The Road to Regulatory Harmonization

AHWP Technical Committee

Update

IR. SASIKALA DEVI
MEDICAL DEVICE AUTHORITY, MALAYSIA

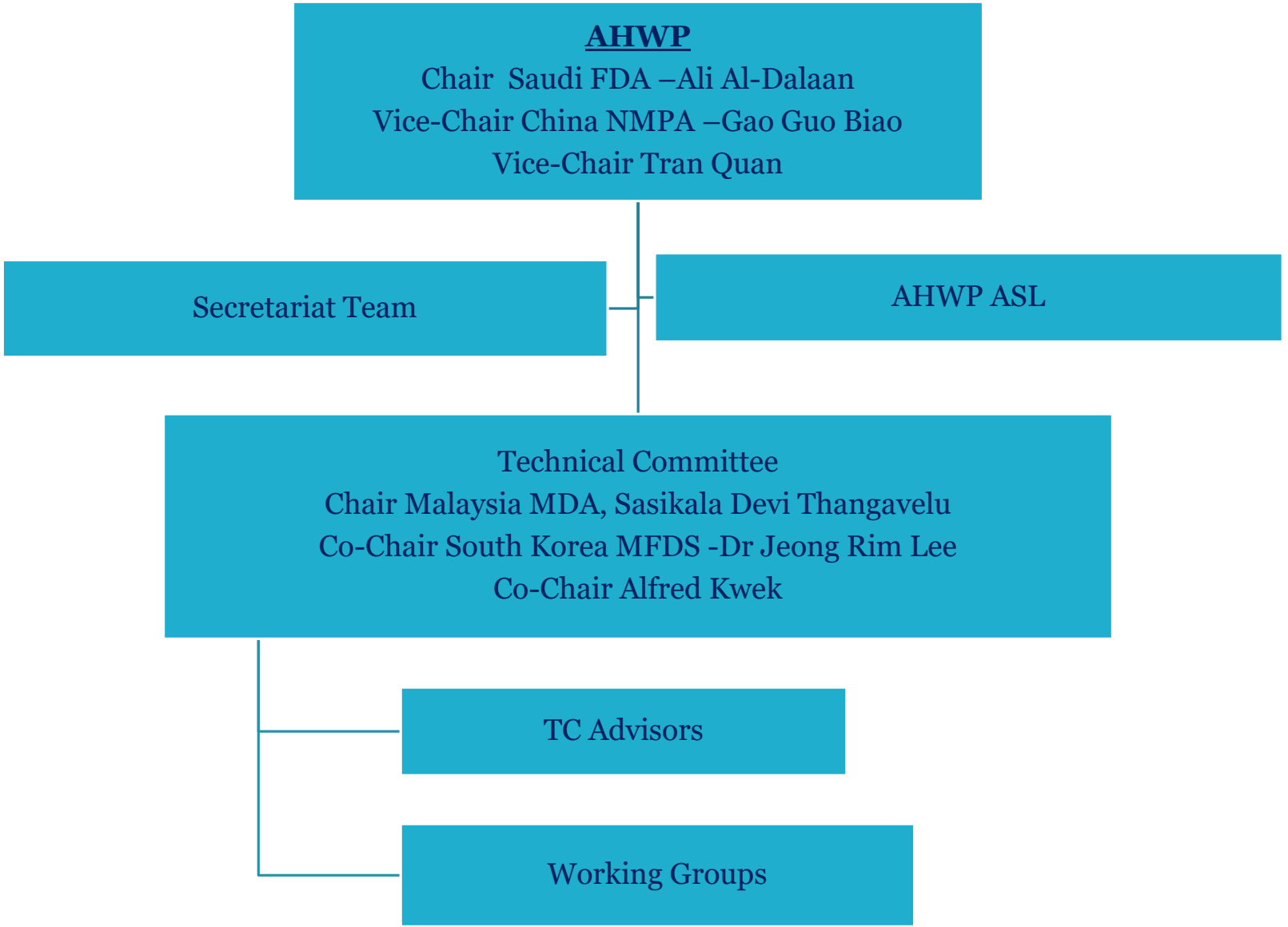
AHWP TC Chair

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Goals

AHWP goals are to develop and recommend ways to converge and 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. Further to promote capacity building in member economies and to foster strategic membership expansion.

AHWP 2018-2020 Term



Current AHWP Membership

AHWP Member Country or Region: 30 (22 Years)

1. Brunei Darussalam	11. Kingdom of Saudi Arabia	21. Singapore
2. Cambodia	12. Republic of Korea	22. South Africa
3. Chile	13. Laos	23. State of Kuwait
4. Chinese Taipei	14. Malaysia	24. Sultanate of Oman
5. Hong Kong SAR, China	15. Mongolia	25. Tanzania
6. India	16. Myanmar	26. Thailand
7. Indonesia	17. Pakistan	27. United Arab Emirates
8. Jordan	18. People's Republic of China	28. Vietnam
9. Kazakhstan	19. Philippines	29. Yemen
10. Kingdom of Bahrain	20. Republic of Kenya	30. Zimbabwe

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
- ❑ Convergence and 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
- TC Tele-conference, July 9,2019
- TC Tele-conference ,Sept 18 2019

Capacity Building Program

- Identify Priority Working Area/experts/ Champions economy
- Country /Regional Trainings
- Regulatory Competency Handbook
- Develop Training Modules

3-year Work Plan

- Development of AHWP Guidelines
- Pre- and post-market control, UDI, PMSV Reporting Template
- Placements
  -Good Submission and Review Practice
  -Fast track placement of innovative device
- QMS, Clinical evidence, Standards, Conversion of GMP to ISO13485

Harmonization in Key Areas

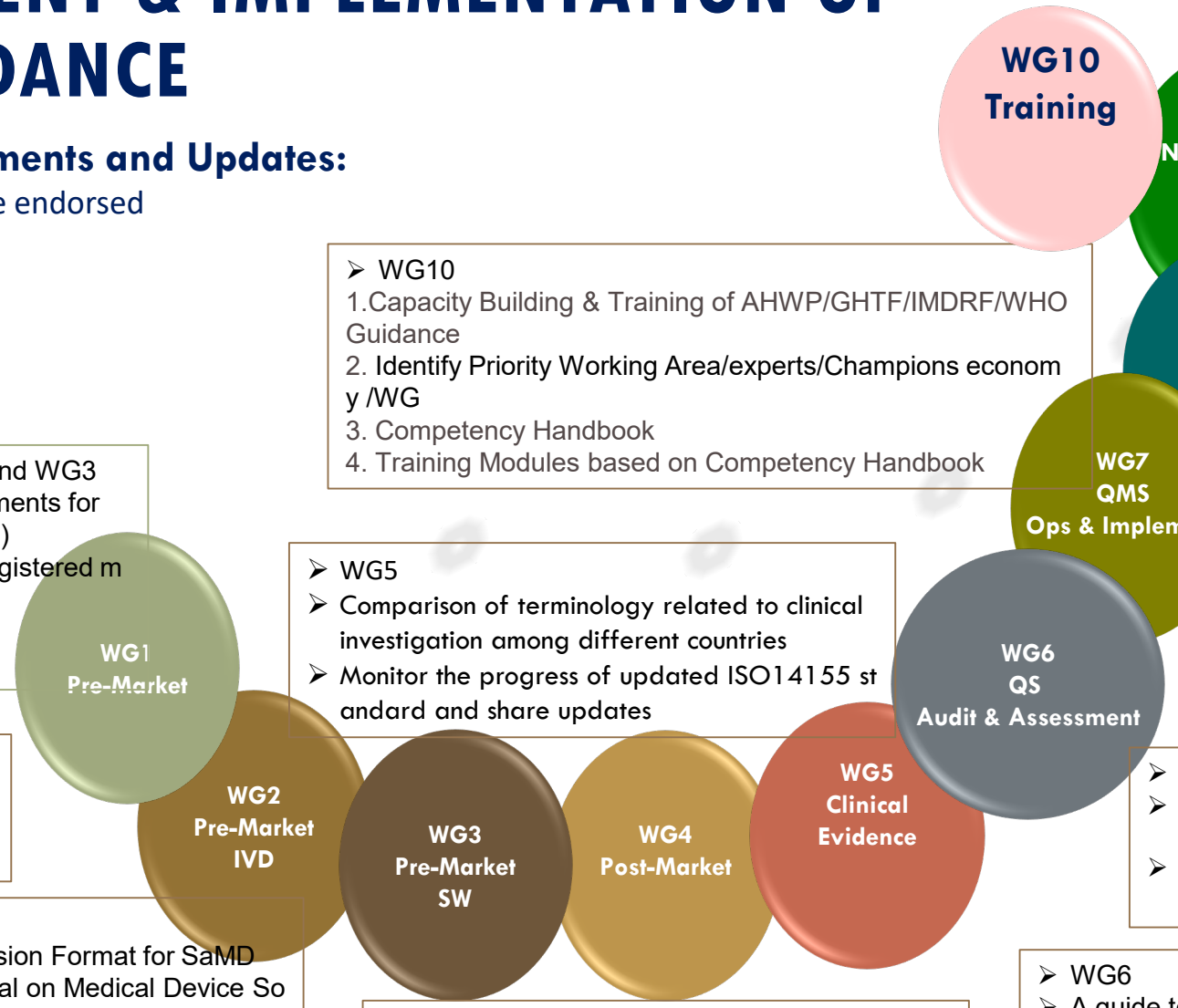
-Play book to be upgraded to regulatory handbook
-Develop framework for medical device regulations based on AHWP,GHTF /IMDRF ,ISO and WHO Guidance
--Identify key areas -premarket,placement & post market
-Identify key elements –Definition,Classification,CSDT,EPSP,Standards
-Implementation of GHTF/AHWP Guidelines

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



- WG1 in collaborating with WG2 and WG3
- Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)
- Categorisation of changes to a registered medical device
- Target endorsement at the 2019 Annual Meeting

- 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

- WG10
1.Capacity Building & Training of AHWP/GHTF/IMDRF/WHO Guidance
2. Identify Priority Working Area/experts/Champions economy /WG
3. Competency Handbook
4. Training Modules based on Competency Handbook

- WG5
- Comparison of terminology related to clinical investigation among different countries
- Monitor the progress of updated ISO14155 standard and share updates

- WG4
- Supporting TC to develop the AHWP Handbook on Actual Implementation of a Regulatory System

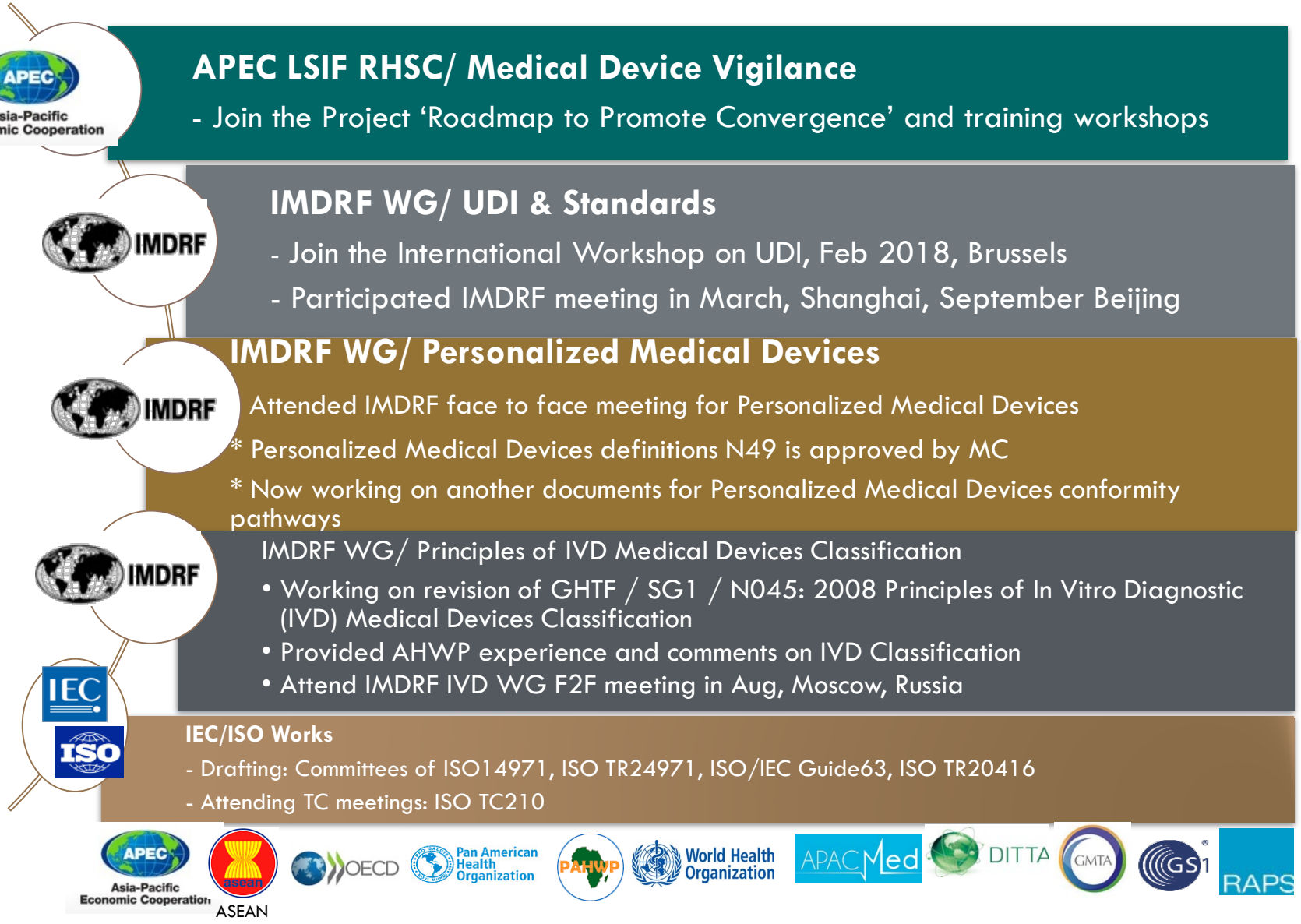
WG9
- **AHWP UDI Whitepaper**
- Target endorsement at 2019 Annual meeting

- WG8
- Adoption ISO 16142-2:2017, Medical devices - Recognized essential principles of safety and performance of medical devices
- Gathering information and creating a list of standards used for medical devices regulatory purposes that are recognized by AHWP member countries

- WG7
- Comparison study of new ISO13485 vs. QMS requirements in each country
- QMS Consideration for manufacturers and importers for localisation

- WG6
- A guide to understanding best practices in audit life cycle management
- A guidance on how assessment for critical suppliers shall be performed by AOs.

Continuous Efforts for Global Harmonization




본부동

AWP
MONIZATION
NG PARTY


AHWP TC WG1-WG2-WG3 Joint Meeting
2019 Aug. 13-15, Taipei
FDA

Collaboration with the OECD

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

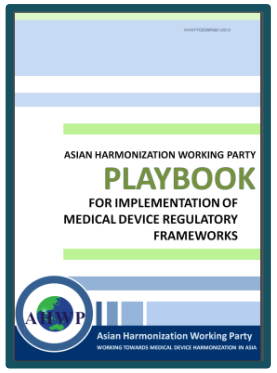
A Case Study of the AHWP on Medical Devices

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

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

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

AHWP Capacity Building Projects

2019

Regulatory Fundamentals

- Premarket Review
- Essential Principles of Safety and Performance
- Risk Classification (GMD & IVD)
- Product Grouping (GMD & IVD)
- Step Wise Approach – Expedited Routes
- Post Market Surveillance

Technical Tracks

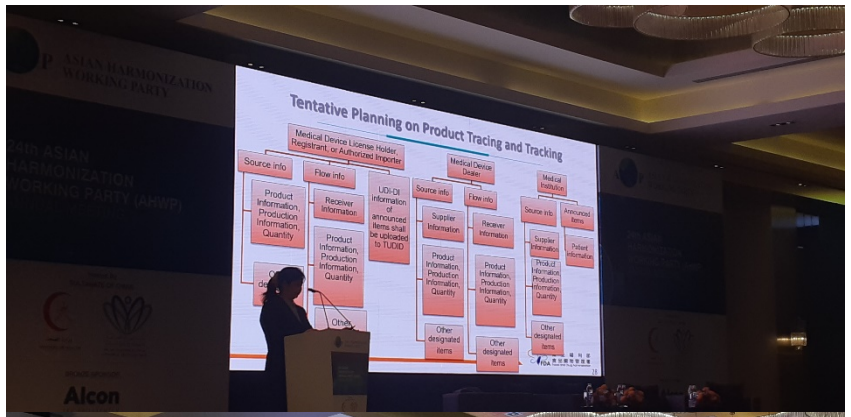
- Regulatory Pathways for Companion Diagnostics
- UDI
- Digital Health Innovation and What It Means for the Regulators
- Digital Transformation in Regulatory Processes
- AI Global Regulatory Development, Regulatory Guidelines and Application in Hospitals

AHWP Capacity Building Projects

2019

Technical Tracks

- DITTA – Networked Medical Devices Cybersecurity and Patient Safety
- UDI Implementation Experience
- Updates on QMS ISO 13485: 2016



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.

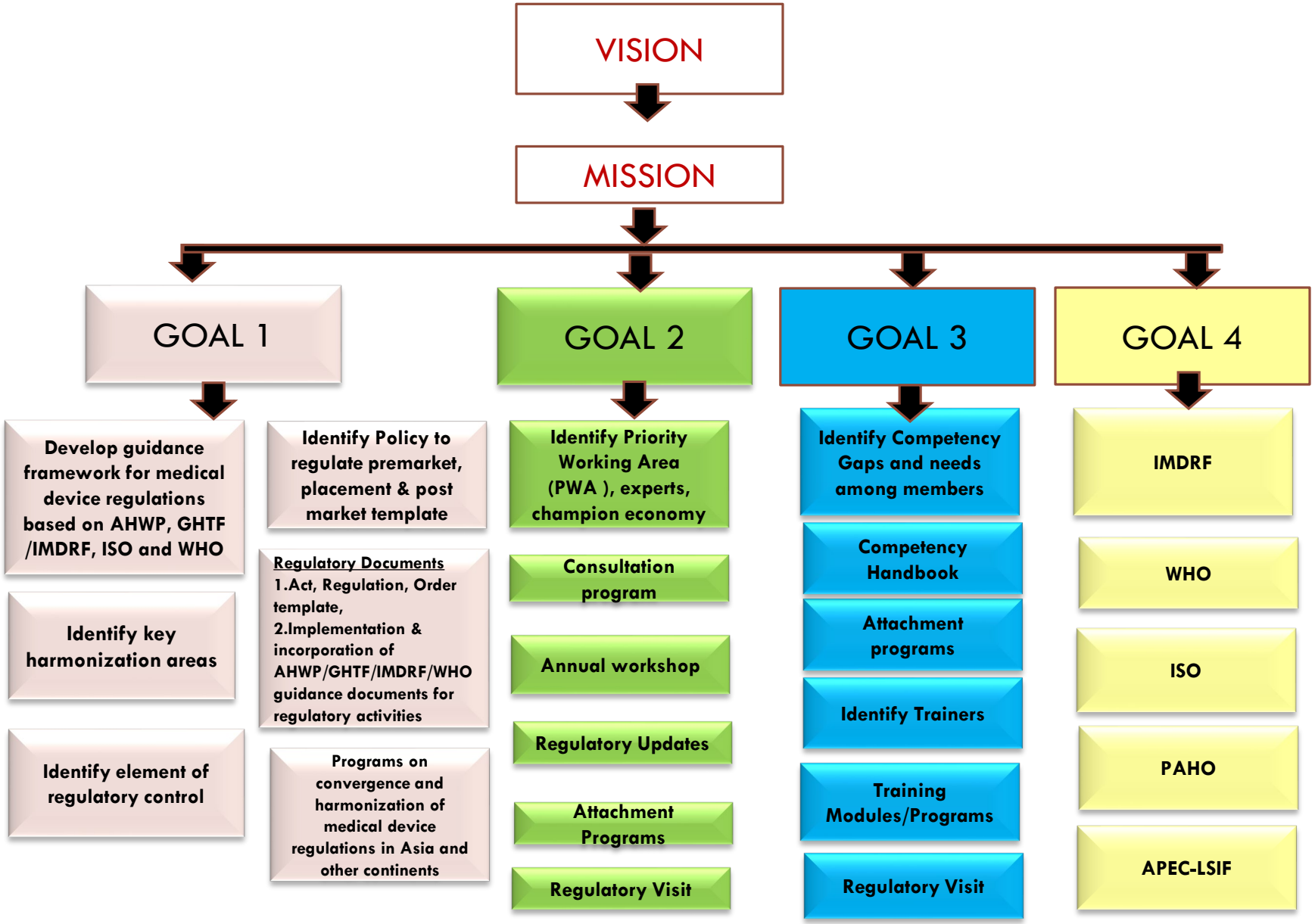
GOAL3

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



Thank you