

Tran Quan

VP Regulatory Affairs, APACMed



- Masters in Clinical Pharmacy, London School of Pharmacy
- 29 years in Healthcare
- Previous experience includes Hospital pharmacy management; senior Regulatory, Clinical & Quality roles in multinational pharmaceutical and medical device companies such as GSK, J&J and GE
- Currently Vice Chair of the Asia Harmonization Working Party (AHWP) of 26 member economies, Regulator and Industry group of Asia, Middle East, South America and Africa region. Also represent APACMed as the Industry Coalition Lead for APEC RHSC

AHWP Update

The Road to Harmonization

Tran Quan

AHWP Vice-Chair (Industry)

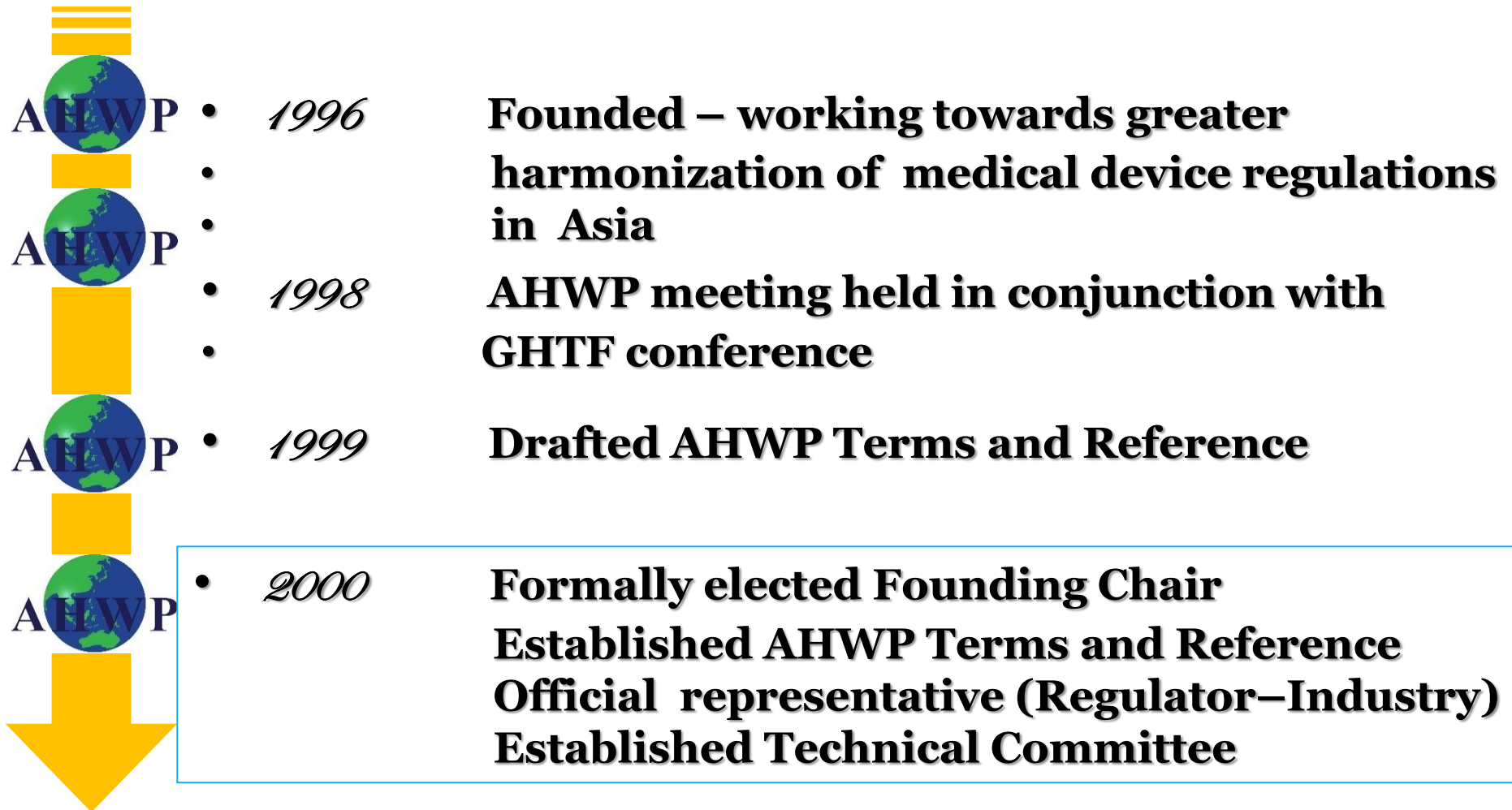
VP of Regulatory Affairs, APACMed

25 November 2016



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

In the beginning...



The Work of Two Decades

- *2016* **AHWP Vision & Mission to be endorsed**



MORE TRAINING in future...

AHWP Annual Meetings Footprint



Global Participants > 5000

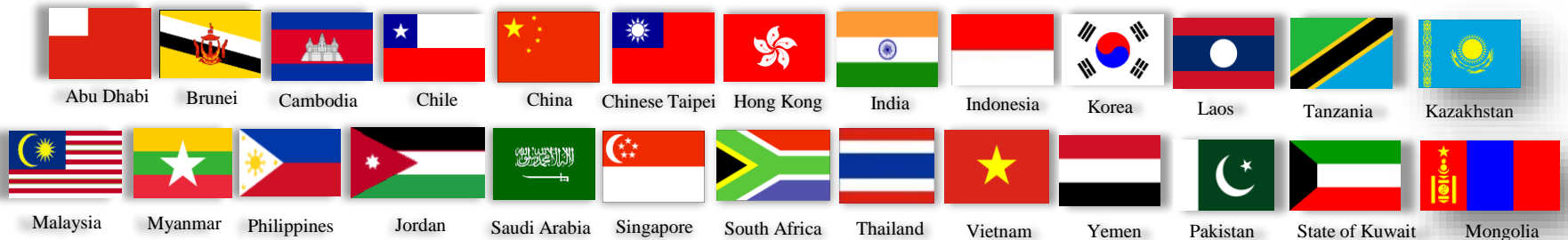
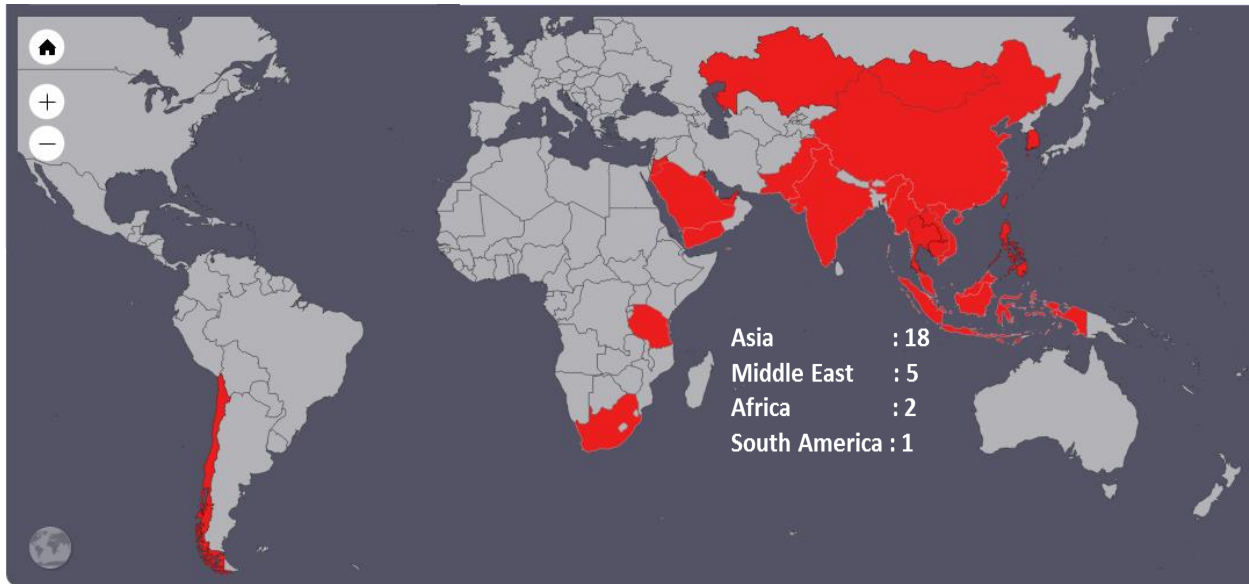
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|----------------------------------|--|--|
| • 1998 4 th Australia | • 2002 9 th Singapore | • 2010 15 th Saudi Arabia |
| • 1999 5 th USA | • 2005 10 th Malaysia | • 2011 16 th Indonesia |
| • 2000 6 th Canada | • 2006 11 th Korea | • 2012 17 th Chinese Taipei |
| • 2000 7 th Singapore | • 2007 12 th China | • 2013 18 th Malaysia |
| • 2001 8 th Malaysia | • 2008 13 th India | • 2014 19 th Korea |
| • 2002 9 th Singapore | • 2009 14 th Hong Kong, SAR PRC | • 2015 20 th Thailand |
| | | • 2016 21 th Philippine |

From Strategy to Implementation

- Next 5 years...



Expansion of AHWP Member Economies



- 26 member economies as of September 2016
- 4 new member applications from Africa and Middle-East
- Asia, Middle East, South America. Middle-East

AHWP Global Collaboration



Capacity Building and Training



AHWP Meeting
2-3 Nov
Thailand



2016

Phase II

- Build Curricula
- Develop Competency Assessment Tools



IMPLEMENTATION

PLAN & TIMELINE

2015

INITIAL
KICK OFF

In-country Training

- 28 – 29 July, Indonesia
- 25 – 26 August, Vietnam

Training Workshop Annual Meeting

21 – 25 Nov, Philippines

2017

NEXT PHASE

Harmonization

Timely access to Safe and Quality products

Future

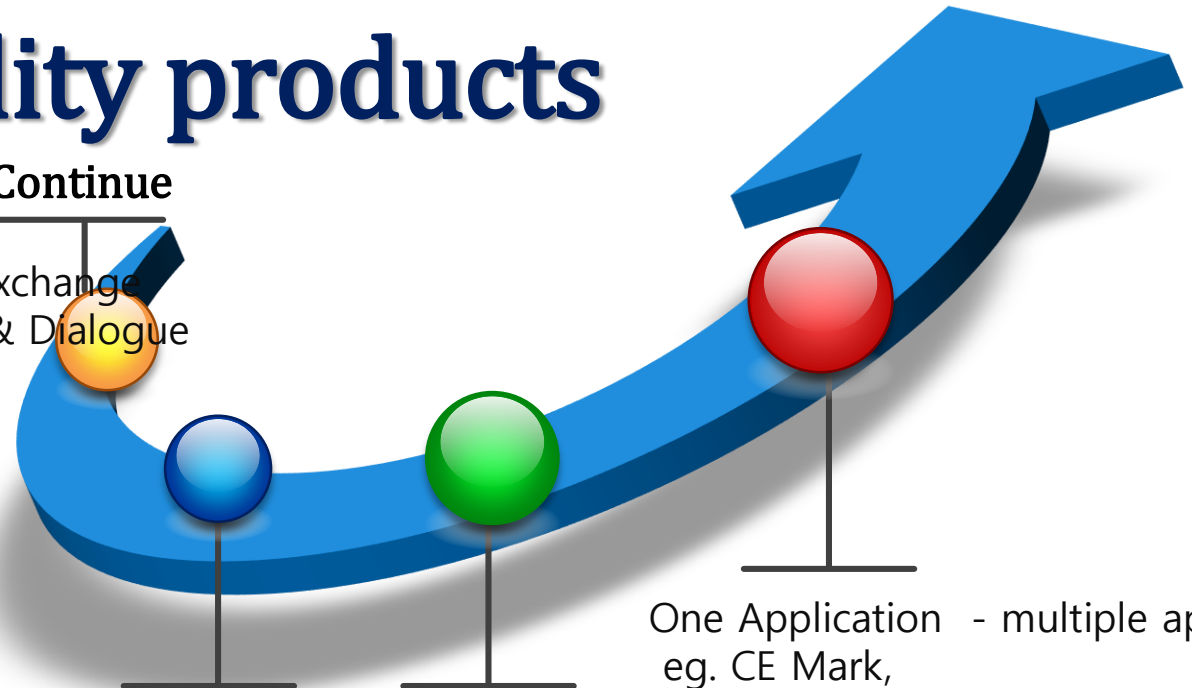
Continue

- International Collaboration
- Platform for information exchange
- Stakeholder Engagement & Dialogue
- Capacity building
- Share of best practice

Reliance

Mutual recognition
Eg. EU-TGA

One Application - multiple approval
eg. CE Mark,



Appendix

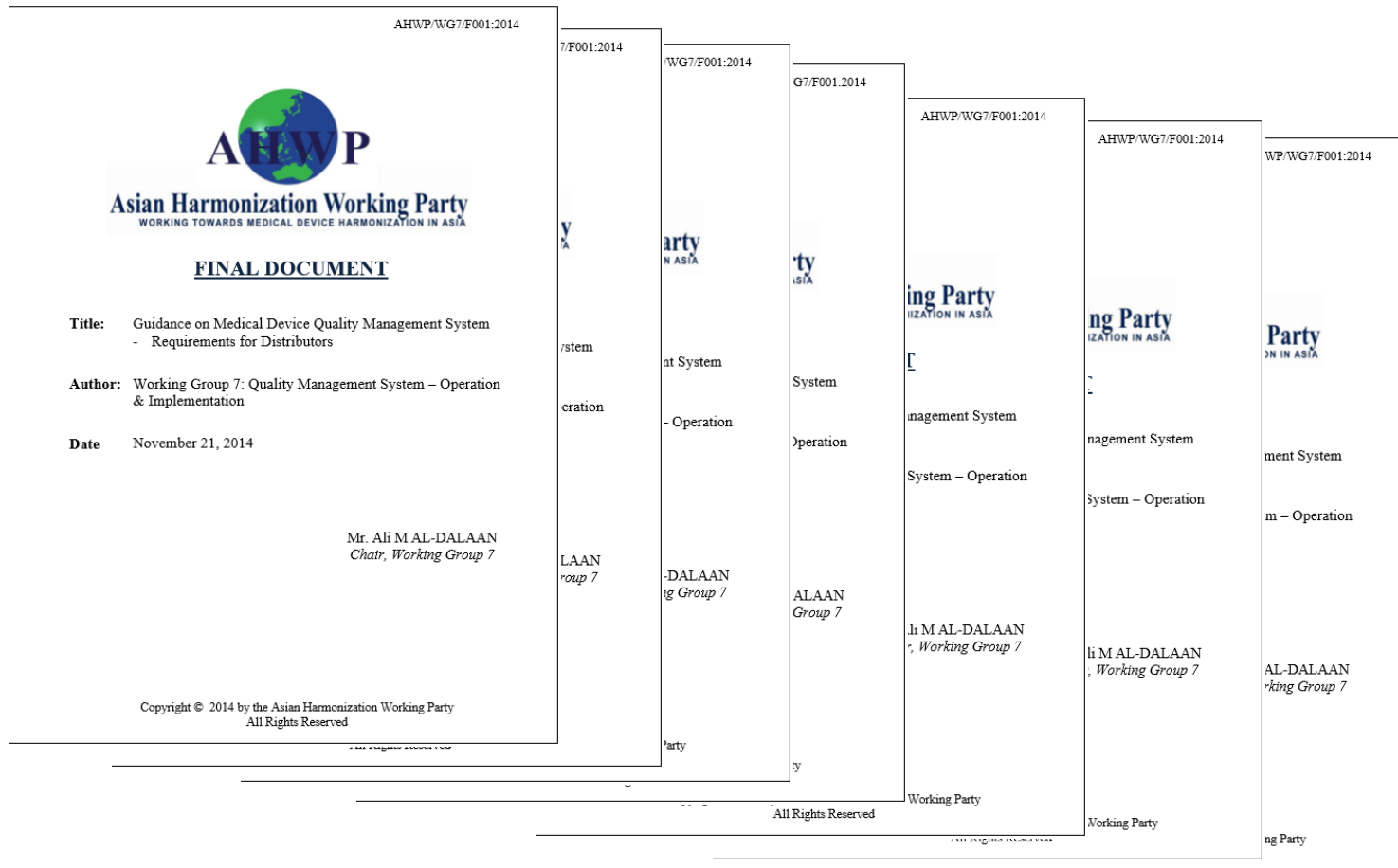
The Work of Two Decades

- *2014* **Published AHWP Playbook**



The Work of Two Decades


- *2015* **Published 32 Guidance Document**



The Work of Two Decades

- *2016* **New Guidance document to be endorsed**

Guidance on Medical Device Quality Management System-Requirements for Distributors
Work Group 7 AHWP/WG7/P001: 2016



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED DOCUMENT

Title: Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative


Authoring Group: Work Group 7, Quality Management System: Operation & Implementation

Date: November, 2016

Aidahwaty M. Olaybal
Chair, Work Group 7

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The Work of Two Decades

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