



Ministry of Health & Family Welfare
Government of India



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



AHWP

The Road to Harmonization

2015-2017

Tran Quan

AHWP Vice-Chair (Industry)

VP of Regulatory Affairs, APACMed

8 December 2017



20th Anniversary of AHWP

Celebration Ceremony

Certificate of appreciation for all 30 members & 3 liaison members



300 International participants
40 countries



AHWP Website Enhancement

New AHWP Website for Easier Access and Better Communication



AHWP Meetings

2015

20th AHWP Annual Meeting

Nov 2-6th in Bangkok

- 241 participants, 28 countries
- 11 main themes and 6 panel discussions with 36 speakers
- 2 new member economies



TC Leaders Meeting

Mar 19-20th in Singapore



2016

21st AHWP Annual Meeting

Nov 21-25th in Cebu

- 300 participants, 40 countries
- 12 main themes and 5 panel discussions with 66 speakers
- 4 new member economies
- 1 new liaison



TC Leaders Meeting

April 27-29th in Seoul

2017

TC Leaders Meeting

Mar 2-3rd in Hong Kong

- Development of guidance documents with AHWP leaders, advisors and WG members
- International conference

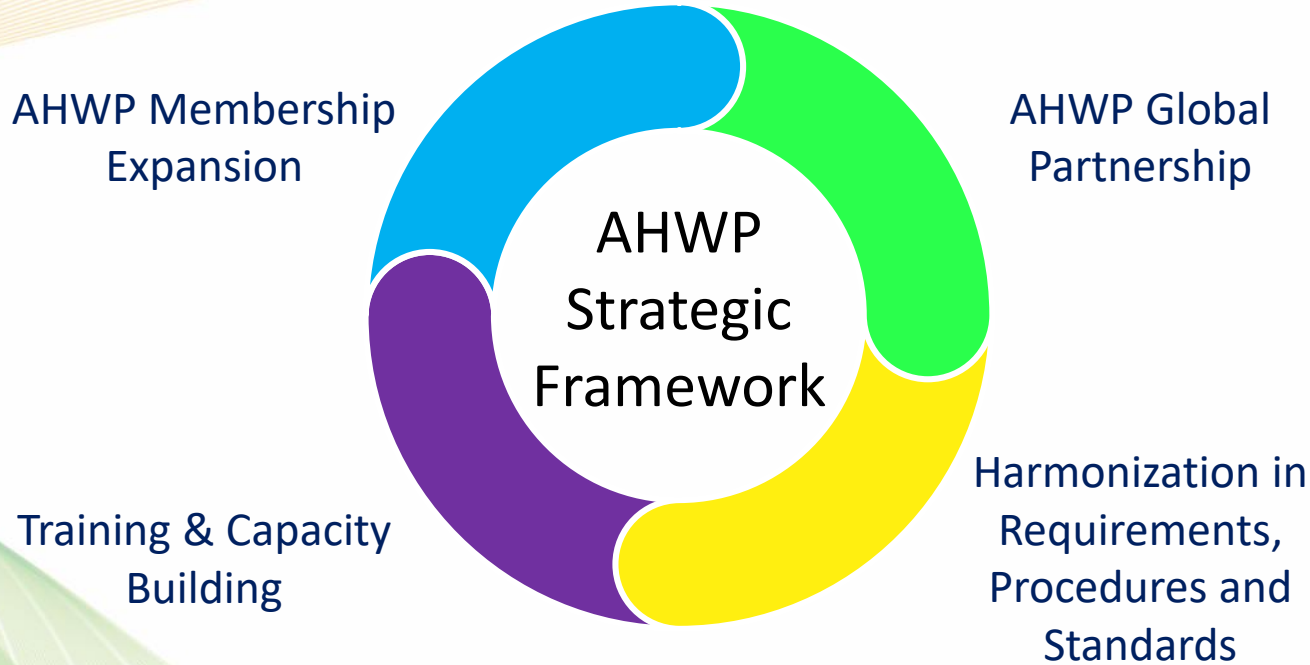


22nd AHWP Annual Meeting

Dec 4-8th, New Dehli, India



From Strategy to Implementation



AHWP Membership Expansion

2 new countries
joined in 2015



Total of 30 members
ASIA, MIDDLE EAST, AFRICA

+

1 new
application
received in 2017

4 new countries
joined in 2016



AHWP Activities with Liaisons



- GS1 training workshop
- Participation in AHWP meetings to present on updated works done by GS1



DITTA

- Annually holding an AHWP-DITTA joint workshop
- Active participation in AHWP TC working group activities

APACMed

- Participation in APACMed Forum
- Contribution to AHWP workshop & capacity building training



AHWP Global Partnership



AHWP Capacity Building Program

Overview: Kick-off CB Workshop Nov'15, Thailand; Nov'16, Philippines; Dec'17, India



Indonesia

- July 28-29th, 2016
- 50 Indonesia regulators
- 20 experts from industry
- Topics: AHWP's essential principles of safety and performance and Clinical studies



Vietnam

- August 25-26th, 2016
- 50 Vietnam regulators and experts from industry
- Topics: classification of medical devices & IVDs, pre-market approval, post-market surveillance



Malaysia

- August 10th, 2017
- 200 international regulators, experts and industry
- Topics: software, information technology, post-market considerations

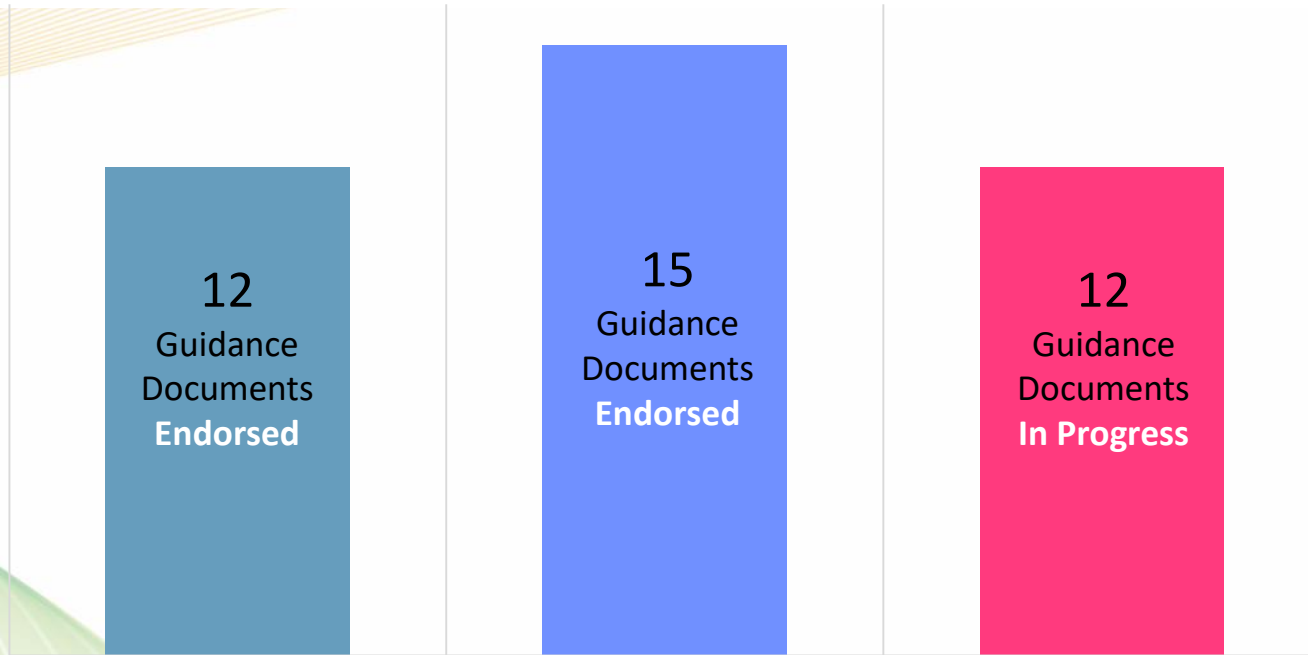


Kazakhstan

- October 23-24nd, 2017
- 25 regulators and experts from testing lab
- Topics: CSDT for premarket registration submission, Risks classification, Good distribution practice; QMS audit of manufacturing sites



AHWP Guidance Documents



2015

2016

2017

