Updates

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

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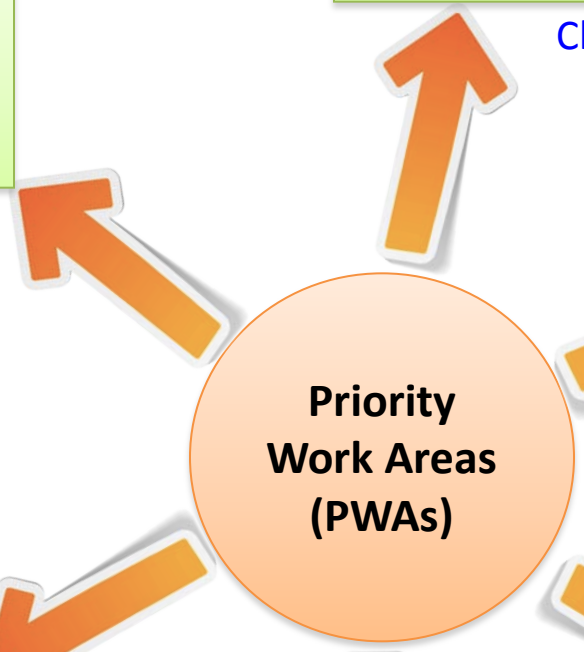
Mandate:

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)

Multi Regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspections

Champion Country (Japan&Thailand)

Global Medical Product Quality and Supply Chain Integrity

Champion Country (USA)

Cell and Tissue-based Therapies

Champion Country (Singapore)

Biotherapeutics

Champion Country (Korea)

Good Registration Management (GRM)

Champion Country (Chinese Taipei&Japan)

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 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

Institution as formal APEC Regulatory Training CoEs	Pilot CoEs	Workshops
Northeastern University (Biotherapeutics)	Harvard BWH (Pilot, MRCT/GCP Inspection)	Workshop in Latin America (November, Biotherapeutics)
Peking University (MRCT/GCP)	KIDS (second Pilot, Pharmacovigilance & Medical Device Vigilance)	Workshop in Korea (September, Pharmacovigilance)
PMDA Japan (MRCT/GCP)	Duke/NUS Singapore (Pilot, Cell and Tissue-based Therapies)	Medical Device Vigilance Workshop in Korea (September)
Duke/NUS Singapore (MRCT/GCP)	COFEPRIS (GRM)	
RAPS, cooperate with Taiwan FDA (GRM)	University of Tennessee HSC (Supply Chain Integrity)	
PMDA Japan (Pharmacovigilance & Medical Device Vigilance)	USP (Supply Chain Integrity)	

SOM-1 LSIF-RHSC Deliverables

Endorsed

Final Report	CoEs Operating Model	Steps to formalize a CoEs
Supply Chain report	Sect. IV-E : Operating Guidelines	update steps to point to the right places to look in the Operating Model
Supply chain security toolkit	Appendix B: CoE Application Form	
	Appendix C: CoE Endorsement Letters	
	Appendix D: CoE MOU	

SOM-1 LSIF-RHSC 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

Asia-Pacific Economic Cooperation

IMDRF International Medical Device Regulators Forum

APEC VIET NAM 2017

THANK YOU