The Road to Regulatory Harmonization

AHWP Update

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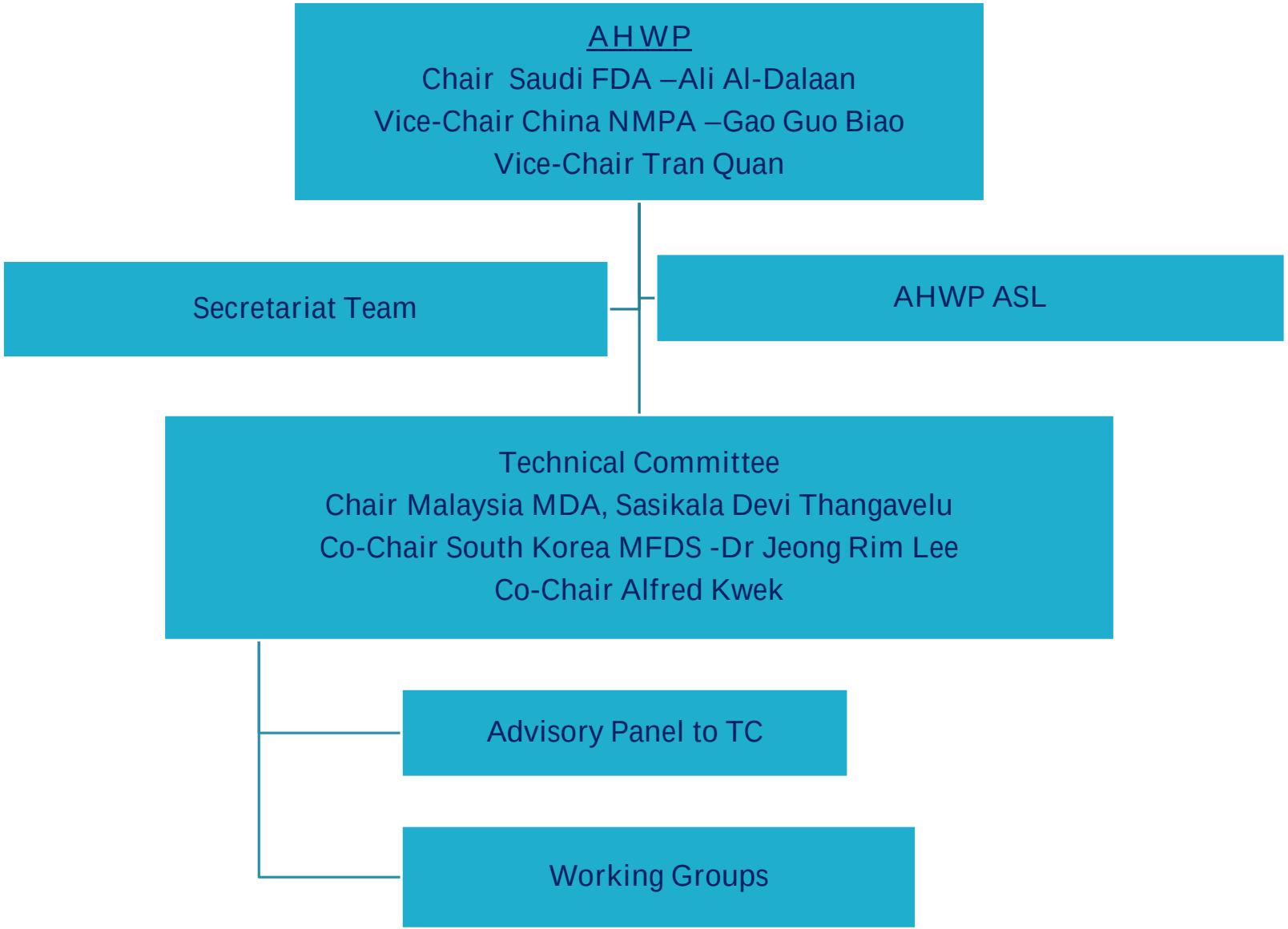
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Goals

AHWP goals are to study and recommend ways to harmonize medical device regulations in the Asia and other continents and to work in coordination with the International Medical Device Regulators Forum (IMDRF), APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

AHWP 2018-2020 Term



Current AHWP Membership

AHWP Member Country or Region: 31 (22 Years)

Brunei Darussalam	Kingdom of Saudi Arabia	Singapore
Cambodia	Kyrgyz Republic	South Africa
Chile	Republic of Korea	State of Kuwait
Chinese Taipei	Laos	Sultanate of Oman
Hong Kong SAR, China	Malaysia	Tanzania
India	Mongolia	Thailand
Indonesia	Myanmar	United Arab Emirates
Jordan	Pakistan	Vietnam
Kazakhstan	People's Republic of China	Yemen
Kingdom of Bahrain	Philippines	Zimbabwe
	Republic of Kenya	

Asia, Middle East, Africa, S. America

23rd AHWP Annual Meeting

October 22-25, 2018, Kuala Lumpur, Malaysia

- AHWP Annual Meeting
  - Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
  - Joint workshop plans with liaisons
  - Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation

AHWP TC Meeting - Riyadh (9-10 April 2019)

- AHWP Technical Committee Short-term & long-term Plans update
  - Guideline topics and development plans by each WGs
  - Development of Competency Handbook by AHWP TC
  - In-country training plans

AHWP - Strategic Framework Towards 2020

Key Elements:

- ❑ Training and Capacity Building
- ❑ Develop AHWP Competency hand book
- ❑ Harmonization in Key Areas based on IMDRF Principles and AHWP Guidance

Collaborating Activities

- TC Tele-conference, Jan 2018
- TC Leaders Meeting, May 2018,Beijing
- TC Tele-conference, Q3, 2018
- TC Annual Meeting, Oct 2018, Malaysia
- TC Leaders Meeting, April 2019 Riyadh

3-year Work Plan

- Development of AHWP Guidelines
- Pre- and post-market control, UDI
- QMS, Clinical evidence, Standards

Capacity Building Program

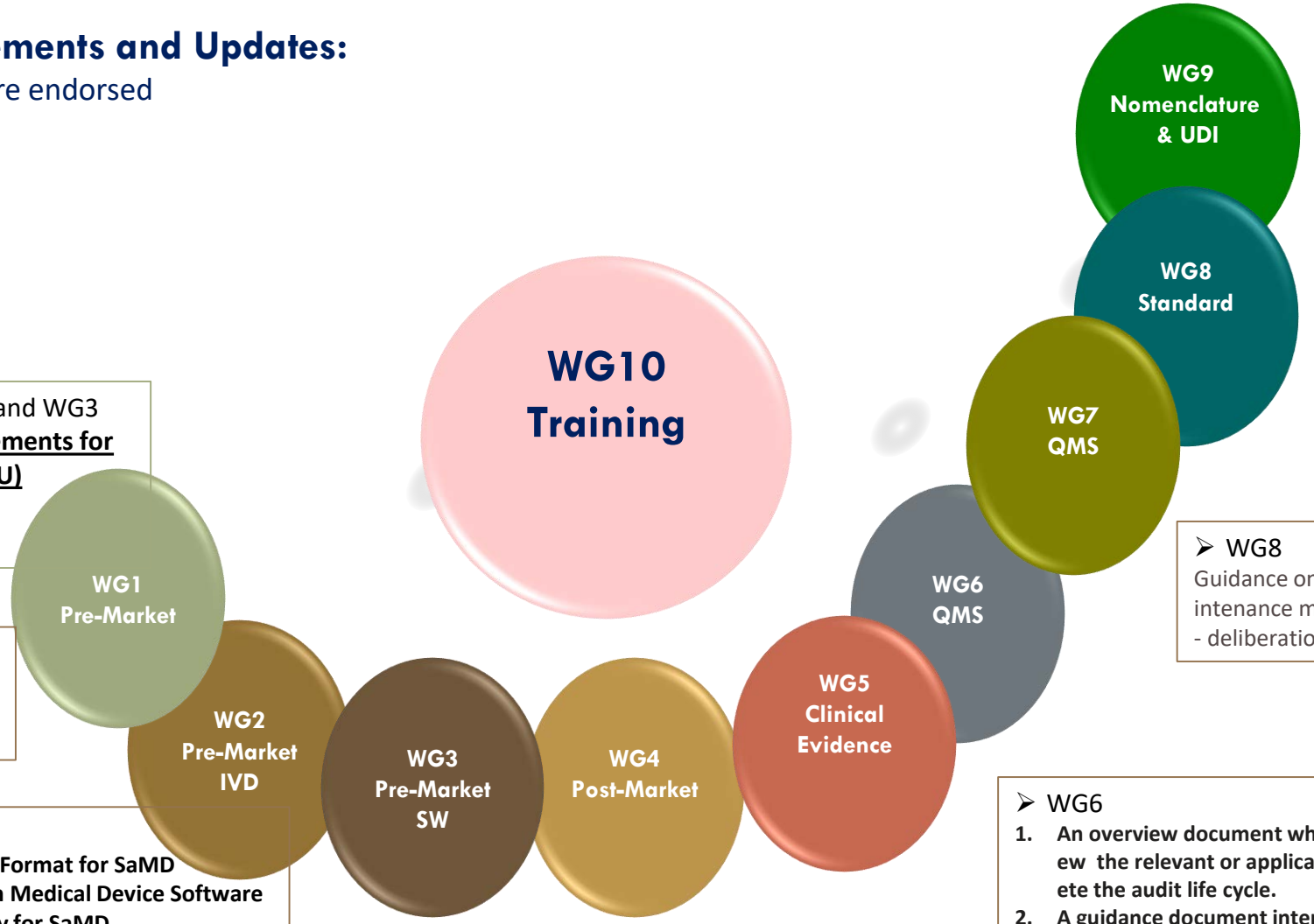
- In-country Trainings
- Implementation of Guidelines
- Regulatory Competency Handbook

DEVELOPMENT & IMPLEMENTATION OF AHWP GUIDANCE

AHWP WG Achievements and Updates:

Guidance documents were endorsed

- 12 in 2015
- 15 in 2016
- 3 in 2017
- 5 in 2018
- 7-8 in 2019



- **AHWP UDI Whitepaper** by WG9
- Target endorsement at 2019 Annual meeting

- WG1 in collaborating with WG2 and WG3
- **Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)**
- Target endorsement at the 2019 Annual Meeting

- WG8

Guidance on Code of practice for good engineering maintenance management of medical devices,
- deliberation is still in progress

- WG2 in collaboration with WG1 and WG3
- **Change Management Document (ongoing)**

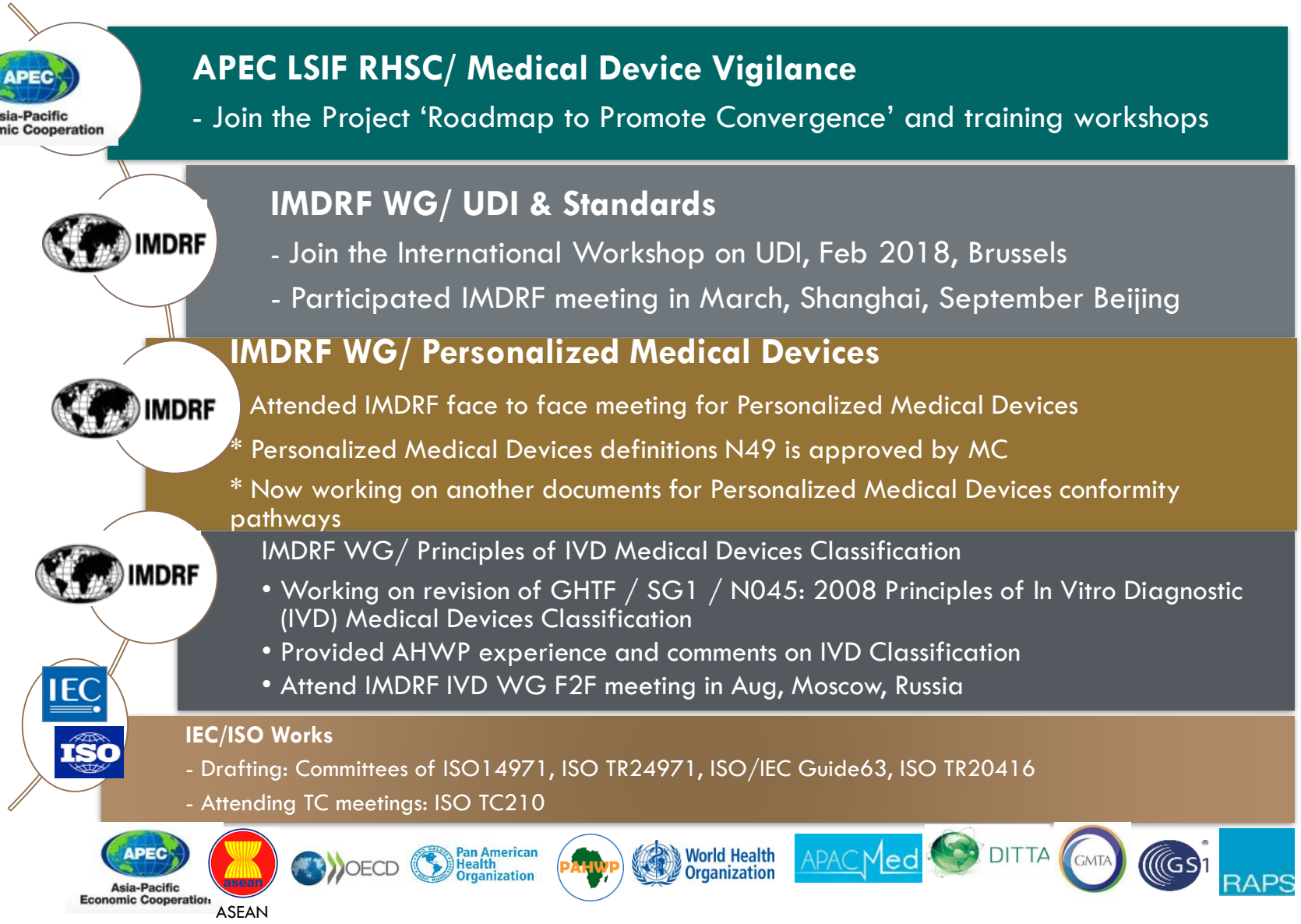
- WG3
- **Guidance for Pre-Market Submission Format for SaMD**
- **Guidance for Review and Approval on Medical Device Software**
- **Guidance document on Cyber Security for SaMD**
- Drafting phase

- WG6

1. **An overview document which will allow the Regulatory authority to view the relevant or applicable IMDRF documents which serve to complete the audit life cycle.**
2. **A guidance document intended as overview document for audit duration calculation.**

Target endorsement at 2019 Annual meeting

Continuous Efforts for Global Harmonization



Collaboration with the OECD

The Contribution of Trans-Governmental Networks of Regulators to International Regulatory Co-operation


OECDpublishing

Please cite this paper as:

Abbott, K., C. Kauffmann and J. Lee (2018), "The contribution of trans-governmental networks of regulators to international regulatory co-operation", *OECD Regulatory Policy Working Papers*, No. 10, OECD Publishing, Paris. http://dx.doi.org/10.1787/538ff99b-en

OECD Regulatory Policy Working Papers No. 10

The contribution of trans-governmental networks of regulators to international regulatory co-operation

Kenneth W. Abbott, Céline Kauffmann, Jeong-Rim Lee

JEL Classification: F5, F53, F55, F59, H7, K2, K33

OECD

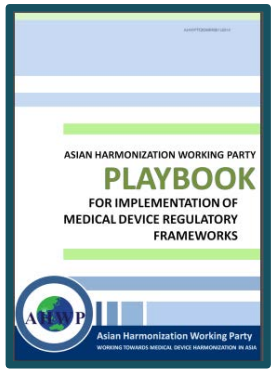
A Case Study of the AHWP on Medical Devices

1. Overview	- History - Intended objectives of regulatory co-operation - Landscape of regulatory actors - Collaboration with other IOs
2. Governance & Operational Modalities	- AHWP Membership - Structure and governance - Institutional setup - The range of AHWP instruments - Implementation mechanism (CBP) - Quality mechanism of instruments
3. Assessment	- Benefits - Challenges

Participation in publishing the OECD Report (2018)

Enhancing Regulatory Agencies and Industries
Our Capacity Building Journey

2014 - 2017	2018 - 2019



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

BỘ Y TẾ MINISTRY OF HEALTH

Government of India Ministry of Health & Family Welfare Department of Health & Family Welfare

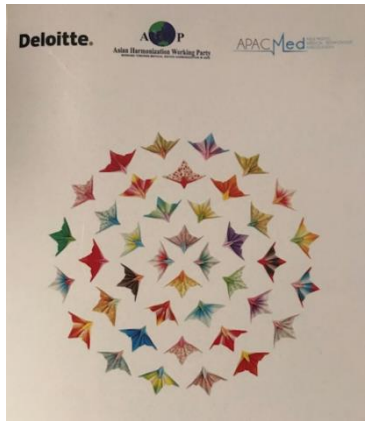
MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN

สำนักงานคณะกรรมการอาหารและยา Food and Drug Administration

FDA Food and Drug Administration PHILIPPINES

Medical Device Authority Ministry of Health Malaysia

Competency Framework for Medical Technology Regulators



สำนักงานคณะกรรมการอาหารและยา Food and Drug Administration

Thailand in-country regulator training – 35 participants

White Paper

1. Approach to Develop the Competency Framework
2. Survey Findings
3. Introducing Framework
4. Guidelines on Use of Framework

Webinar

AHWP Capacity Building Projects

3 Capacity Building Workshops & 4 In-country Trainings (2015-2017)

- CB Workshops: Thailand Nov'15; Philippines Nov'16; India Dec'17
- In-country Trainings: Indonesia '16; Vietnam '16; Malaysia '17; Kazakhstan '17
- Topics: CSDT for pre-market registration submission, Risk classification, Good distribution practice, QMS audit, SW, Information technology, Post-market considerations

2018

- In-country trainings
- Republic of Kenya (TBD)
- Thailand

ASIAN HARMONIZATION WORKING PARTY

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

Deloitte.

Launch Competency Framework for MedTech Regulators

A joint initiative of AHWP, APACMed and Deloitte

AHWP – TC Strategic Plan 2019-2020

GOAL1

To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

GOAL2

To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

GOAL3

To promote capacity building in member economies and to foster strategic membership expansion.

GOAL4

To work in collaboration with related international organizations such as International Medical Device Regulators Forum(IMDRF), WHO, ISO, IEC.

AHWP – TC Strategic Plan 2019-2020

The 24rd AHWP Annual Meeting & The 23rd AHWP TC Meeting

Sultanate of Oman, Muscat
November 11th – 14th, 2019

AHWP Capacity building Workshop,
Technical Committee Workshop
Joint Sessions with liaison members,
Technical Committee meeting
AHWP Annual meeting

Thank you