Updates

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

NHA TRANG – VIET NAM, 20-21 FEBRUARY, 2017

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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
Priority Work Areas (PWAs)

- Pharmacovigilance & Medical Device Vigilance
  Champion Country (Japan & Korea)

- Global Medical Product Quality and Supply Chain Integrity
  Champion Country (USA)

- Multi Regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspections
  Champion Country (Japan & Thailand)

- Cell and Tissue-based Therapies
  Champion Country (Singapore)

- Biotherapeutics
  Champion Country (Korea)

- Good Registration Management (GRM)
  Champion Country (Chinese Taipei & Japan)
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 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
Benefits of CoE Model

• Sustainable
• Offloads execution to training experts
• Solves reliance on shrinking APEC funds and the current project proposal - workshop – report - closeout paradigm
• RHSC's role - design, oversight, periodic assessment and action where needed
• AHC’s role – coordinate selection & implementation, assure sustained quality CoE operations
# SOM-1 LSIF-RHSC Deliverables

**Endorsed**

<table>
<thead>
<tr>
<th>Institution as formal APEC Regulatory Training CoEs</th>
<th>Pilot CoEs</th>
<th>Workshops</th>
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<tr>
<td>Northeastern University (Biotherapeutics)</td>
<td>Harvard BWH (Pilot, MRCT/GCP Inspection)</td>
<td>Workshop in Latin America (November, Biotherapeutics)</td>
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<td>Peking University (MRCT/GCP)</td>
<td>KIDS (second Pilot, Pharmacovigilance &amp; Medical Device Vigilance)</td>
<td>Workshop in Korea (September, Pharmacovigilance)</td>
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<td>PMDA Japan (MRCT/GCP)</td>
<td>Duke/NUS Singapore (Pilot, Cell and Tissue-based Therapies)</td>
<td>Medical Device Vigilance Workshop in Korea (September)</td>
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<tr>
<td>Duke/NUS Singapore (MRCT/GCP)</td>
<td>COFEPRIS (GRM)</td>
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<td>RAPS, cooperate with Taiwan FDA (GRM)</td>
<td>University of Tennessee HSC (Supply Chain Integrity)</td>
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<tr>
<td>PMDA Japan (Pharmacovigilance &amp; Medical Device Vigilance)</td>
<td>USP (Supply Chain Integrity)</td>
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<tr>
<td>Final Report</td>
<td>CoEs Operating Model</td>
<td>Steps to formalize a CoEs</td>
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<tr>
<td>Supply Chain report</td>
<td>Sect. IV-E : Operating Guidelines</td>
<td>update steps to point to the right places to look in the Operating Model</td>
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<td>Supply chain security toolkit</td>
<td>Appendix B: CoE Application Form</td>
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<td>Appendix C: CoE Endorsement Letters</td>
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<td>Appendix D: CoE MOU</td>
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Discussion Topics:

• Proposal for PWA Performance Indicators linked to a CoE core curriculum
• Proposal for a dedicated APEC Sub Fund for CoE activities
• Proposal for an APEC LSIF High Level Dialogue on Regulatory Convergence at SOM-3 that will be held on August 2017.
Ongoing process

• CoE concept comes to fruition – 6 CoEs launched with several Pilot CoE Programs and workshops in the pipeline

• Significant progress continues in all PWAs

• Funding of CoE programs is a critical factor – discussion on options will continue

• RHSC continues moving forward in activities to advance regulatory convergence on a global scale in a sustainable manner
THANK YOU