



**Asia-Pacific  
Economic Cooperation**



**IMDRF** International Medical  
Device Regulators Forum

# Updates

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

**HO CHI MINH – VIET NAM, 18-19 August, 2017**

**ARIANTIANAYA**

**Director**

**Medical Devices and**

**Household Health Products Evaluation**

**Ministry of Health, Republic Indonesia**

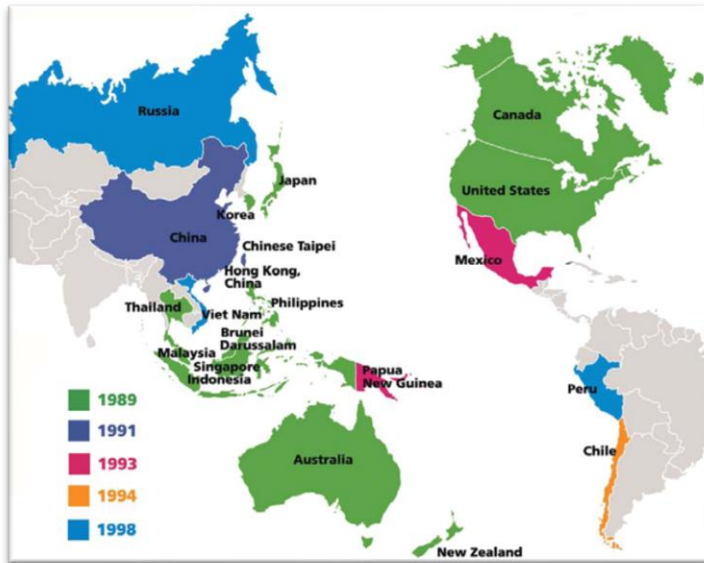
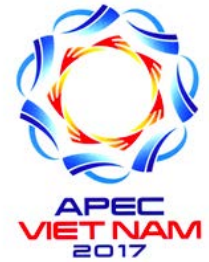


Ministry of  
Health  
Republic of  
Indonesia



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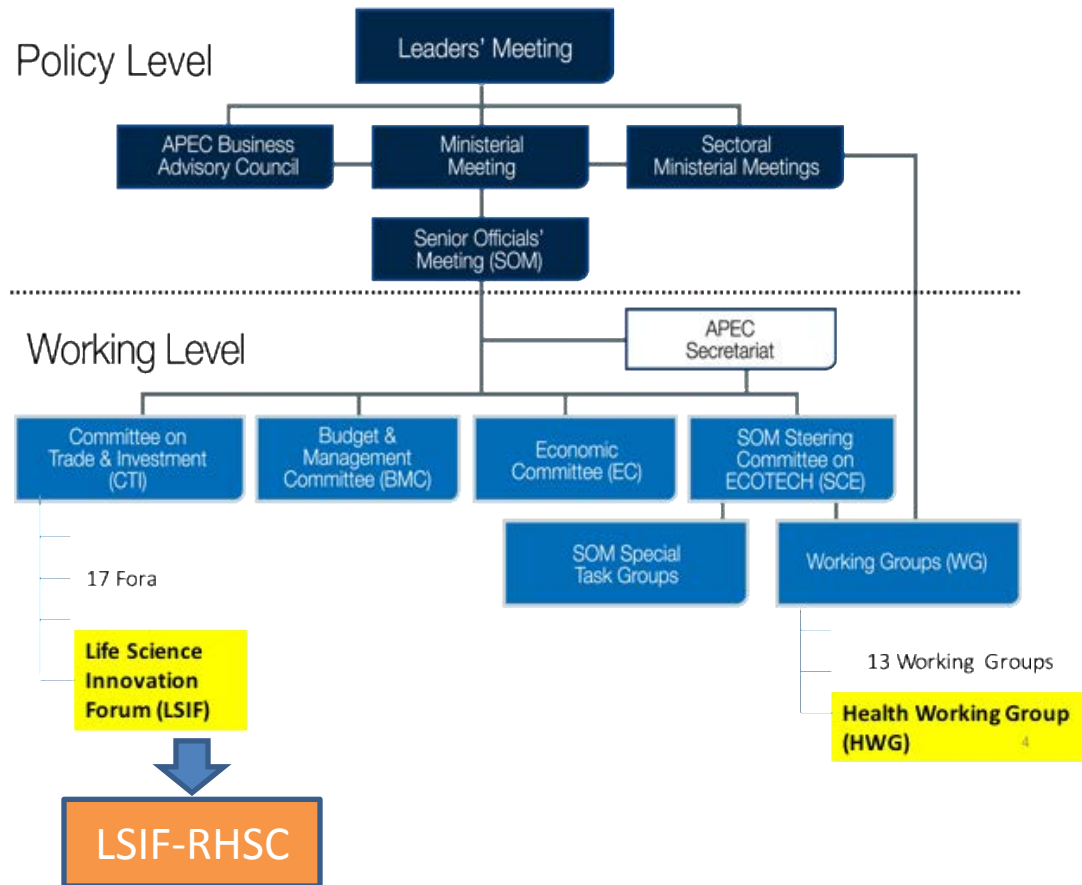
# APEC



**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



# 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**



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Vision

# Regulatory Convergence in the APEC

**RHSC**  
Priority  
Work  
Areas

Biotherapeutics  
(Korea)

PV & MDV  
(Korea)

MRCT & GCP  
inspection  
(Japan,  
Thailand)

Good Review  
Management  
(Chinese Taipei)

Supply Chain  
Integrity  
(U.S.A)

Advanced Cell  
and Tissue  
Therapy  
(Singapore)

1

To facilitate **regulatory convergence** in the region and beyond

2

To support access to **best practices** and **international guidelines**

3

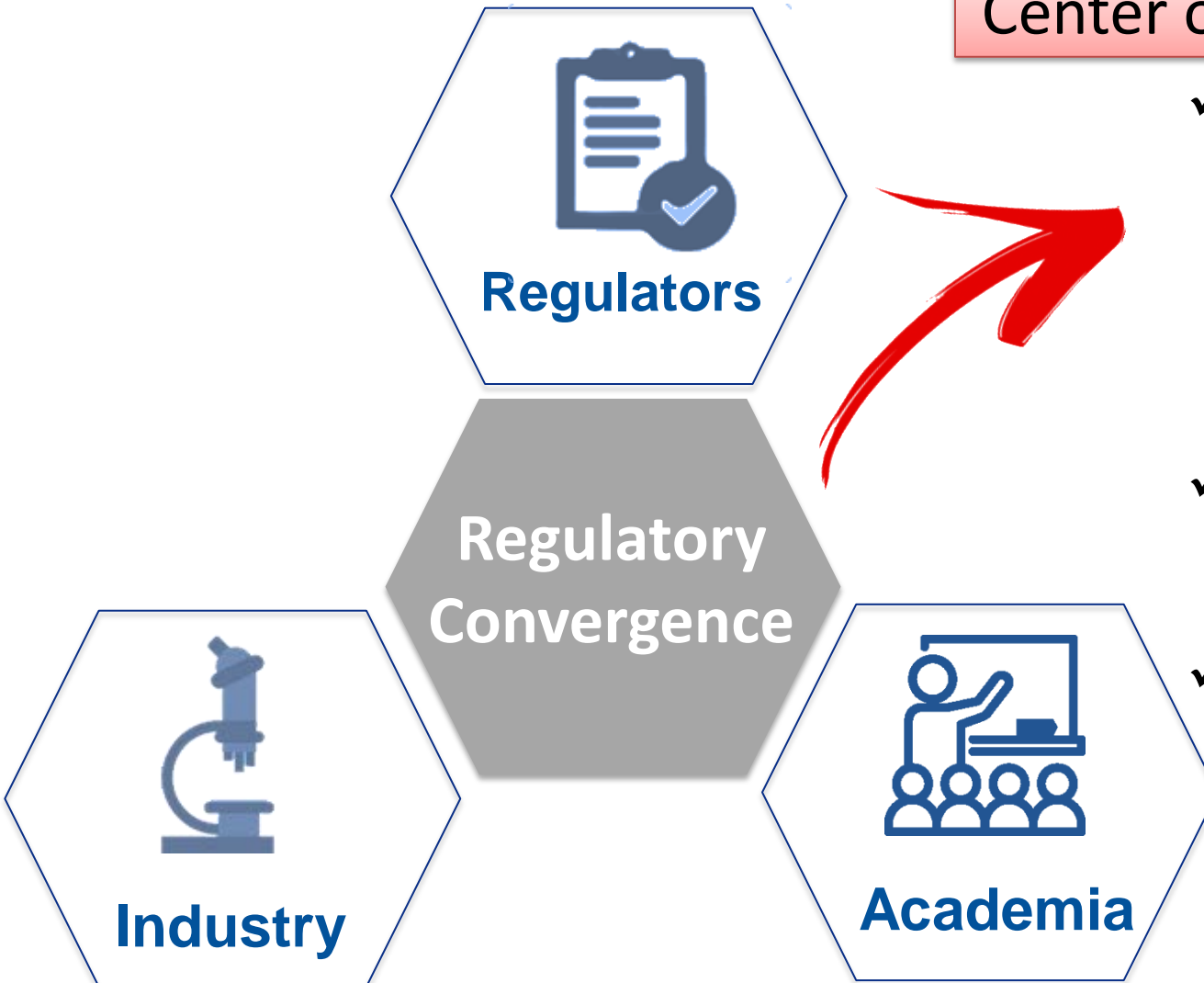
To promote **collaborative actions** and **information sharing**

4

To enhance **quality, safety and efficacy** of medicinal products

**AHC**

## Center of Excellence (CoE)



- ✓ Partnership of academia, regulators and industry to deliver and maintain educational programs
- ✓ Benefit must be realized by all 3 partners
- ✓ Oversee & certify performance via APEC RHSC and AHC

# Center of Excellence

- **Center of Excellence (CoE): Sustainable platform** for long-term efforts to implement the roadmaps to facilitate regulatory convergence

## Endorsed formal / pilot CoE hosting institutions (until SOM1)

| Priority Work Areas           | Formal/Pilot | Hosting Institutions    |
|-------------------------------|--------------|-------------------------|
| Biotherapeutics               | Formal CoE   | Northeastern University |
| MRCT/GCP Inspection           | Formal CoE   | Peking University       |
|                               | Formal CoE   | PMDA                    |
|                               | Formal CoE   | Duke-NUS Singapore      |
|                               | Pilot CoE    | Harvard MRCT BWH        |
| Cell & Tissue-based Therapies | Pilot CoE    | Duke-NUS Singapore      |
| Good Registration Management  | Formal CoE   | Chinese Taipei - RAPS   |
|                               | Pilot CoE    | COFEPRIS                |
| Pharmacovigilance             | Formal CoE   | PMDA                    |
|                               | Pilot CoE    | KIDS                    |
| Supply Chain                  | Pilot CoE    | University of Tennessee |
|                               | Pilot CoE    | USP                     |

# APEC Harmonization Centre Trainings



Since 2009

Total **35** Trainings  
**8,713** Participants  
Supported **289** Trainees

## 2009

- MRCT
- Biosimilar
- GMP Validation

## 2010

- Supply Chain
- MRCT
- Medical Devices

## 2011

- MRCT
- QbD
- Medical Devices
- Asia Regulatory Conference

## 2012

- Pharmacovigilance
- Biotherapeutics
- Medical Devices
- AHC/RHSC Awareness

## 2013

- Pharmacovigilance
- Biotherapeutics
- Supply Chain Integrity
- AHC/RHSC Awareness

## 2014

- CTT
- MRCT & GCP Inspection
- Biotherapeutics
- Medical Devices

## 2015

- Pharmacovigilance
- Biotherapeutics
- Supply Chain Integrity (2 times)
- Generic Drug

## 2016

- Supply Chain Integrity
- Biotherapeutics (2 times)
- Pharmacovigilance & Medical Device vigilance
- Good Review Management

## 2017

- Supply Chain Integrity (2 times)
- CTT(advanced therapeutics)

\* Pilot CoE

# SOM-3 LSIF-RHSC Deliverables Endorsed

| COE        | Institution  | PWA  |
|------------|--|--|
| Pilot CoE  | MDITAC - Korea                                     | Medical Device Vigilance   |
| Formal CoE | KIDS - Korea<br>University of Tennessee HSC<br>USP | Pharmacovigilance<br>Supply Chain Security<br>Quality and Global Supply<br>Chain Integrity |





# SOM-3 Discussion Topics:



1. Proposal for PWA Performance Indicators linked to a CoE core curriculum
2. Endorsed new PWA – Medical Devices
3. Endorsed new CoE coalition
4. Endorsed AHC role as CoE coordinator
5. Looking forward to High Level Dialogue on Innovation, Regulatory Systems and Regulatory Convergence



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**THANK YOU**