AHWP UPDATE

Ali M. Aldalaan

Vice Executive President, Medical Devices Sector
AHWP Chair

IMDRF – 15. 19-21 March 2019 Moscow, Russia

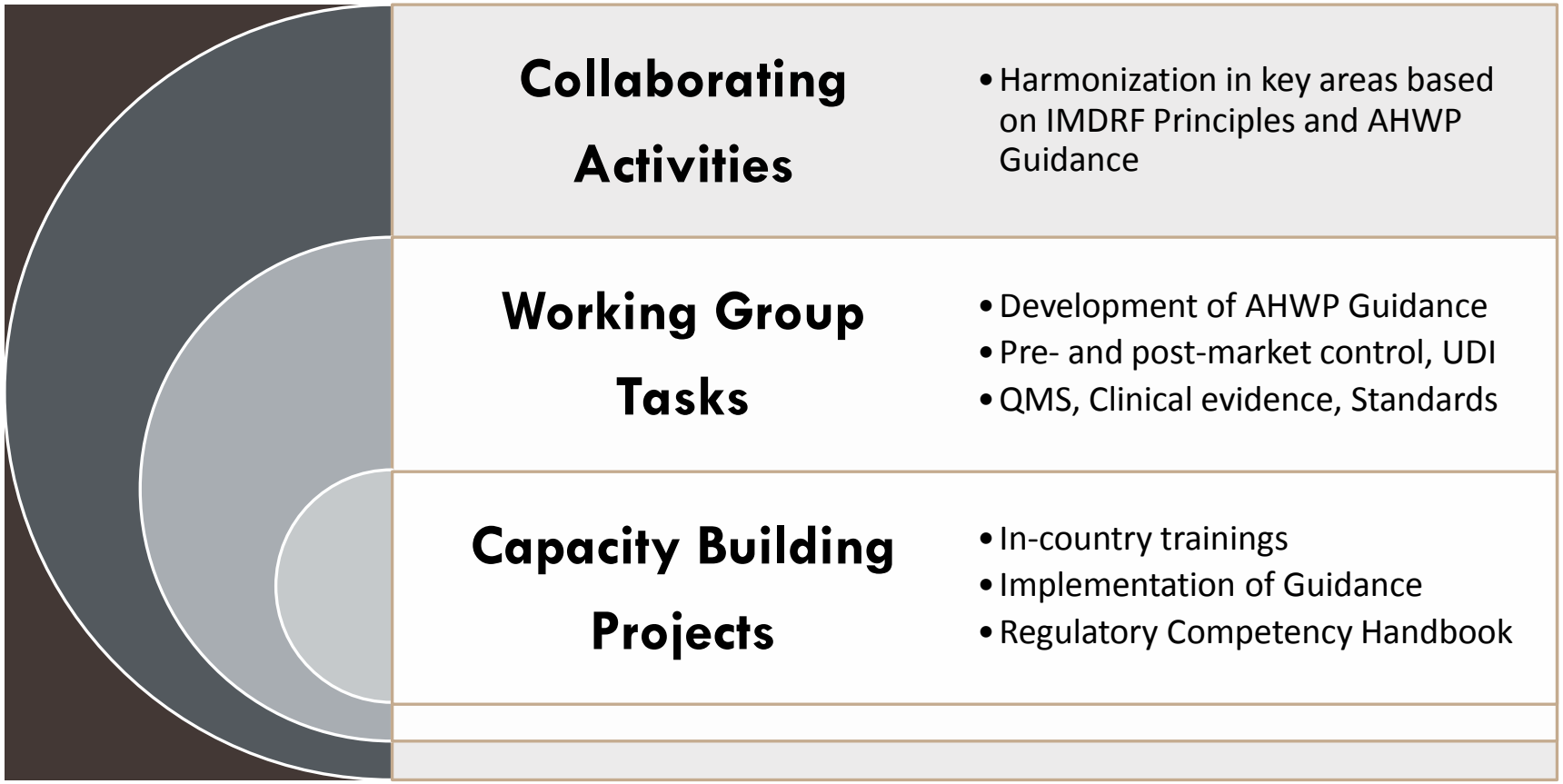
AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Current AHWP Membership

AHWP Member Country or Region: 30 (as of Mar 2019)

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

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

AHWP Leadership Team

AHWP Chair:

Mr. Ali Al dalaan,

Vice Executive President, Medical Devices Sector, Saudi Arabia

AHWP Vice-chair:

Mr. Guobiao Gao,

Deputy Director General, National Medical Product Administration, China

AHWP Vice-chair:

Ms. Tran Quan, Industry

AHWP TC Team

TC Office Bearers	Positions
Chair	Ms.Sasikala Devi Thangavelu
Co-Chair	Dr Jeong-Rim Lee
Co-Chair	Mr Alfred Kwek
Secretary	Mr Jack Wong
	Ms Chadaporn Tanakasemsub (Miang)
	Ms Carol Yan
	Ms Soo-Kyeong Shin
Work Groups	**Positions**
WG1: Pre-market	Chair - Mr. Se-il Park Co-Chair - Ms. Kate Hyeong Joo Kim
WG2: Pre-market - IVDD	Chair - Mr. Wen-Wei TSAI Co-Chair - Ir. Albert POON
WG3: Pre-market - Software as a Medical Device	Chair - Dr. Abdullatif Alwatban Co-Chair - Mr Tony Yip
WG4: Post-market Scope includes post-market aspect of WG 1-3 device categories	Chair - Ms. Jennifer MAK Co-Chair - Ms Kitty Mao
WG5: Clinical Evidence for performance & safety	Chair - Ms. Yuwadee PATANAWONG Co-Chair - Ms. Sumati Randeo
WG6: Quality Management Systems: Audit & assessment	Chair - Mr. Abdullah AL RASHEED Co-Chair - Mr. Vincent LAM Chee-Choong
WG7: Quality Management Systems: Operation & implementation	Chair - Ms. Wang Aijun Co-Chair - Mr. Ee Bin Liew
WG8: Standards	Chair - Mrs. Salibiah Yaakop Co-Chair – Mr Tony Low
STC (UDI & Nomenclature)	Chair - Mr. Jun LI Co-Chair – Ms Victoria Qu

AHWP TC PLAN

2018 - 2020

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) • AI guidance in consideration	Q4, 2018 TBD Q4, 2019 TBD
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	Ongoing Ongoing Ongoing

WG Plans for 2018 - 2020 (2)

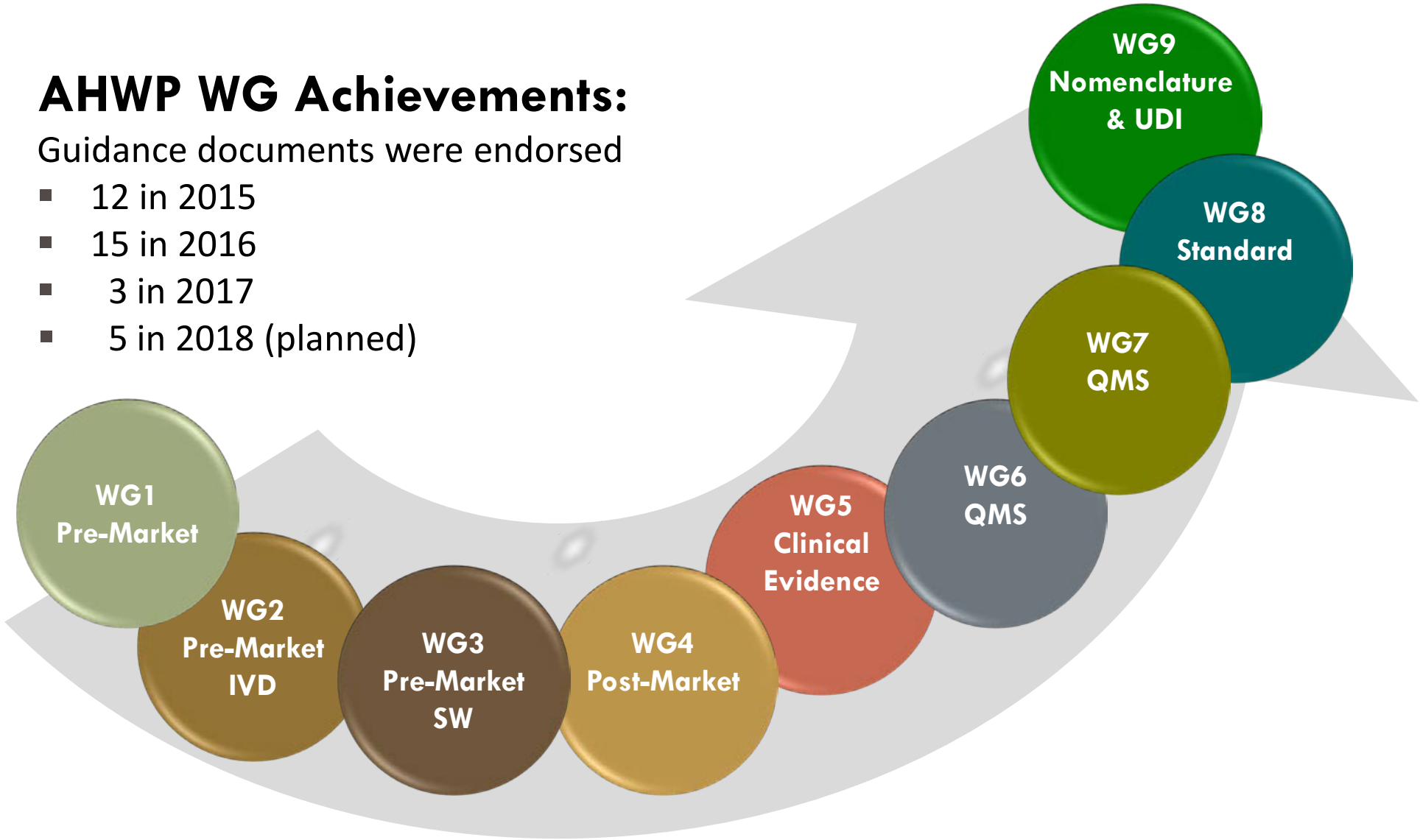
WG	Tasks	Timeline
WG5	• Annual review SWOT analysis of WG5 framework • Guidance document on general principles of clinical investigation audit & inspection for medical devices • Training: WG5 & AHWP members • Survey: country regulations/guidelines and implementation	Q4, 2018 Q4, 2018 Q4, 2018 Q4, 2019
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

Development & Implementation of AHWP Guidance

AHWP WG Achievements:

Guidance documents were endorsed

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



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

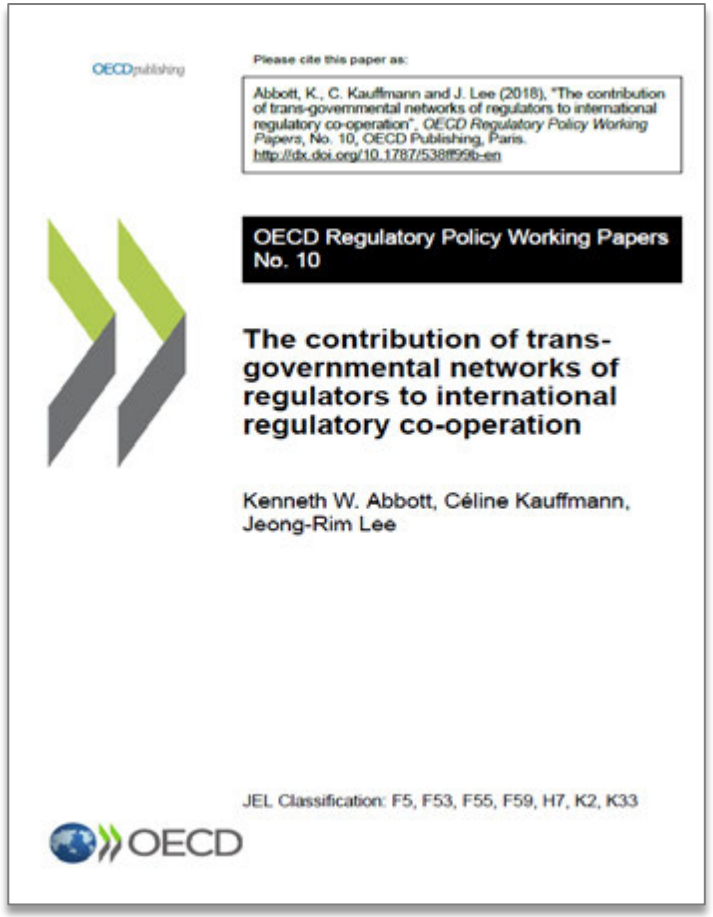
IEC/ISO Works

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

ASEAN

Collaboration with the OECD

Title: 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 drafting the 2nd OECD Report (2017 - 2018)
- Published as an OECD report (September, 2018)

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 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

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
- 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
Bangkok, Thailand
Feb 22-23, 2019

Capacity Building in Thailand

Day 1:

- ✓ AMDD- Areas of harmonization in place in ASEAN states- summary update
- ✓ Definition of a Medical Device (Recap)
- ✓ Risk Management
- ✓ Risk classification and grouping
- ✓ CSDT
- ✓ Discussion on 1 application for product registration received by TFDA (Optional)

Day 2:

- ✓ Essential Principles - what and why this is necessary
- ✓ Standards - application of standards in the context of Essential Principles
- ✓ Post Market (articles in AMDD)
- ✓ Areas of Post market to be applied.

- 35 Regulators attended training

Capacity Building in Thailand

- Training met my expectation? ~92% Strongly Agree and Agree

Part I: AMDD Summary

Strongly Agree	Agree	Disagree	Strongly Disagree	No Response
15	6	1	0	0

Part II: Premarket

Strongly Agree	Agree	Disagree	Strongly Disagree	No Response
13	8	0	0	1

Part III: Post market

Strongly Agree	Agree	Disagree	Strongly Disagree	No Response
13	6	1	0	2

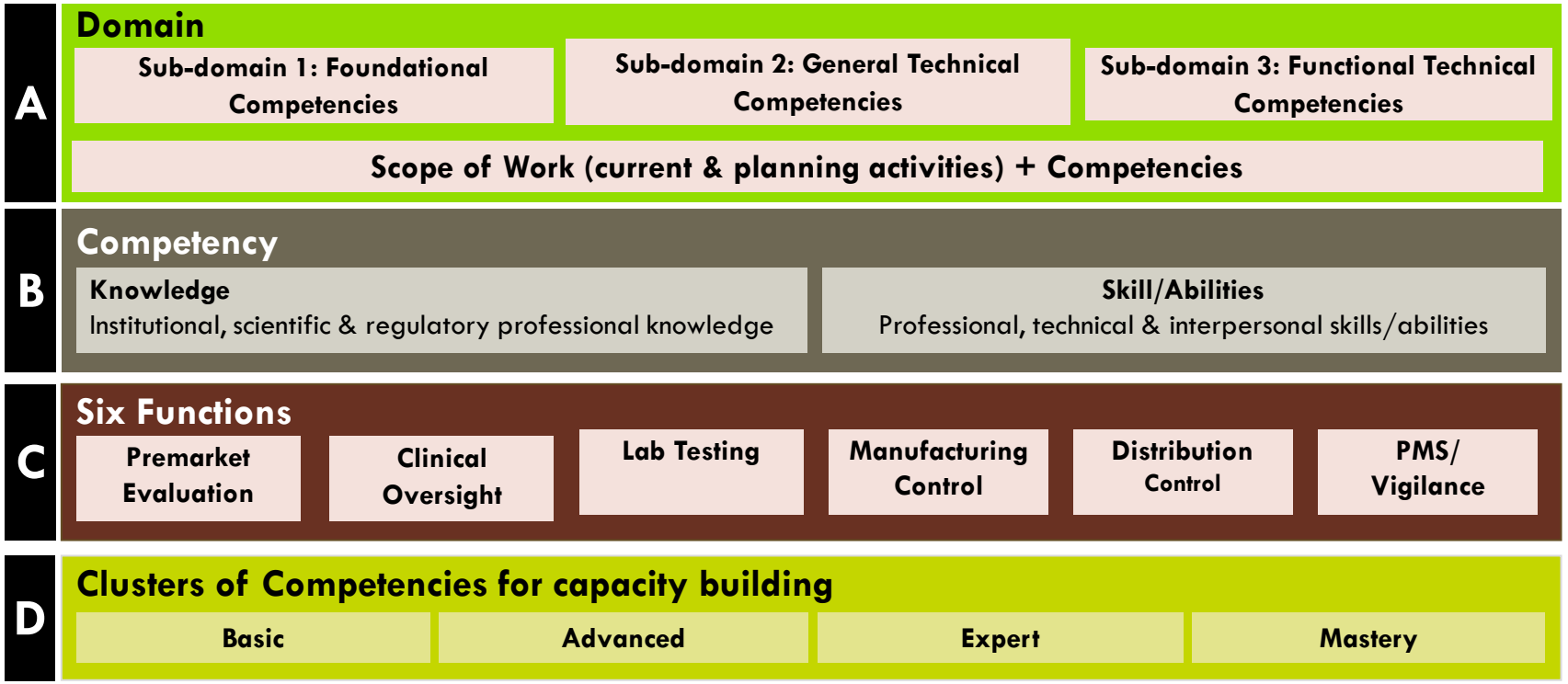
Note: 22 attendees participated after-training feedback

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



Thank you