Updates

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

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

ARIANTI ANAYA
Director
Medical Devices and
Household Health Products Evaluation
Ministry of Health, Republic Indonesia
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
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
Regulatory Convergence in the APEC

Vision

To facilitate regulatory convergence in the region and beyond

To support access to best practices and international guidelines

To promote collaborative actions and information sharing

To enhance quality, safety and efficacy of medicinal products

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)
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)

<table>
<thead>
<tr>
<th>Priority Work Areas</th>
<th>Formal/Pilot</th>
<th>Hosting Institutions</th>
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<tbody>
<tr>
<td>Biotherapeutics</td>
<td>Formal CoE</td>
<td>Northeastern University</td>
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<tr>
<td>MRCT/GCP Inspection</td>
<td>Formal CoE</td>
<td>Peking University</td>
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<td></td>
<td>Formal CoE</td>
<td>PMDA</td>
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<tr>
<td></td>
<td>Pilot CoE</td>
<td>Duke-NUS Singapore</td>
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<td></td>
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<td>Harvard MRCT BWH</td>
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<tr>
<td>Cell &amp; Tissue-based Therapies</td>
<td>Pilot CoE</td>
<td>Duke-NUS Singapore</td>
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<tr>
<td>Good Registration Management</td>
<td>Formal CoE</td>
<td>Chinese Taipei - RAPS</td>
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<td></td>
<td>Pilot CoE</td>
<td>COFEPRIS</td>
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<tr>
<td>Pharmacovigilance</td>
<td>Formal CoE</td>
<td>PMDA</td>
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<td>Pilot CoE</td>
<td>KIDS</td>
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<td>Supply Chain</td>
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<td>University of Tennessee</td>
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<td>USP</td>
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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

Total 35 Trainings
8,713 Participants
Supported 289 Trainees
## SOM-3 LSIF-RHSC Deliverables

**Endorsed**

<table>
<thead>
<tr>
<th>COE</th>
<th>Institution</th>
<th>PWA</th>
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<tbody>
<tr>
<td>Pilot CoE</td>
<td>MDITAC - Korea</td>
<td>Medical Device Vigilance</td>
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<tr>
<td>Formal CoE</td>
<td>KIDS - Korea</td>
<td>Pharmacovigilance</td>
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<td></td>
<td>University of Tennessee HSC USP</td>
<td>Supply Chain Security Security</td>
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<td>Quality and Global Supply Chain Integrity</td>
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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
THANK YOU