24th Asian Harmonization Working Party (AHWP) Annual Meeting

Tran Quan

AHWP Vice-Chair (Industry)

Vice President, Regulatory/Government Affairs/Quality Assurance

Asia Pacific, Align Technology

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

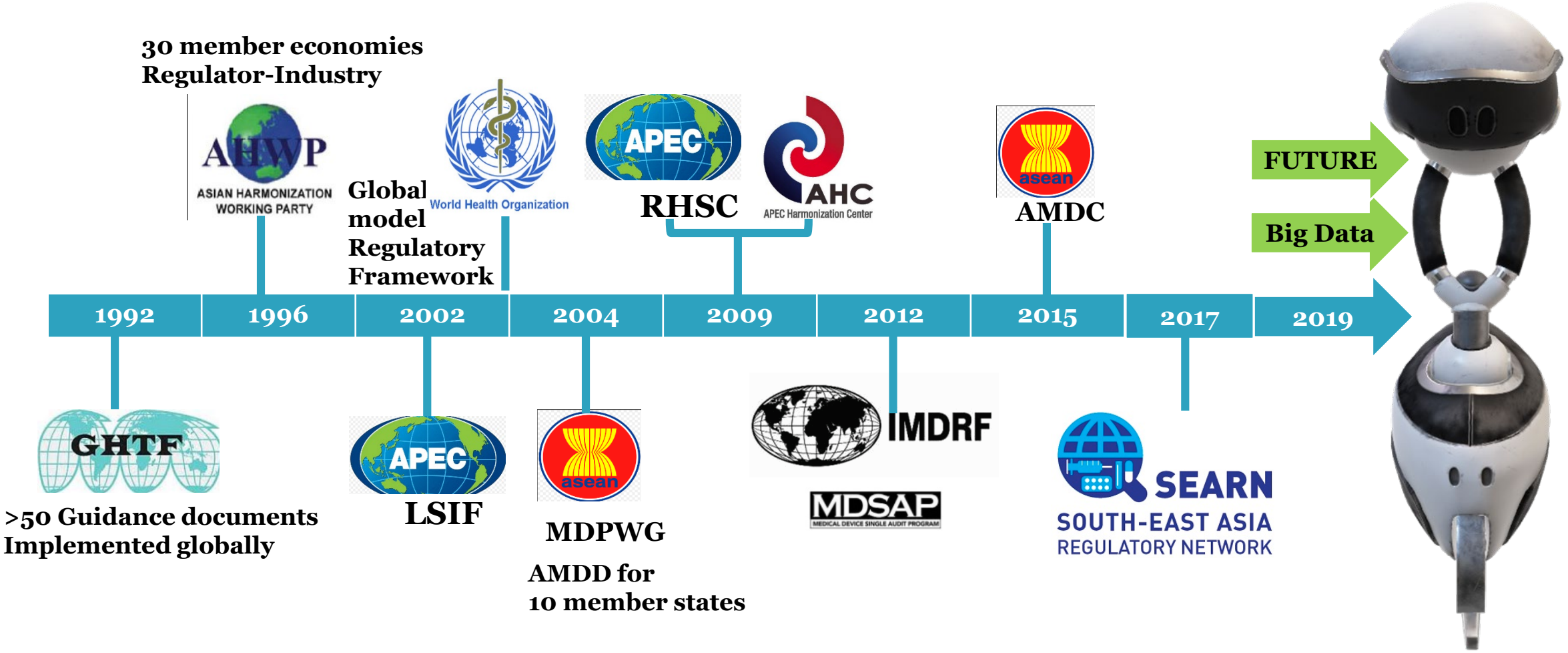
Purpose of Medical Device Regulations

Why Regulate Medical Devices?

- Protect and promote public health
- Block or remove unsafe and ineffective products from market
- Deter counterfeiting
- Control promotional practices

Images courtesy of google.com

Our Journey to Regulatory Harmonization



23rd AHWP Annual Meeting

October 22-25, 2018, Kuala Lumpur, Malaysia

- **AHWP Annual Meeting (200+ Participants)**
  - Participation of global organizations (IMDRF, WHO, APEC, OECD, etc)
  - Joint workshop plans with liaisons
  - Strategy for Improvement of Regulatory Capacity, Enforcement and Co-operation

23rd AHWP TC Meeting

April 09-10, 2019, Riyadh Saudi Arabia

#SFDA is hosting the opening of the 2019 AHWP TC leader meeting. His excellency, prof. @aljadhey : "#SFDA emphasizes the importance of global and scientific approach in promoting public health from any hazardous resulting from medical devices". #Saudi_FDA #SuLinda_News

- **AHWP Technical Committee Short-term & long-term Plans update**
  - Guideline topics and development plans by each WGs
  - Development of Competency Framework White Paper by AHWP Capacity Building
  - In-country training plans

AHWP Goals

Goal 1

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

Goal 2

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

AHWP Goals

Goal 3

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

Goal 4

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

AHWP Membership

AHWP Member Countries or Regions: 30 (23 Years)

Asia, Middle East, Africa, S. America

Brunei Darussalam
Cambodia
Chile
Chinese Taipei
Hong Kong SAR, China
India
Indonesia
Jordan
Kazakhstan
Kingdom of Bahrain

Kingdom of Saudi Arabia
Republic of Korea
Laos
Malaysia
Mongolia
Myanmar
Pakistan
People's Republic of China
Philippines
Republic of Kenya

Singapore
South Africa
State of Kuwait
Sultanate of Oman
Tanzania
Thailand
United Arab Emirates
Vietnam
Yemen
Zimbabwe

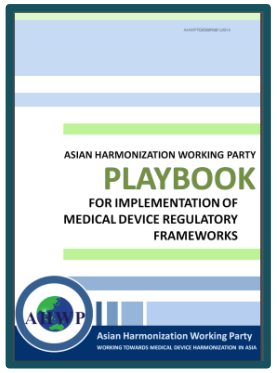
To be endorsed at
24th AHWP
Annual meeting, 2019

Kyrgyz Republic

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

24th AHWP Annual Meeting

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

Track 1: Regulatory Fundamentals

Conformity Assessment

Essential Principles of Safety & Performance

Risk Classification

Product Grouping

Expedited Routes (Referencing/Reliance)

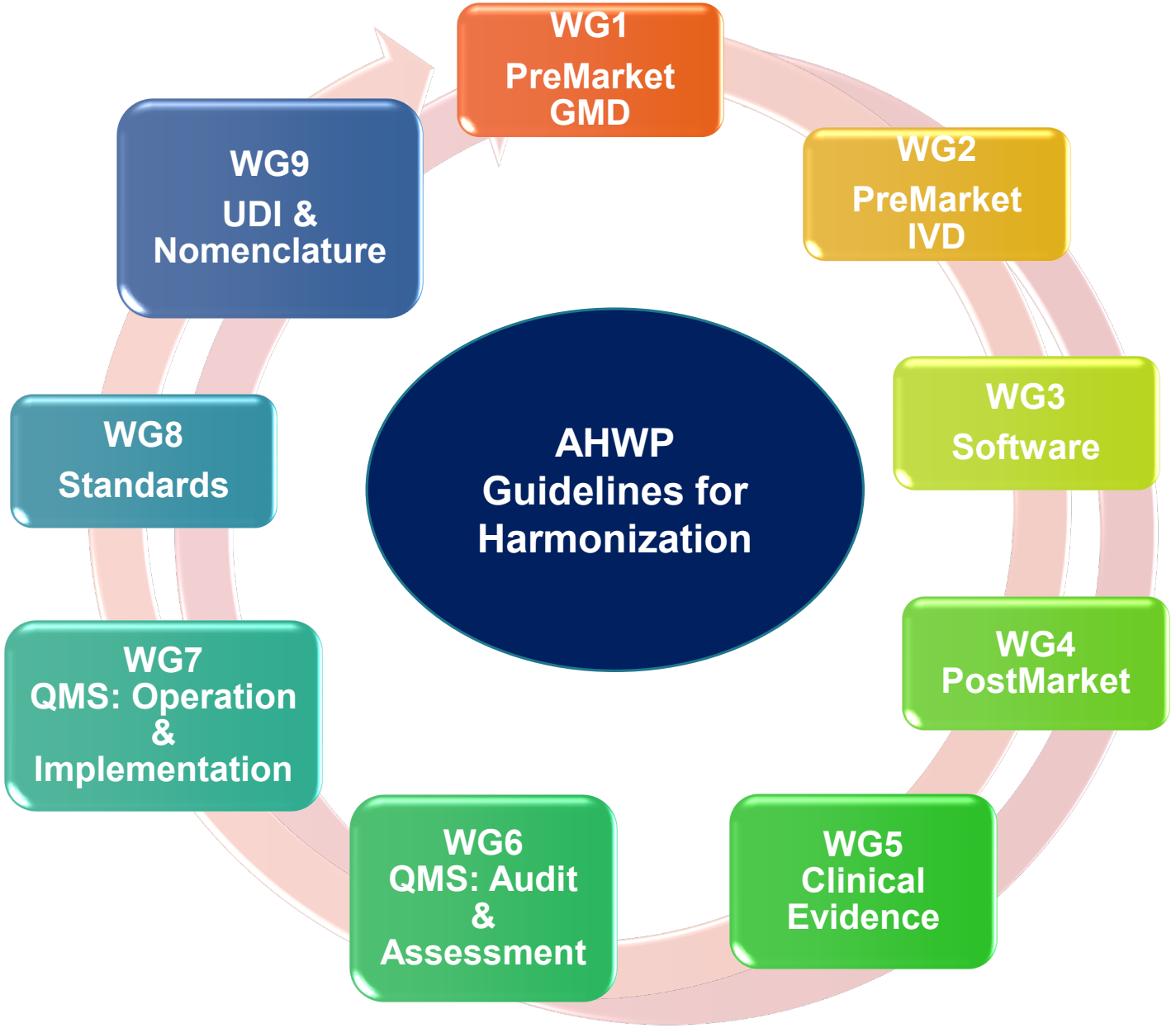
Post market surveillance/ investigation/change management

24th AHWP Annual Meeting

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

Track 2: New Technology & Emerging Regulatory Trends

- Real World Evidence
- Companion Diagnostics
- UDI
- Digital Health
- Artificial Intelligence


WG1
PreMarket
GMD
WG2
PreMarket
IVD
WG3
Software
WG4
PostMarket
WG5
Clinical
Evidence
WG6
QMS: Audit
&
Assessment
WG7
QMS: Operation
&
Implementation
WG8
Standards
WG9
UDI &
Nomenclature
AHWP
Guidelines for
Harmonization

Continuous Efforts for Global Harmonization

APEC LSIF RHSC/ Medical Device Vigilance

- Join the Project 'Roadmap to Promote Convergence' and training workshops

IMDRF WG/ UDI & Standards

- Join the International Workshop on UDI, Feb 2018, Brussels
- Participated IMDRF meeting in March, Shanghai, September Beijing

IMDRF WG/ Personalized Medical Devices

- Attended IMDRF face to face meeting for Personalized Medical Devices
* Personalized Medical Devices definitions N49 is approved by MC
* Now working on another documents for Personalized Medical Devices conformity pathways

IMDRF WG/ Principles of IVD Medical Devices Classification

- Working on revision of GHTF / SG1 / N045: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- Provided AHWP experience and comments on IVD Classification
- Attend IMDRF IVD WG F2F meeting in Aug, Moscow, Russia

IEC/ISO Works

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

24th AHWP Annual Meeting - Day 1

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

Collaboration between Regulators and Industry
- Right competency
- Good Submission Practice
- Good Review Practice

→ **Innovative/High Quality Medical Devices** → **Patients**

24th AHWP Annual Meeting

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

thank you very much

shukran jaziilan

شُكراً جَزِيلاً

AHWP Capacity Building

Ali Al Dalaan & Tran Quan

AHWP Chair & Vice-Chair (Industry)

14 Nov 2019

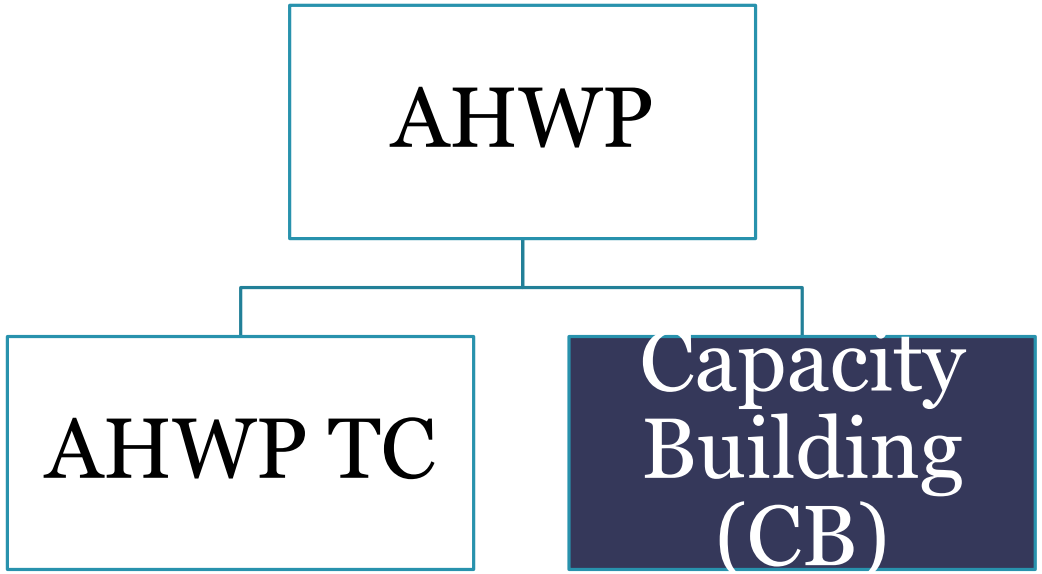
Asian Harmonization Working Party

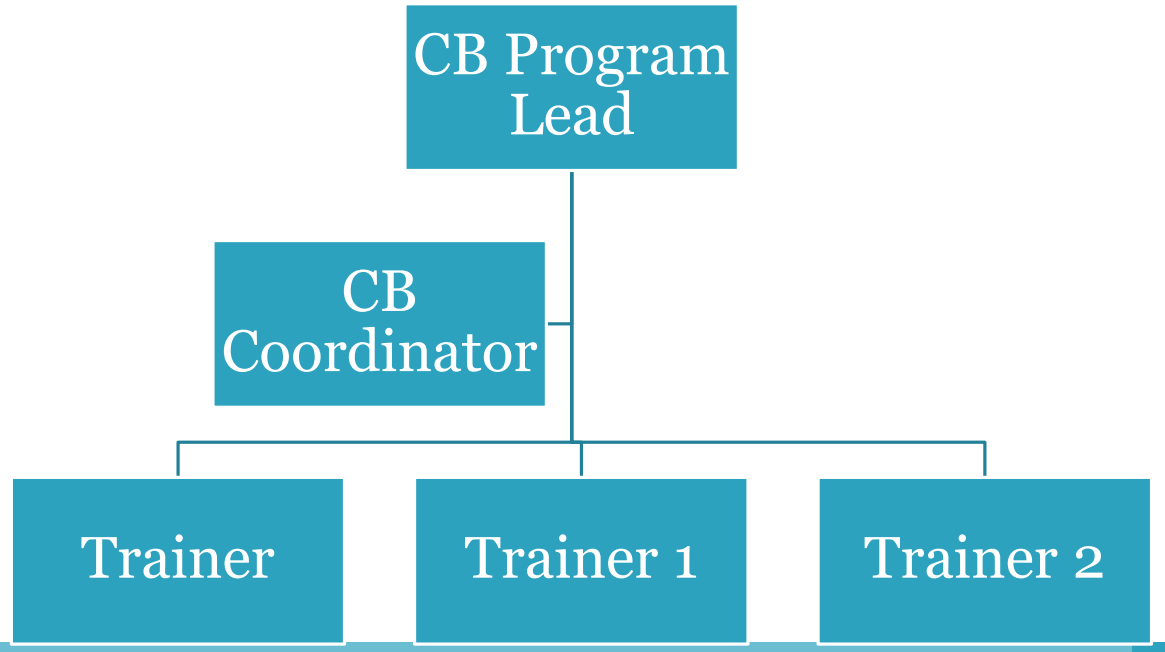
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

GOAL

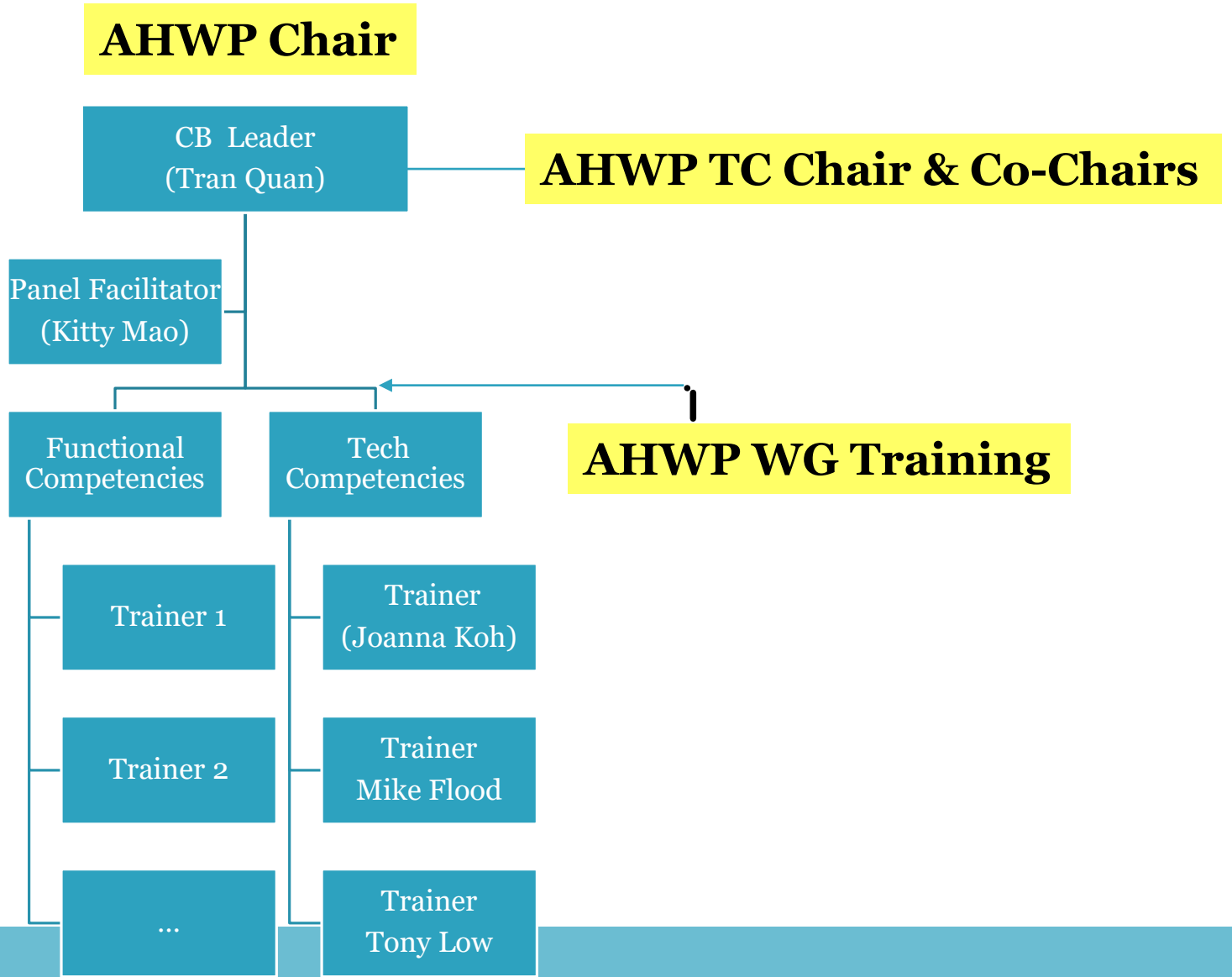
To study and recommend ways to harmonize medical device regulations in the Asian & other regions & to work in coordination with other international organizations of similar objectives

Formalization of Capacity Building Structure

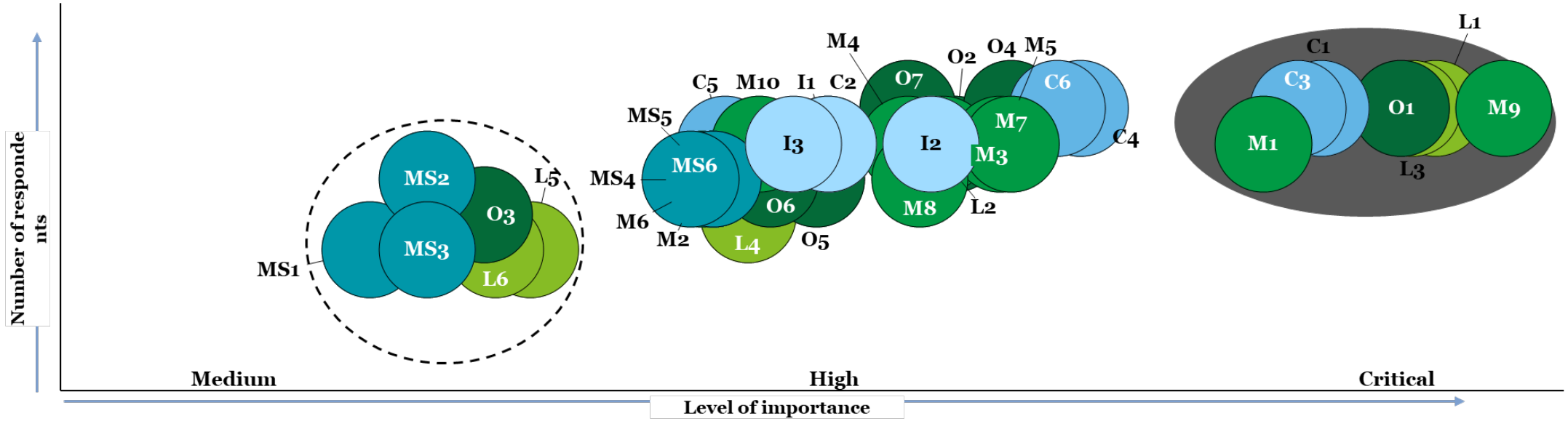




Capacity Building Trainer Panel Proposal – Structure



AHWP Competency Framework



Legal	Operation	Communication	Management	Multisector partnership	Industry Insights
1 Understand & assess Legal documents (local)	1 Code of conduct	1 Effective Communication	1 Quality Mgmt. system	1 Foreign Languages & Culture	1 Local industry landscape
2 …Legal documents (international)	2 Critical Thinking & Problem Solving	2 Public Speaking	2 Project Mgmt.	2 Diplomatic and Foreign Affairs Policy	2 Emerging technologies and products
3 Understand & assess Technical documents (local)	3 Budget Planning & Management	3 Interpersonal Skills	3 Risk Mgmt.	3 Healthcare Ecosystem	3 International industry landscape
4 …Technical documents (international)	4 Documentation & Filing	4 Negotiation	4 Crisis Mgmt.	4 Stakeholder Engagement	
5 Understand Legislative process	5 Customer Service	5 Information Dissemination & Media Strategy	5 People Mgmt.	5 International Initiatives and networks	
6 Legal writing	6 IT Skills	6 Public Education	6 Mentoring & Coaching	6 Public Health	
	7 Technical Report Writing		7 Training		
			8 Leadership		
			9 Good Regulatory Practice		
			10 Policy Analysis		

Functional Competencies ⟷ Regulator /Industry

Functional Tech Competencies

Work Group trainings ⟷ Each WG nominate 2 candidates

CB Panel Selection Proposal - Approval

Trainer must commit to conduct min. 1 in-country training

Functional Competencies

Tech Competencies

↔ Regulator/ Industry

General Tech Competencies

↔ each WG nominate 2 candidates

↑

Approver

AHWP Chair, Vice Chair (s)
AHWP TC Chair, TC Co-Chair (s)

↑

AHWP TC Chair, TC Co-Chair (s)

Criteria for Trainer

Functional Competency

- ✓ a NRA* background
- ✓ at least 5 years of regulatory controls as a Medical Device regulator
- ✓ able to communicate well, think on the feet to answer impromptu questions.
- ✓ be able to discuss how such training can close gaps for Industry
- ✓ be able to have respect of participants/regulators

General Tech Competency

- ✓ at least 5 years in area of technical support
- ✓ good technical skills, mostly from Industry
- ✓ has the knowledge in top 5/10 areas of diseases and their treatment
- ✓ basic coverage of the technology of that medical device
- ✓ be widely read, knowing what's new in the market

NRA* National regulatory agency

Thank You!