



Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



REGULATORY AFFAIRS  
PROFESSIONALS SOCIETY  
*Driving Regulatory Excellence™*

18<sup>TH</sup> ASIAN HARMONIZATION WORKING PARTY ANNUAL MEETING  
17<sup>TH</sup> AHWP TECHNICAL COMMITTEE MEETING  
1<sup>ST</sup> AHWP-RAPS JOINT CONFERENCE

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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

$$\text{Idea} = P(K+I)$$

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

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



Copying vs  
Copying right

# Costs of regulatory divergence



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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
- Share more RA from different perspective