AHWP UPDATE

September 2018

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Current AHWP Membership

AHWP Member Country or Region: 30 (as of Mar 2018)

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

Continuous Efforts for Global Harmonization

IMDRF WG/ UDI

- Join the International Workshop on Global Use & Application of UDI, Feb 12th 2018, EC, Brussels, Belgium

IMDRF WG/ Personalized Medical Devices

- Participation in drafting report and tele-conferences

IMDRF WG/ Standards

- F2F meeting will be held parallel to AHWP annual meeting in Malaysia
- IMDRF representative will participate in AHWP sessions to make a presentation on Standards

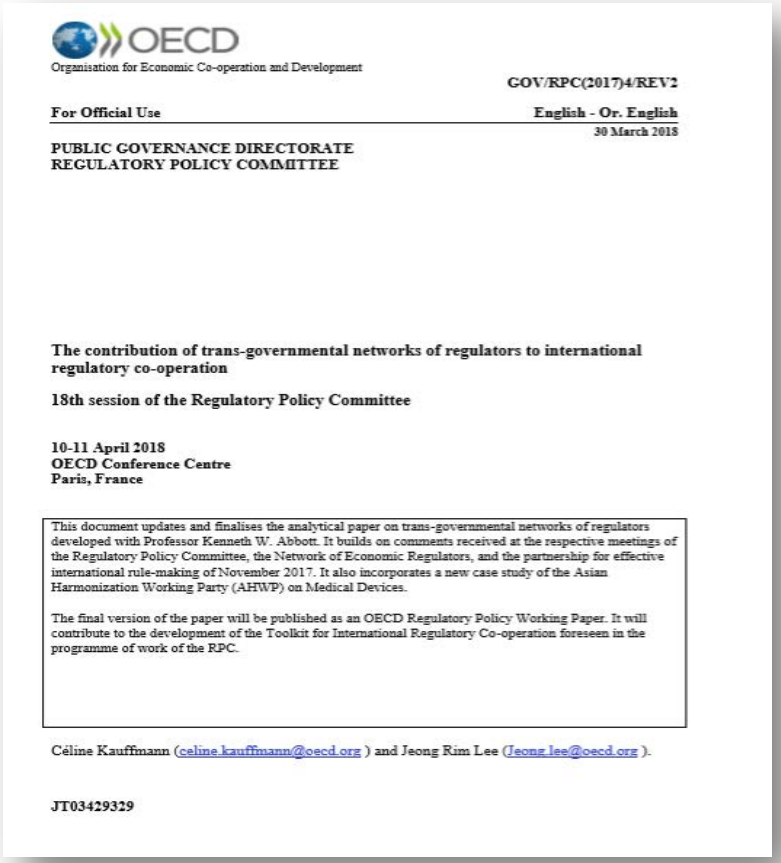
IEC/ISO Works

- Drafting: Committees of ISO14971, ISO TR24971, ISO/IEC Guide63, ISO TR20416
- Attending TC meetings: ISO TC210

APEC Asia-Pacific Economic Cooperation · ASEAN · OECD · Pan American Health Organization · PAHWP · World Health Organization · APACMed · DITTA · GMTA · GS1 · RAPS

Collaboration with the OECD

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



OECD
Organisation for Economic Co-operation and Development

GOV/RPC(2017)4/REV2

For Official Use — English - Or. English

30 March 2018

PUBLIC GOVERNANCE DIRECTORATE
REGULATORY POLICY COMMITTEE

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

18th session of the Regulatory Policy Committee

10-11 April 2018
OECD Conference Centre
Paris, France

This document updates and finalises the analytical paper on trans-governmental networks of regulators developed with Professor Kenneth W. Abbott. It builds on comments received at the respective meetings of the Regulatory Policy Committee, the Network of Economic Regulators, and the partnership for effective international rule-making of November 2017. It also incorporates a new case study of the Asian Harmonization Working Party (AHWP) on Medical Devices.

The final version of the paper will be published as an OECD Regulatory Policy Working Paper. It will contribute to the development of the Toolkit for International Regulatory Co-operation foreseen in the programme of work of the RPC.

Céline Kauffmann (celine.kauffmann@oecd.org) and Jeong Rim Lee (Jeong.lee@oecd.org).

JT03429329

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 drafting the 2nd OECD Report (2017 - 2018)
- Introduction at the OECD meeting (2018)

AHWP TC Leaders Meeting in 2018

May 8th - 9th 2018, Beijing, China

- **AHWP Technical Committee Short-term & long-term Plans**
  - Guideline topics and development plans by each WG
  - Development of Competency Handbook by AHWP TC
  - In-country training plans
  - Introduction of OECD case study

- **AHWP Annual Meeting Plans**
  - Participation in global events (IMDRF, WHO, APEC, OECD, etc)
  - Joint workshop plans with liaisons
  - Meeting program agenda
  - Progress of AHWP website update

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 (Oct, TBD)

AHWP ASIAN HARMONIZATION WORKING PARTY

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

Deloitte.

Launch Competency Framework for MedTech Regulators

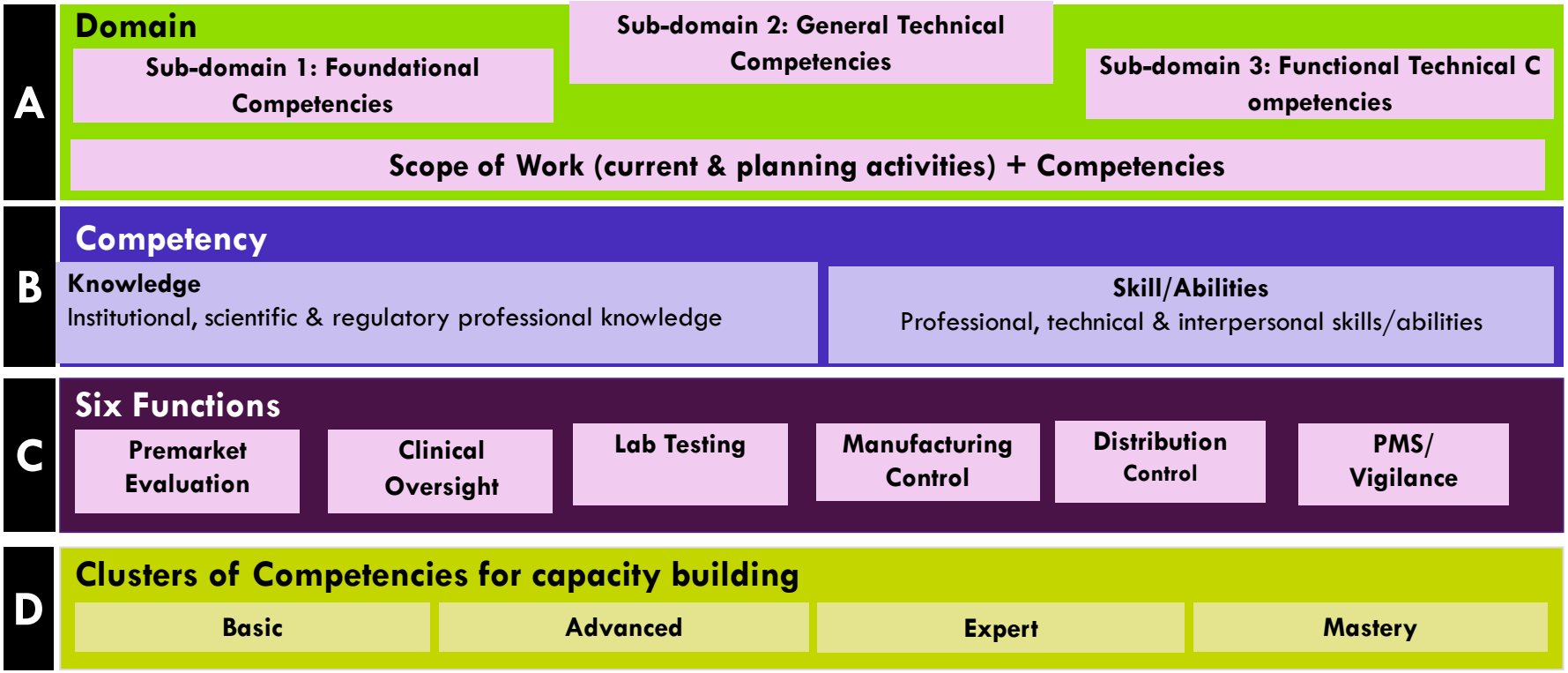
A joint initiative of AHWP, APACMed and Deloitte

Competency Handbook for Medtech Regulators

PROJECT SCOPE:

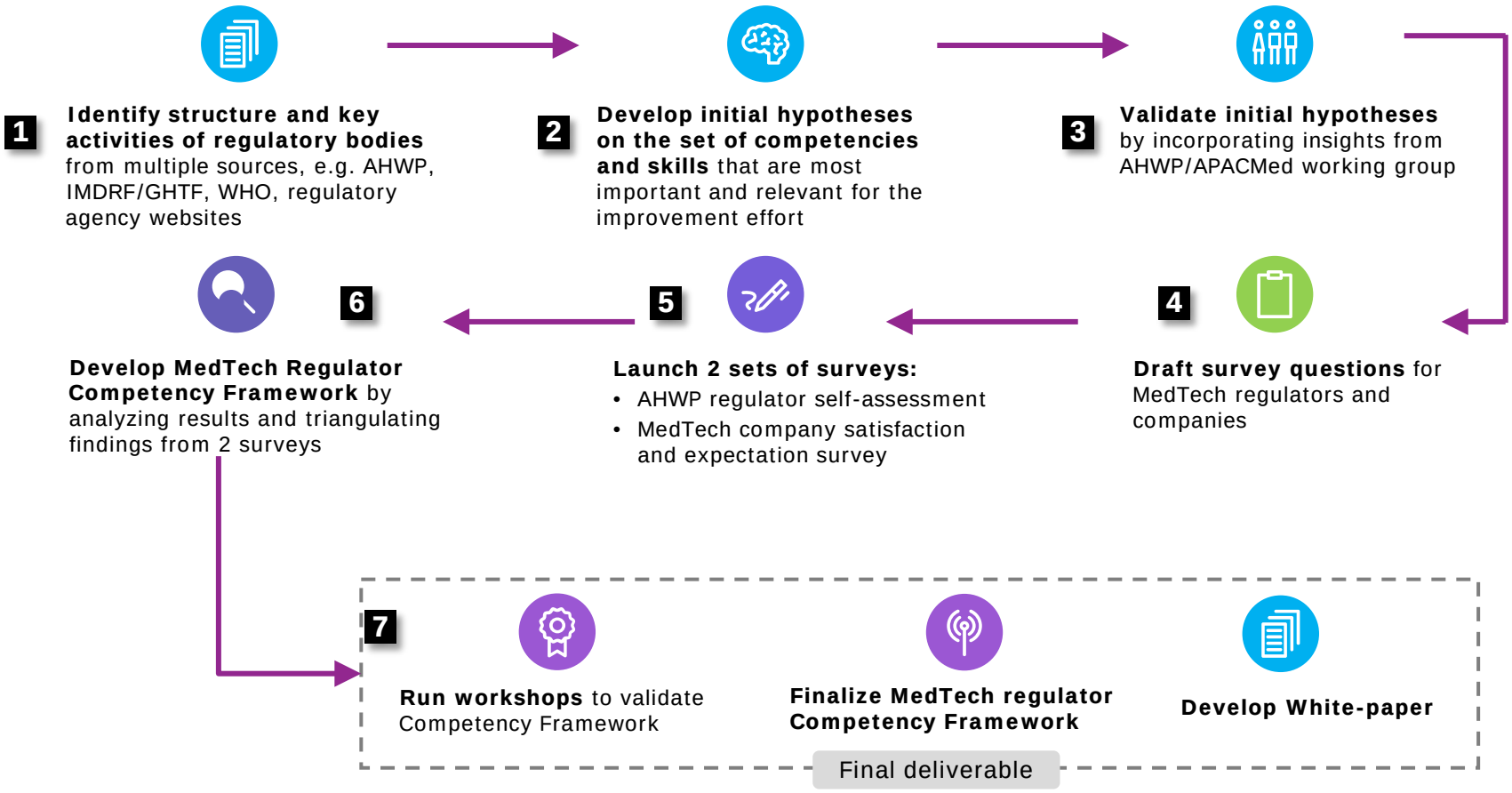
- AHWP survey for regulators among its 30 member countries and regions
- APACMed launching similar survey among companies to assess satisfaction & expectation

High-Level Competency Framework for MedTech Regulators



Competency Handbook for Medtech Regulators

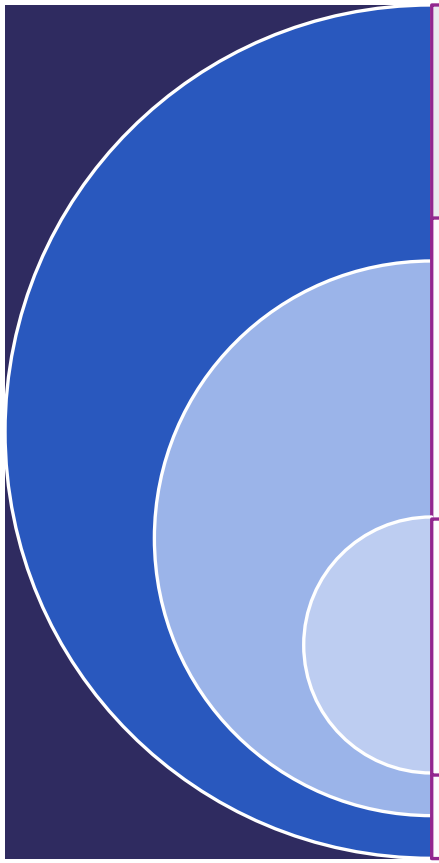
METHODOLOGY & PROCESS



AHWP TC PLAN

2018 - 2020

AHWP TC Strategic Plan



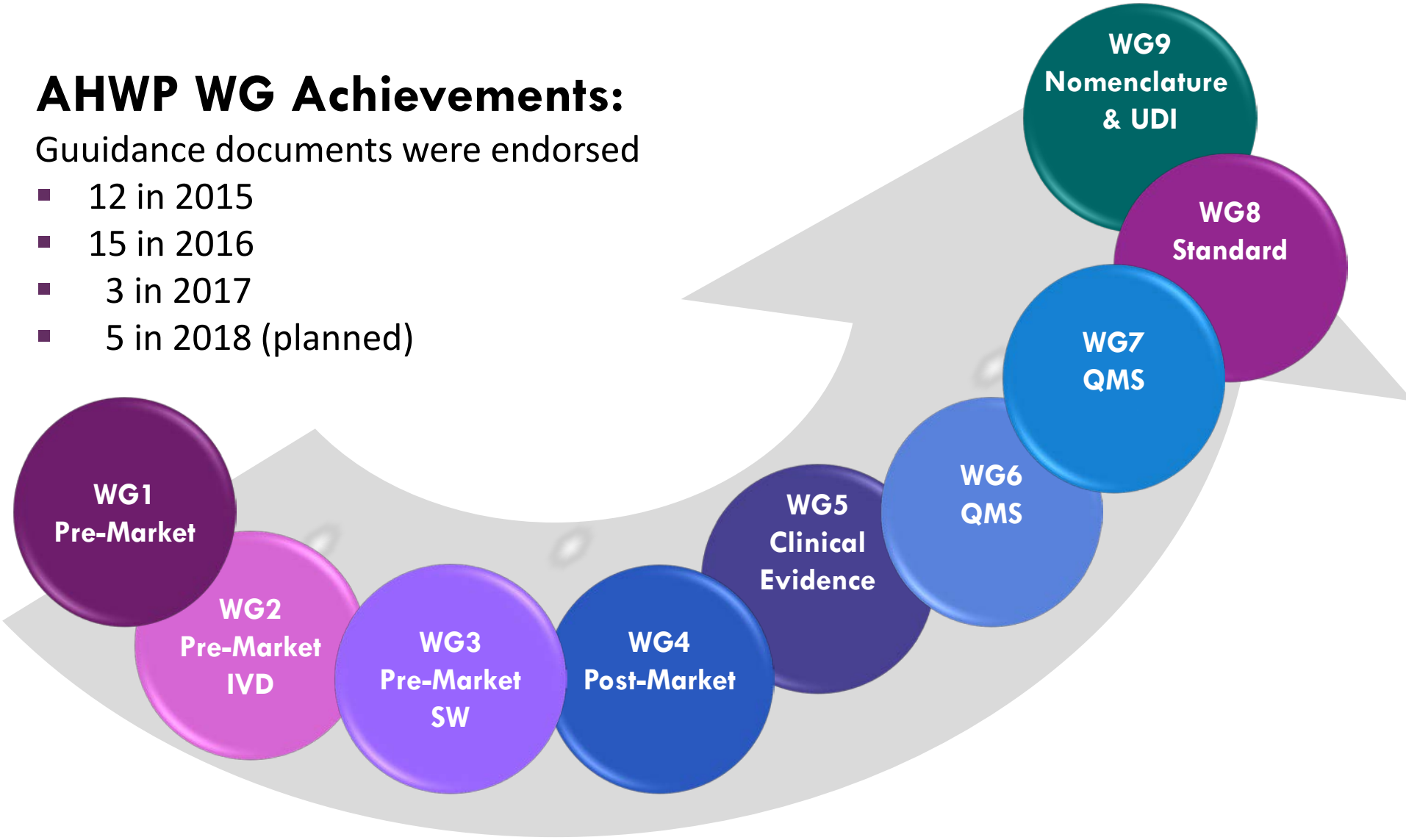
Collaborating Activities	• Harmonization in key areas based on IMDRF Principles and AHWP Guidance
Working Group Tasks	• Development of AHWP Guidance • Pre- and post-market control, UDI • QMS, Clinical evidence, Standards
Capacity Building Projects	• In-country trainings • Implementation of Guidance • Regulatory Competency Handbook

Development & Implementation of AHWP Guidance

AHWP WG Achievements:

Guuidance documents were endorsed

- 12 in 2015
- 15 in 2016
- 3 in 2017
- 5 in 2018 (planned)



WG Plans for 2018 - 2020 (1)

WG	Tasks	Timeline
WG1	• E-labeling/e-IFU guideline (collaboration with WG2 & WG3) • 3D printing handbook update • Change management for medical device registration guideline (collaboration with WG2 & WG3)	Q4, 2018 TBD Q4, 2019
WG2	• E-labeling/e-IFU guideline (collaboration with WG1 and WG3) • Change management for medical device registration guideline (collaboration with WG1 & WG3) • Guidance document for approval of reagent for instrument family • Future trend study & survey: Bridging LDT and IVD	Q4, 2018 Q4, 2019 Q4, 2020 Q4, 2020
WG3	• White paper on pre-market initial submission format for SaMD • E-labeling/e-IFU guideline (collaboration with WG2 & WG3) • White paper on cybersecurity for SaMD • Change management for medical device registration guideline (collaboration with WG2 & WG3) • Guidance document for pre-market submission format for SaMD (draft)	Q4, 2018 Q4, 2018 Q1, 2019 Q4, 2019 Q3, 2019
WG4	• Updating the post-market resource centre • Gap analysis on the implementation of AHWP guidance among AHWP members • Participation in the development works of ISO TC210/WG6	TBD TBD TBD

WG Plans for 2018 - 2020 (2)

WG	Tasks	Timeline
WG5	• Annual review SWOT analysis of WG5 framework • Guidance document on general principles of clinical investigation audit & inspection for medical devices • Training: WG5 & AHWP members • Survey: country regulations/guidelines and implementation	Q4, 2018 Q4, 2018 Q4, 2018 Q4, 2019
WG6	• Guidance document on understanding the roles of IMDRF documents concerning auditing (draft) • Guidance document on the current best practice in determination of regulatory audit duration (draft)	Q4, 2018 Q2, 2019
WG7	• Comparison study of new ISO13485 vs QMS requirements in each country • QMS consideration for manufacturers and importers for localization	Q2, 2020 Q4, 2020
WG8	• Guidance document on code of practice for good engineering maintenance management of medical devices • Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries	TBD TBD
WG9	• AHWP UDI report • AHWP UDI rule	TBD TBD

The 23rd AHWP Annual Meeting

Kuala Lumpur, Malaysia, October 22nd – 25th, 2018

4-days event : AHWP TC Workshops, Joint Sessions with APACMed and DITTA, the 22nd AHWP TC Meeting, the 23rd AHWP Annual Meeting

Thank you