



18™ ASIAN HARMONIZATION WORKING PARTY ANNUAL MEETING 17™ AHWP TECHNICAL COMMITTEE MEETING 1ST AHWP-RAPS JOINT CONFERENCE

Quan Tran Vice President, QARA GE Healthcare APAC

AHWP-RAPS Joint Regulatory Conference Dec 2-3, Kuala Lumpur, Malaysia

Purpose

- ✓ To discuss issues related to developing regulatory capacity & capability related to medical devices, among countries/regions w established & developing regulatory agencies.
- ✓ To establish a platform for education, training, exchanges, dialogue & collaboration w multi-disciplines of Healthcare professionals, regulators & industry towards greater regulatory convergence
- ✓ To expand AHWP global presence through the organization of a Joint AHWP/RAPS Regulatory Affairs Conference



- 327 delegates
- 32 Countries from Asia, Middle East, Africa, USA & Europe regions

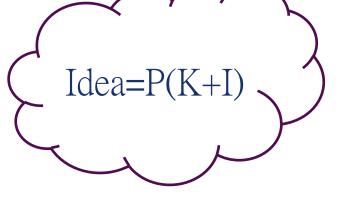


AHWP-RAPS Joint Regulatory Conference Dec 2-3, Kuala Lumpur, Malaysia

1.5 days event & exhibition

- ✓ Opening session
 - Innovation & Global Regulatory Landscape
 - Device Innovation & Regulatory Controls. Is a new paradigm needed?
- ✓ 2 Plenary sessions
 - Regulatory Convergence What is Next?
 - Implementation & Regulatory Capacity
- ✓ 5 Key themes w 12 expert speakers
 - 1. Building a Regulatory Framework- The ASEAN Experience
 - 2. Medical Device Single Audit Program (MDSAP)
 - 3. Building a Regulatory Framework-Essential Elements of Compliance/Surveillance
 - 4. UDI-Purpose, Implementation and Challenges
 - 5. Postmarket Surveillance: Changing Global Perspective

"Innovation & Global Regulatory Landscape" by Fredrik Haren

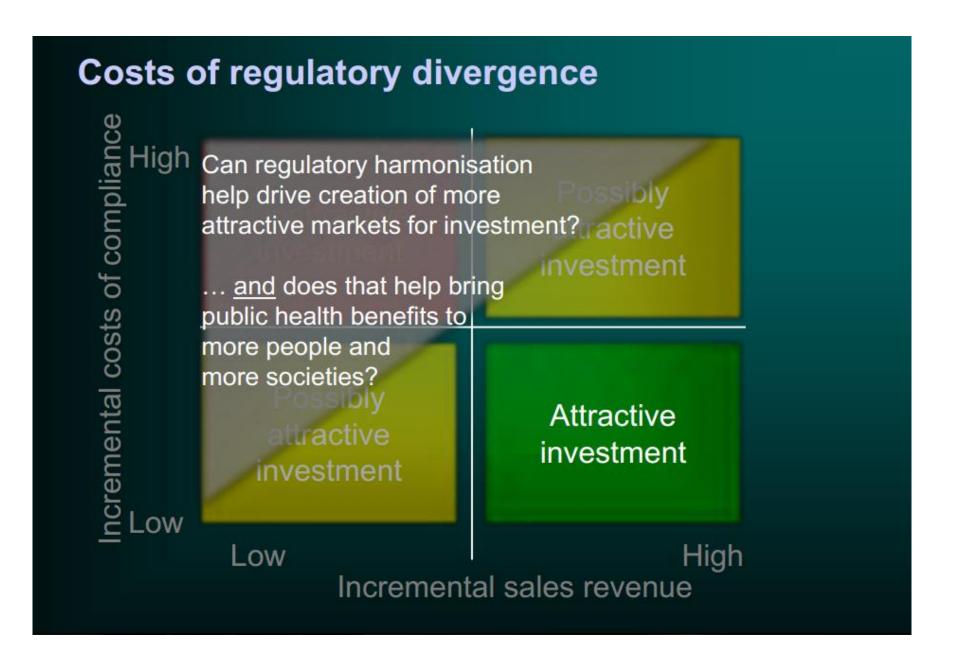


People from developing economy is better place for the explosive change vs developed world has slowed down innovation because they think they are done



Asian has low creativity confidence, but has potential to be creative

Copying vs Copying right



Source: by Michael Gropp, 2013

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Feedback

- ✓ Joined conference is very good model
- Creative open plenary brought new perspective
- ✓ Interesting topics ··· good insights
- ✓ Link RA with business ··· making sense to biz



 Good to have handout before conference

Like

Share more RA from different perspective