# Updates on AHWP 2015

Jeong Hee Kyo

Abdul Rahman Zamane

Tran Quan

20th AHWP Annual Meeting

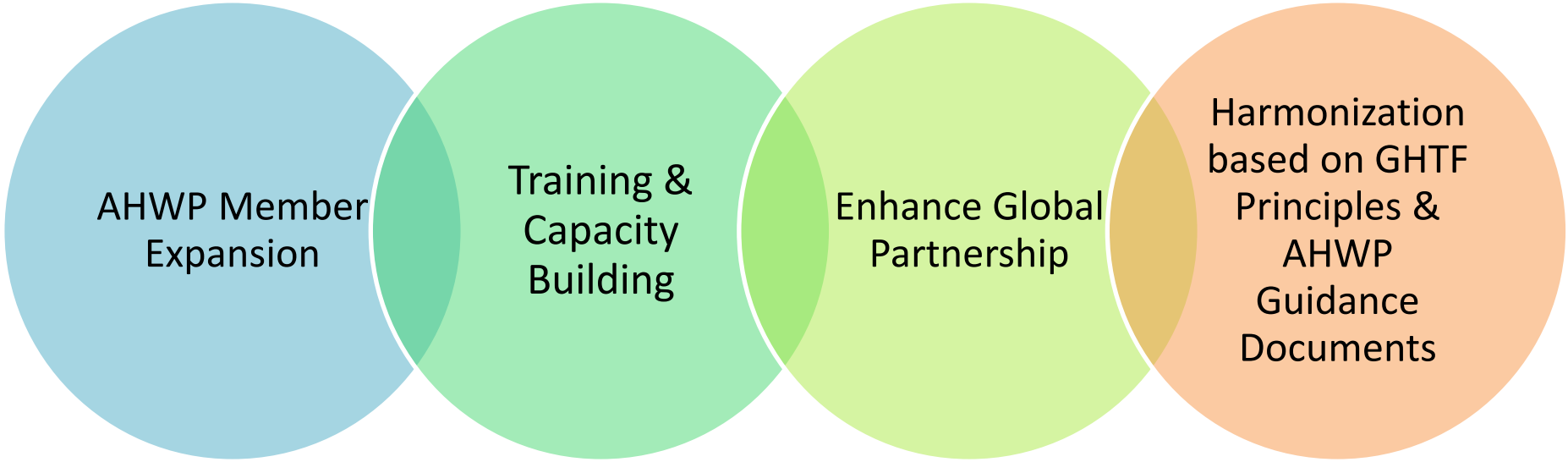
6 Nov 2015, Bangkok, Thailand

AHWP Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# AHWP Strategic Framework
# Harmonization & Regulatory Convergence

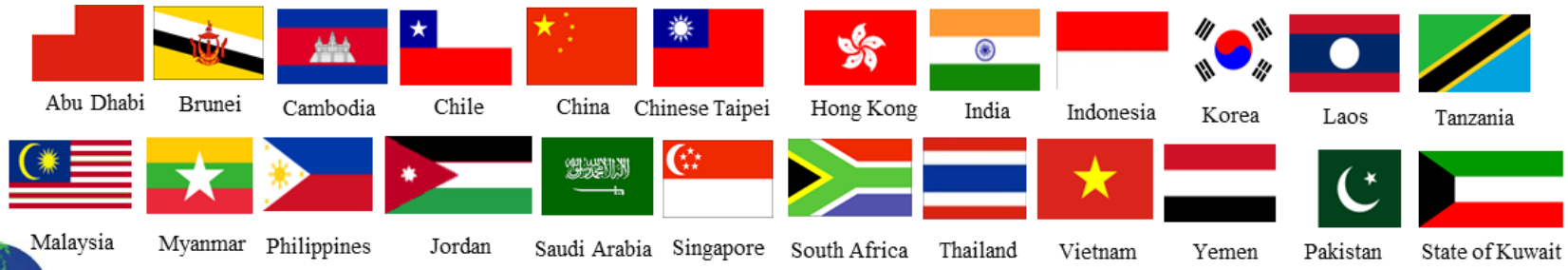
4 Framework Elements:




ASIAN HARMONIZATION WORKING PARTY

# AHWP Member Expansion

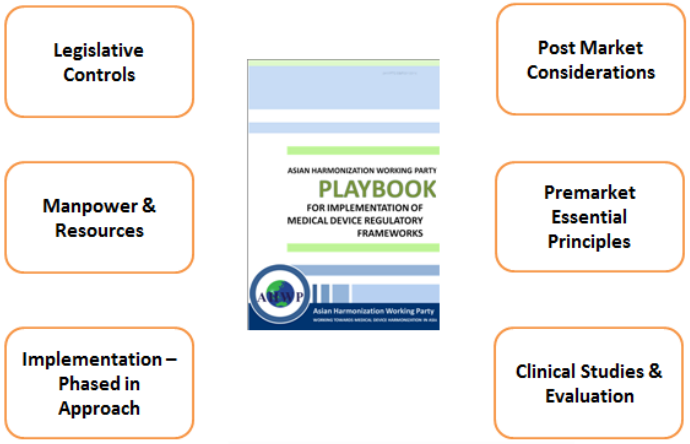
- Currently 24 Member Economies
  - Tanzania, the newest member economy joined in 19th AHWP meeting, Seoul
- Membership applications for endorsement at 2015 Annual Meeting:
  - Mongolia, Kazakhstan
- More countries considering AHWP Membership




AHWP
ASIAN HARMONIZATION WORKING PARTY

# Training and Capacity Building

- AHWP Training Workshop – 2-4 Nov
  - AHWP Playbook  Workshop (1.5 days)
  - Post-market
  - Clinical Evaluation
  - Patient Registries
  - MDSAP
  - Quality Management  System Audit
  - Medical Device Software – AHWP-DITTA Workshop (0.5 days)




- AHWP Capacity Building – Leadership Roundtable
- Capacity Building Project to be endorsed in the 20th AHWP Annual Meeting

ASIAN HARMONIZATION WORKING PARTY

# Enhance AHWP's Global Partnership

- AHWP as an affiliate organization to IMDRF
  - AHWP leadership presented at 7th & 8th IMDRF meetings
- AHWP Liaison member: **DITTA**, **GS1**
  - **DITTA**: Joint workshop with AHWP on Software as a Medical Device
- 20th AHWP Annual Meeting – Presentation by:
  - APEC
  - WHO
  - ASEAN MDPWG
  - IEC
  - PAHWP
- AHWP Playbook presented at 1st Mena conference


ASIAN HARMONIZATION WORKING PARTY

# Harmonization in Key Areas Based on GHTF Principles and AHWP Guidance

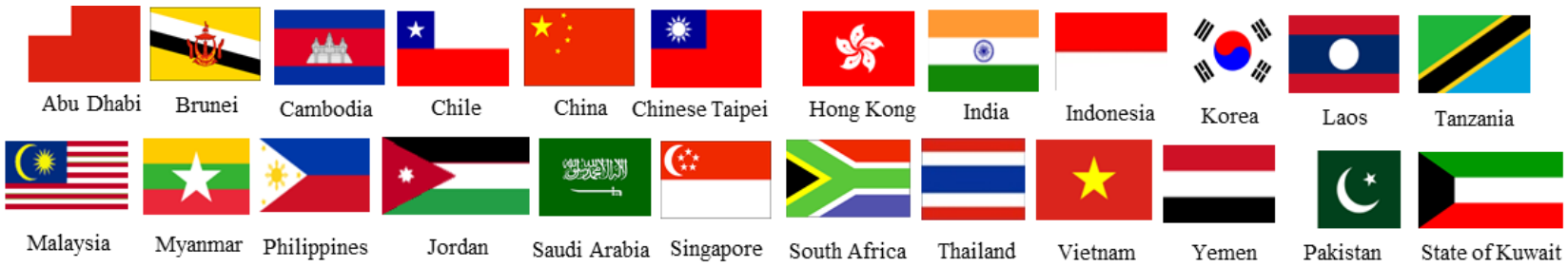
- Draft AHWP Guidance Documents & Reference Documents to achieve harmonization in key areas of medical device

- 13 guidance papers developed by Technical Committee to be endorsed in 2015 in the following areas:
  - Pre-market CSDT Guidance
  - Pre-market submission – IVDD Definitions
  - Qualification and Classification of Medical Device Software
  - Post-market surveillance on AE Reporting
  - Clinical Evidence on IVD Medical Devices
  - Regulatory Audit Report
  - Medical Device Nomenclature

AHWP
ASIAN HARMONIZATION WORKING PARTY

# Area of Focus - 2016

- AHWP Capacity Building , from Strategy to Implementation
  - Build on the foundation of AHWP Playbook
  - In-country training
- Review Strategic Framework elements
  - Direct resources to better support member economies
  - Meaningful international collaboration and liaison




ASIAN HARMONIZATION WORKING PARTY

# Together We Go Far

ASIAN HARMONIZATION WORKING PARTY