MINISTRY
OF HEALTH
REPUBLIC
OF INDONESIA

ASIAN HARMONIZATION
WORKING PARTY

Asia-Pacific
Economic Cooperation

APEC
CHILE 2019

Updates
APEC Life Science and Innovation Forum
Regulatory Harmonization Steering Committee
(APEC LSIF-RHSC)

Santiago – Chile, 27 February – 1 March, 2019

Puerto Varas – Chile, 15 – 18 Agustus, 2019

Directorate of Medical Device and Household Health Product Evaluation
Directorate General of Pharmaceutical and Medical Device
Ministry of Health Republic of Indonesia

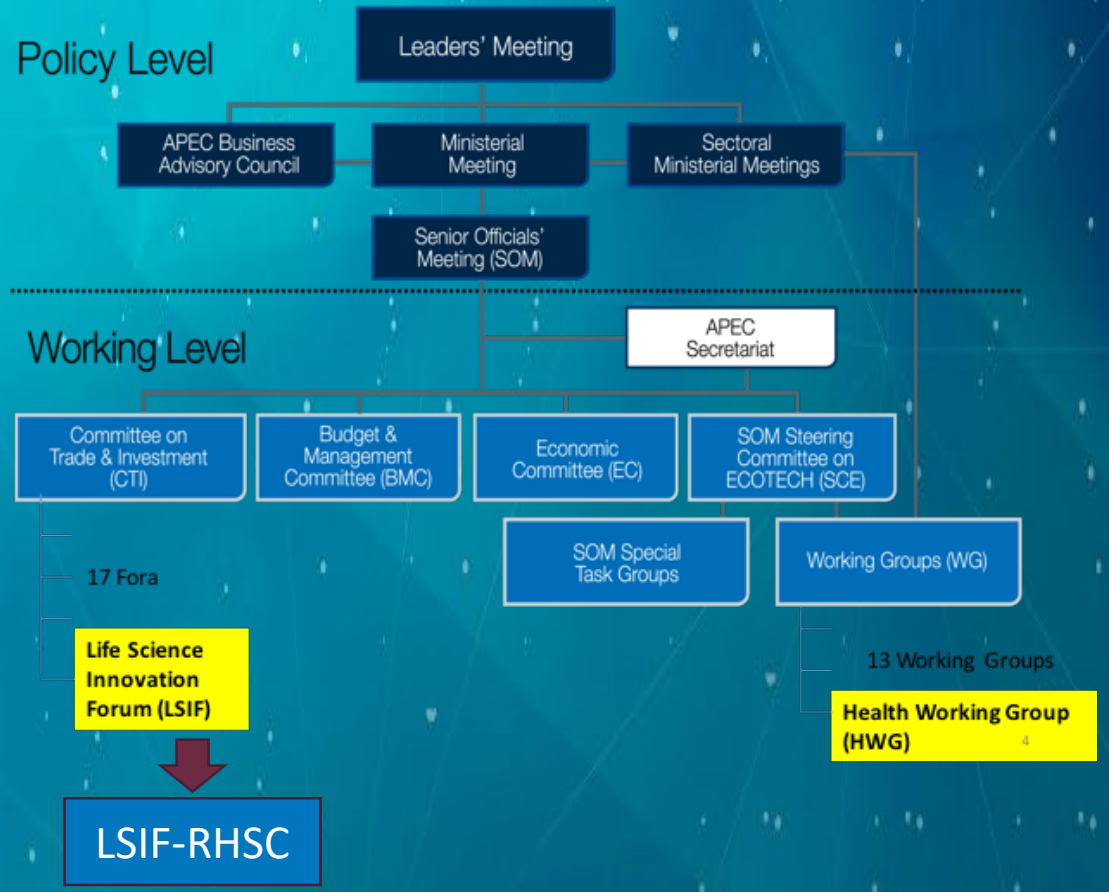
Asia-Pacific Economic Cooperation

APEC

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

Health Fora in APEC Structure



Asia-Pacific Economic Cooperation

APEC
LSIF - RHSC

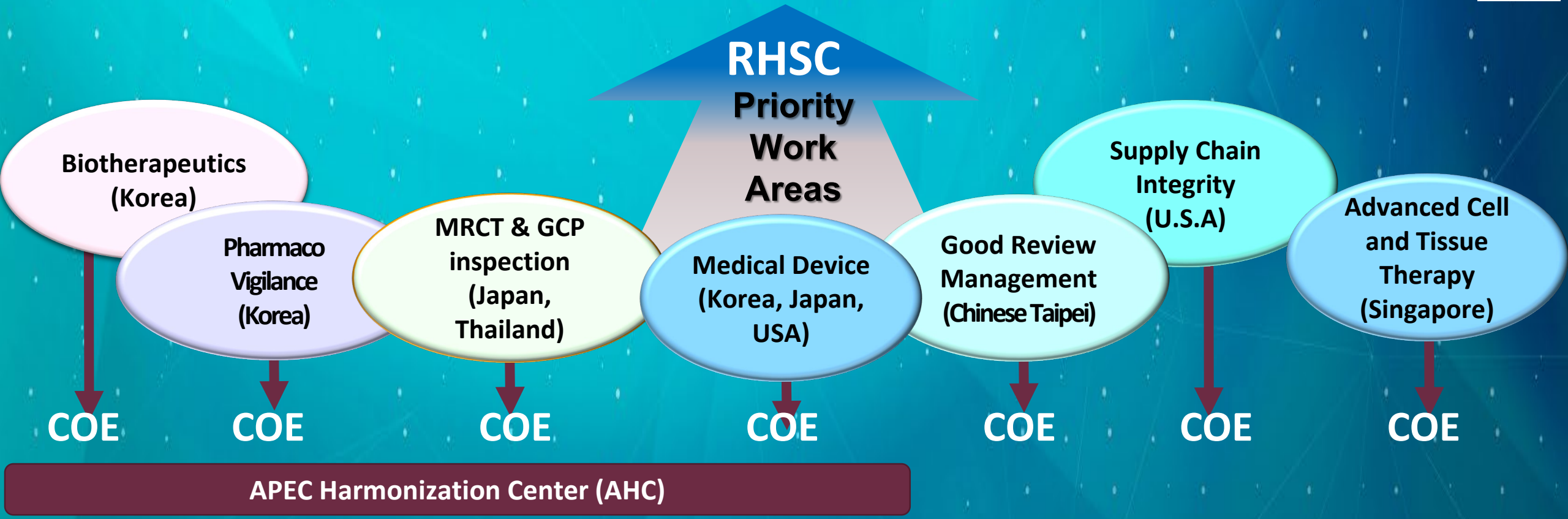
Mandate:

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**

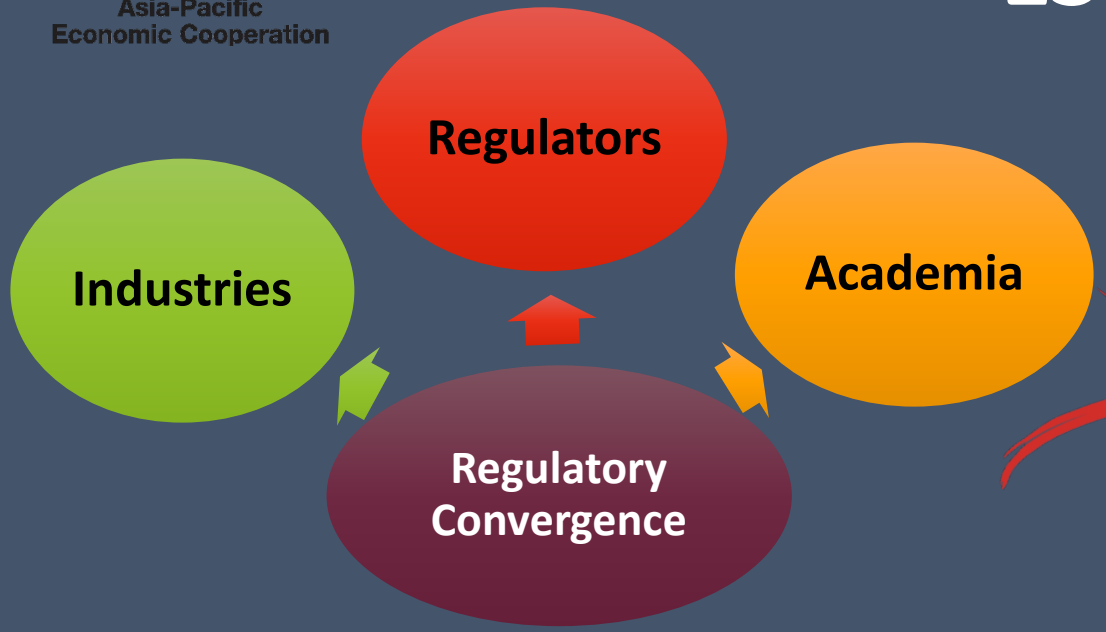
VISION

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**

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)

ICH, IMDRF

Key Enabler:
RHSC + APEC Harmonization Center

APEC

Key role played by WHO

LSIF - RHSC

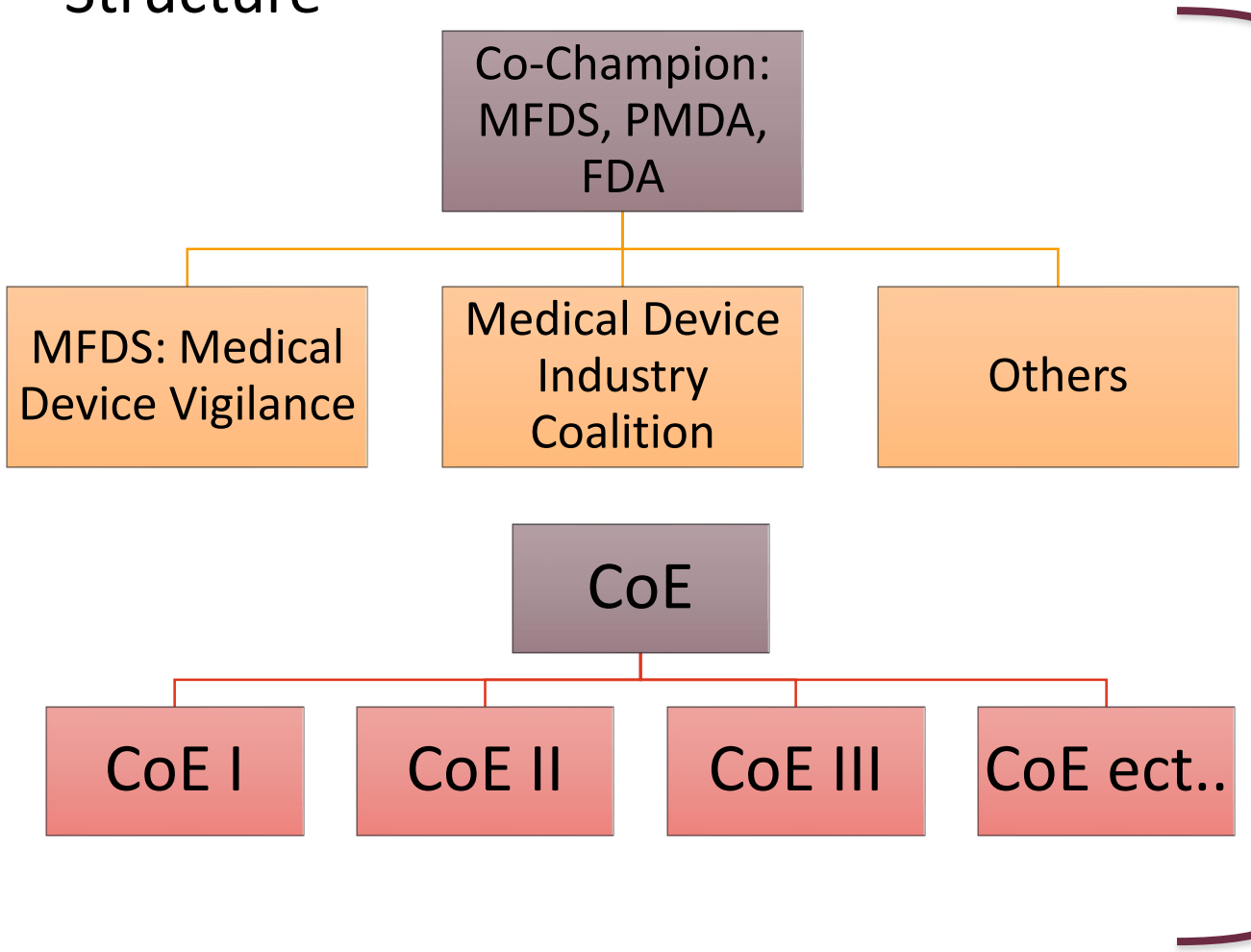
Center of Excellence (CoE)

- ✓ The Vision
  - ✓ A sustainable platform for promoting regulatory convergence, capacity and cooperation in areas of medical products
  - ✓ Science and best practice focus
- ✓ The Approach
  - ✓ Partnership among training institutions/organizations, regulators and industry, to deliver and maintain educational programs
  - ✓ CoE Host Institutions collaborate with PWA Champions, PWA Steering Committee and CoE Coalition
- ✓ Follow principles in CoE Operating Model
- ✓ Ensure quality & consistent training programs via PWA roadmap, Core Curriculum, PI & periodic assessments

- ✓ **APEC Regulatory Training CoEs**
  - ✓ PMDA (Pharmacovigilance & Medical Device Vigilance)
  - ✓ NIDS (Medical Devices)
  - ✓ USC (Medical Devices)
  - ✓ TFDA, Chinese Taipei (Medical Devices)

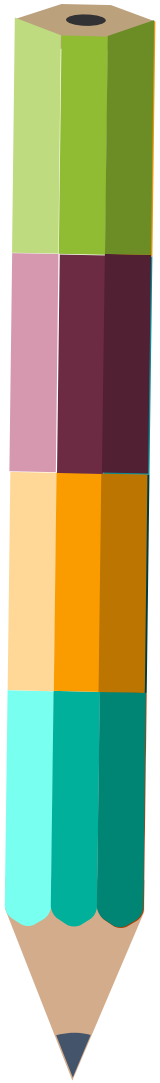
Medical Device PWA

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



APEC Harmonization Centre Trainings

Since 2009 | Total **41** **Workshops** | **9500** **Participants** | **Supported 353 Trainees**

2009 - 2011

- MRCT
- Biosimilar
- GMP Validation
- Medical Devices
- Supply Chain
- ICH Quality by Design

2012 - 2014

- Pharmacovigilance
- Biotherapeutic
- GMP Validation
- Supply Chain Integrity
- Cell and Tissue Therapy
- MRCT & GCP Inspection

2015 - 2018

- Pharmacovigilance
- Biotherapeutic
- Generic Drug
- Supply Chain Integrity
- MRCT & GCP
- Cell and Tissue Therapy
- Medical Device

2019

- GRM (Nov – Thailand)
- MRCT (Jan – Japan, Feb – Canada, Jul – Singapore, Sept – China)
- Biotherapeutic (Sept – Korea & US)
- Pharmacovigilance (Feb – Japan, Apr – China, Sept – Korea)
- Medical Device (Apr – US)
- Supply Chain (Sept – Malaysia, Aug – Korea)

2019 COE PROGRAMS

Priority Work Area	CoE/Pilot	Organization	Location	Dates
GRM	CoE	TFDA/RAPS	Chinese Taipei	17-19 September 2019
GRM	Pilot CoE	TFDA, Thailand	Bangkok	28-30 October 2019
MRCT/GCP	CoE	PMDA	Japan	21-24 Jan 2019
MRCT/GCP	CoE	MRCT Center	Canada	26-28 February 2019
MRCT/GCP	CoE	Duke-NUS	Singapore	11-12 July 2019
MRCT/GCP	Pilot CoE	KoNECT	Seoul	16-18 September 2019
MRCT/GCP	CoE	Harvard BWH	United States	September 2019
MRCT/GCP	CoE	PKU	Beijing	11-14 November 2019
Biotherapeutic Products	CoE	NEU	Chile	11-13 March (Regulators/Academia) 14-15 March 2019 (Industry)
Biotherapeutic Products	CoE	NEU	USA	16-18 September 2019
Biotherapeutic Products	CoE	AHC	Seoul	September 2019
Biotherapeutic Products	Pilot CoE	Kobe University	Japan	December 2019
Global Supply Chain Integrity	CoE	USP	Santiago	June 2019
Global Supply Chain Integrity	Pilot CoE	Taylor's University	Malaysia	September 2019
Global Supply Chain Integrity	CoE	USP	Latin America	4Q 2019
Advanced Therapy Products	Pilot CoE	NEU	United States	July 2019
Pharmacovigilance	CoE	PMDA	Japan	4-7 February 2019
Pharmacovigilance	Pilot CoE	PKU	China	April 2019
Pharmacovigilance	CoE	KIDS	Korea	September 2019
Medical Devices	Pilot CoE	USC	United States	30 April - 3 May 2019
Medical Devices	Pilot CoE	TFDA, Chinese Taipei	Chinese Taipei	22-24 October 2019
Medical Devices	Pilot CoE	PMDA	Japan	25-29 November 2019
Medical Devices	Pilot CoE	NEU	United States	Q4 2019 or Q1 2020

Asia-Pacific
Economic Cooperation

APEC
CHILE 2019

MINISTRY
OF HEALTH
REPUBLIC
OF INDONESIA

T H A N K Y O U

TERIMA KASIH

شكرا جزيلا