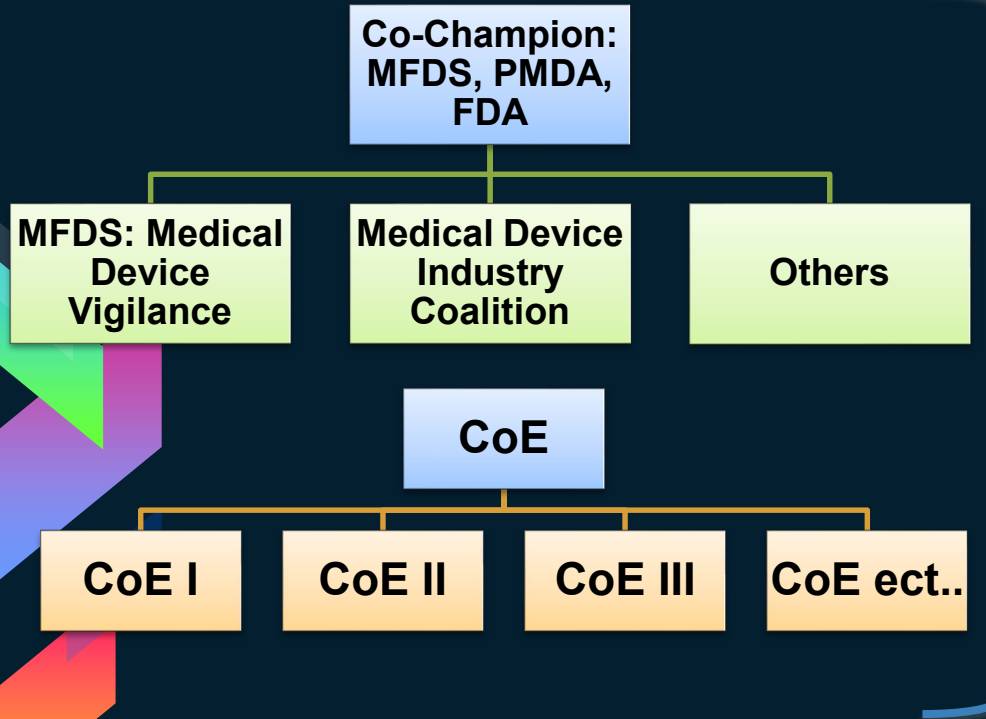
RHSC Task

achieve **regional convergence** on regulatory approval procedures for **medical products** by 2020



Medical Device PWA

Structure



Core Curriculum

1. **Premarket**
 - Definitions
 - Classification
 - Conformity Assessment
 - Reviewer Competence Requirements
 - EPSP
 - Standards
 - Labeling
2. **Postmarket**
 - Adverse Event Report
 - FSN
 - Data Exchange System Requirements
 - CAR
 - NCAR
 - AET
 - Registry
3. **Quality Management System**
 - Requirements and Guidance
 - Auditing
 - MDSAP



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ASIAN HARMONIZATION
WORKING PARTY



THANK YOU