

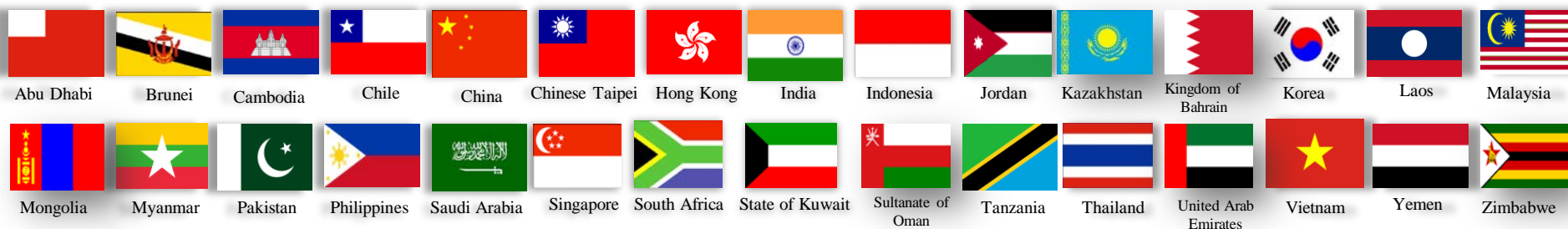
Update on AHWP Work

March 2017



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Member Economies



- 30 member economies as of March, 2017
- 4 new countries joined AHWP as member economies

AHWP Annual Meetings

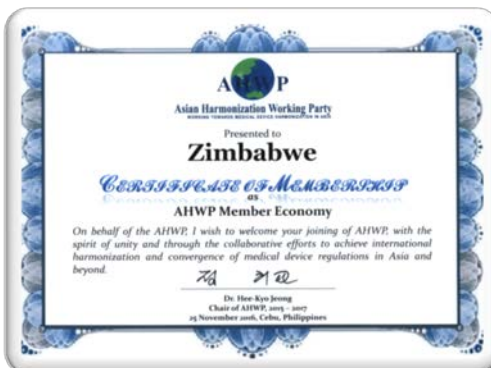
- Held on Nov 21st to 25th, 2016 in Cebu, Philippines
- About **300 Participants** from **40 different countries**
- 9 other international organizations' representatives
- 66 speakers
- 12 main themes & 5 panel discussion sessions
- 4 new member economies
- 1 new industry liaison



20th Anniversary of AHWP



AHWP handed out the certificates to all of 30 member economies as well as 3 liaison organizations, as part of our 20th anniversary celebrations



AHWP Global Partnership



AHWP Collaboration Works in 2016

IMDRF



- Participation in IMDRF meetings
- Participation of IMDRF in AHWP meeting in Cebu in Nov, 2016.
- Participation of AHWP in different IMDRF WGs :
 - ✓ RPS
 - ✓ MDSAP
 - ✓ Adverse Event Terminology

DITTA



- AHWP-DITTA Joint Workshop in Cebu in Nov, 2016

APACMed



- Participation of APACMed as a “NEW” liaison member in 2016
- Participation of AHWP in 2016 Asia Pacific Medtech Forum in Singapore in Nov, 2016

APEC



- Participation of AHWP in various APEC activities :
 - ✓ APEC Harmonization Center (AHC)
 - ✓ APEC Medical Device Vigilance Roadmap

WHO



- AHWP-WHO joint meeting for IVD PQ program in Cebu in Nov, 2016
- Participation of AHWP in WHO Technical consultation on G6PD IVDs in Geneva in Sept, 2016

IEC



- AHWP WG members participate in IEC TC activities :
 - ✓ IEC/TC62

ISO



- AHWP WG members participate in various ISO TC activities :
 - ✓ ISO/TC212
 - ✓ ISO/TC210
 - ✓ ISO/TC194

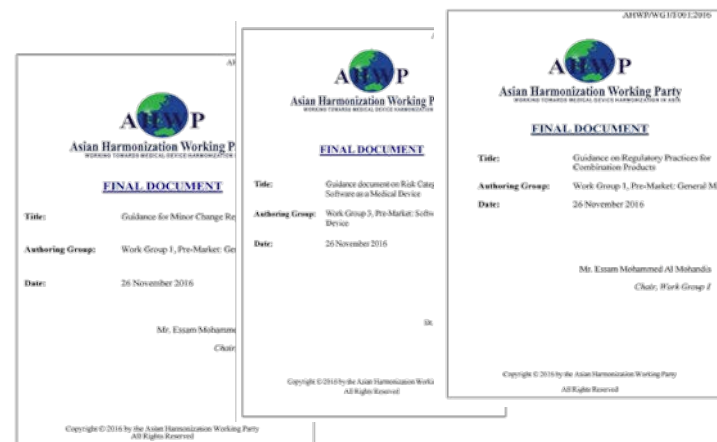


Regulatory Harmonization

2016

Published 15 Guidance Documents

- Guidance for Minor Change Reporting
- Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representatives, etc



2017

Proposed 15 New Topics for Guidance Documents

- E-labeling as an Alternate Method for Compliance to Labeling Requirement
- Post-market Clinical Follow-up Studies
- Analysis of Global and Local AE Reporting, etc



AHWP Capacity Building Project

**KICK OFF
(2015)**

**IMPLEMENTATION
(2016)**

**GROWTH
(2017~)**

Training Workshop

- AHWP Annual Meeting in Thailand



In-country Training

- Indonesia
- Vietnam

Training Workshop

- AHWP Annual Meeting in Philippines

In-country Training Plan

- Malaysia, Kazakhstan
- Thailand, Vietnam(TBC)

Training Workshop

- AHWP Annual Meeting in India

Future Plan: Phase II

- Build Curricula
- Develop Competency Assessment Tools

AHWP Website Renewal

- To enhance the effectiveness & user-friendliness of AHWP website
- To communicate & exchange information with members and stakeholders



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

[HOME](#) [CHAIRMAN'S MESSAGE](#) [HISTORICAL DEVELOPMENT](#) [MEETING CALENDAR](#) [CONTACT](#)



20th AHWP annual meeting in Bangkok, Thailand

MAIN SECTIONS:

- + About AHWP
- + Member Economies
- + Technical Committee
- + News
- + Events Announcements
- + Events
- + Documents
- + SADS On-Line
- + Trade Related Issues

19th AHWP Meeting Photos, Seoul, 18-21 Nov 2014

Submitted by admin on Wed, 11/23/2016 - 14:55

test

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STG (U&N) - Special Task Group on UDI & Nomenclature

Submitted by admin on Mon, 11/21/2016 - 06:55

STG membership status

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Work Group 8 (WG8) - Standards

[USER ACCOUNT MENU](#)

Mobile View





Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



19th AHWP Annual Conference in Seoul, Korea

LOGIN AND REGISTER

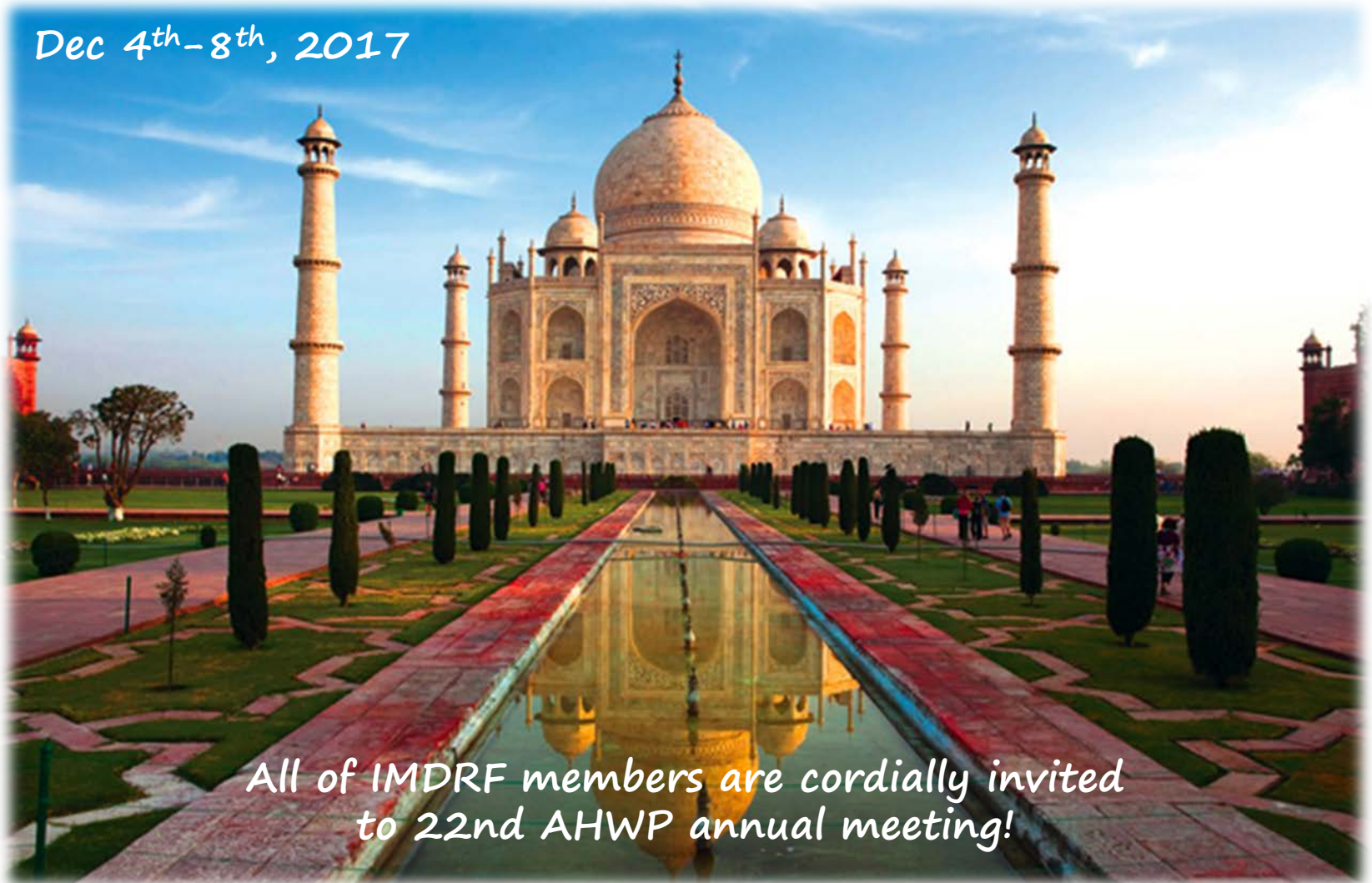
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MAIN SECTIONS:

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- + Member Economies
- + News

Upcoming 22nd AHWP Annual Meeting in Delhi, India

Dec 4th – 8th, 2017



*All of IMDRF members are cordially invited
to 22nd AHWP annual meeting!*

Thank you



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA