



APEC-LSIF

APEC LSIF IV-Update **on Harmonization Initiative**

by

Yuppadee JAVROONGRIT, Ph.D.

Medicines Co-Chair of APEC-LSIF Harmonization Initiative
Drug Control Division, FDA, Thailand

The ICH-Global Cooperation Group Meeting
Westin Michigan Ave. Hotel, Chicago, USA
24 October 2006

APEC LSIF- GCG Chicago Oct. 06

1

Yuppadee JAVROONGRIT, Ph.D.

Co-Chair of ACCSQ/PPWG, ASEAN

Drug Control Division, FDA, Thailand

The ICH-Global Cooperation Group Meeting

Westin Michigan Ave. Hotel, Chicago, USA

24 October 2006



Outcome “Harmonization Initiative”

from
The APEC LSIF IV Meeting
6-7 September 2006, Hoi An, VIETNAM



APEC-LSIF IV Harmonization Initiative (1)

- **Panel**

Session II-Model for Collaboration “Harmonization : When Cooperation Becomes the Key to Successful Innovation Strategies”

Moderator → Y.JAVROONGRIT (Medicines Co-Chair of APEC-LSIF Harmonization Initiative)

Speakers

→ **Asia-Pacific Regional Medical Device Regulatory Harmonization Initiative**

by Michael Gropp (Medical Device Co-Chair of APEC-LSIF Harmonization Initiative)

→ **Partnership in Harmonization-Experience from ‘APEC Network on P’cal**

Regulatory Science 2000-2006 by Dr.Herng-Der Chern (Executive Director, CDE, Chinese Taipei)

→ **Challenges and Efforts towards Harmonization and Integration Process**

by Dr.Truong Quoc Cuong (Deputy Director General, Drug Administration, Vietnam)

→ **Harmonization : When Cooperation Becomes the Key to Successful Innovation Strategies**

by Dr.Stephen W.Cook (Vice President, Regulatory Affairs, Asia Pacific of GSK)



APEC-LSIF IV Harmonization Initiative (2)

Session's Expectation

- realizing the Role of Harmonization
in developing a Climate to attract Innovation
- generating Ideas
for how to Encourage the Harmonization of Std. & Regulatory Practices in LSIF
- gaining Information & Ideas
as Valuable Input for the Group Discussion
- providing Strong Message & Recommendation
to Leaders for endorsement



APEC-LSIF IV Harmonization Initiative (3)

- **Harmonization-Group Meeting**

Co-Chairs :-

- *Michael GROPP* (Medical Device Co-Chair of APEC-LSIF Harmonization Initiative)
- *Yuppadee JAVROONGRIT* (Medicines Co-Chair of APEC-LSIF Harmonization Initiative)

Secretariat :-

- *Maria VODICKA* (PhRMA)

Participants :- ~ 30 from *Aus., Chinese Taipei, Sg., Th., USA, Vn.....*

Topics :-

- *Result of the APEC-LSIF III*
- *Update from APEC-LSIF*
- *Revisiting on Scope & Mandate*
- *Recommendation to the Leaders*



APEC-LSIF IV Harmonization Initiative (4)

Gr.-Recommendation (i)

- **APEC “Ministers & Leaders”** *encourage Regulatory Harmonization*
 - Int’l Best Practice & Standards for Medical Products (Med.Device / P’cals)
 - promote Innovation in LS & Public Health – Sustainable Health System
 - bring Medical Products to Patient Faster
 - facilitate Trade in SAFE & EFFECTIVE Medical Products





APEC-LSIF Harmonization Initiative (5)

Gr.-Recommendation (ii)

- **LSIF IV recommends all APEC Economies**
 - support the existing Strategic Plan
 - support 4 Strategic Plan's Implementation Projects
 - Anti-Counterfeiting of P'cal Products and Med.Devices :Training Seminars for Gov. Officials and relevant Stakeholders *(by USA)*
 - Capacity Building for Drug Regulatory Agencies on Clinical Trial & GCP *(by Tha)*
 - Capacity Building for the ICH "Quality by Design" Guidelines (Q8 & Q9) *(by USA)*
 - Convergence of Practices related to the usage of CPPs *(by USA)*
 - support Participation to Capacity Building & Training *be recommended by Harmonization Steering Group*
 - facilitate Trade in SAFE & EFFECTIVE Medical Products



APEC-LSIF Harmonization Initiative (6)

Gr.-Recommendation (iii)

- **Harmonization Initiative – Working Group**
 - work towards the Harmonization Objectives of the APEC-LSIF Strategic Plan
 - report the continued Progress to the APEC-LSIF



APEC-LSIF IV :-

Final Recommendations → Harmonization Initiative (1)

Key Finding and Conclusion

- the need to promote a *Robust Regulatory Underpinning* has become increasingly important to support Innovative Life Sciences 'R', 'D', 'M&M', and 'Delivery to consumers'
- Minister & Leaders should Renew Efforts to encourage Regulatory Harmonization
- number of APEC economies require Significant Capacity Building



APEC-LSIF IV :-

Final Recommendations → *Harmonization Initiative (2)*

Conclusion

- APEC economies should fully support the 4 Cap. Building Projects on Harmonization of Standards & Regulatory Procedures
- Economies are encouraged to participate in the newly established Harmonization Steering Committee to facilitate implementation of the Har. Recommendations of the Strategic Plan
- LSIF should incorporate APEC Networks on Regulatory Science as a key feature of its Regulatory Harmonization and Cap. Building Program
- LSIF should establish a Platform for partnership b/w Regulators-Industry to improve regulatory capacity, share info., undertake joint Training prog. in Regulatory Science



APEC-LSIF IV :-

Final Recommendations → Harmonization Initiative (3)

Key Recommendation for Action

→ Enhance support for Regulatory Harmonization to International Best Practices & Standards for Med. Device / P'cal products

→ by Supporting :-

- APEC's LSIF harmonization projects
- participation by interested Economies in the newly established Harmonization Steering Group
- inclusion of APEC's network on Regulatory Science, as a key feature of the LSIF Regulatory Harmonization and Capacity Building program



APEC-LSIF IV :-

Final Recommendations → Harmonization Initiative (4)

Key Judgment for Ministers and Leaders

“...should continue to support and encourage the Harmonization of

- Regulatory Procedures
- Projects designed to build capacity in the region”

To Ensure

‘ a Robust Regulatory to support :-

- Advances in Life Sciences products & services
- LS's delivery to address Critical Health Challenges



The Request to ICH-GCG

- provides Trainers → 4 Projects of the APEC-LSIF
- provides Speakers → to APEC-LSIF IV (~ Apr.07, Aus.)
 - present on “ICH principle/work” to the Forum
 - suggest “Harmonization Approach” to the Harmonization Initiative





The Meeting

- **Date** :- September 6-7, 2006
- **Place** :- Hoi an, VIETNAM
- **Participants** :- over 100 from 15 economies
- **Host** :-
- **Organizer** :-