

AHWP Capacity Building

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AHWP Chair & Vice-Chair (Industry)

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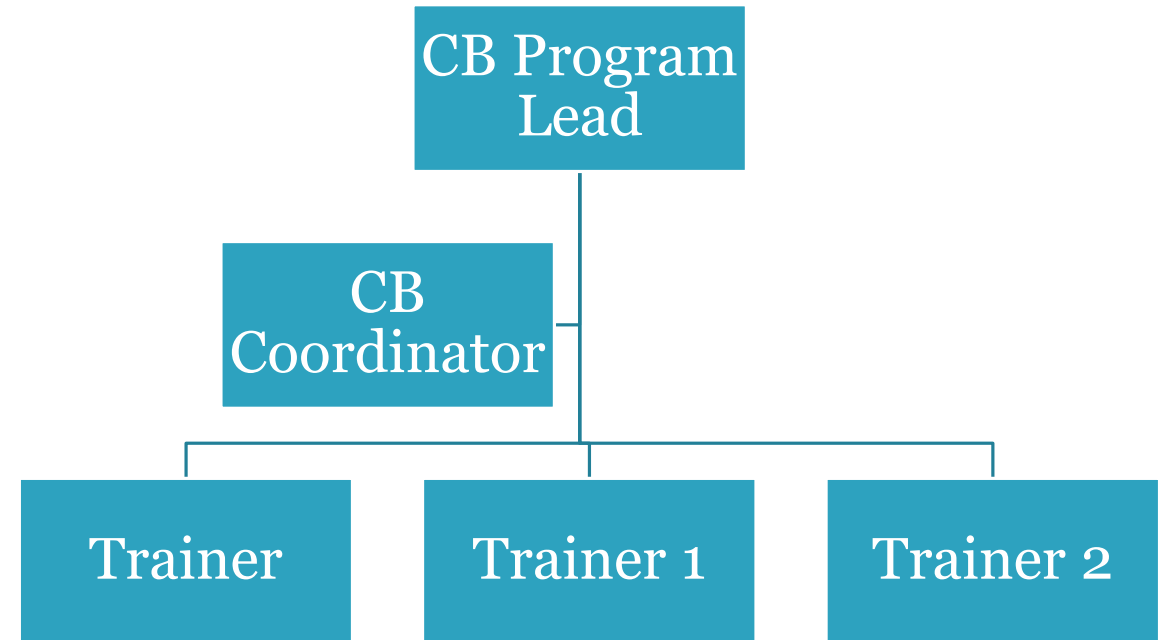
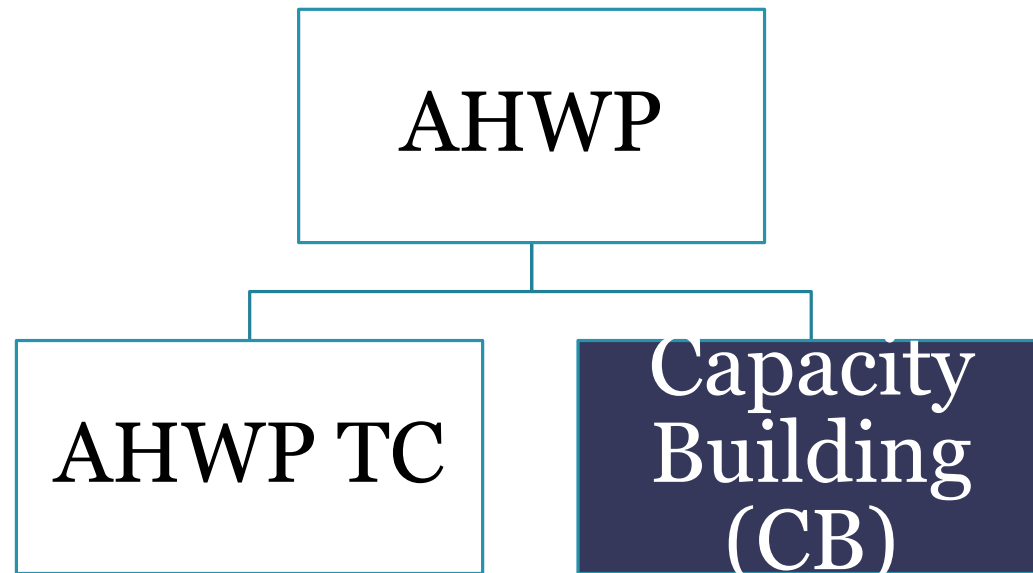
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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

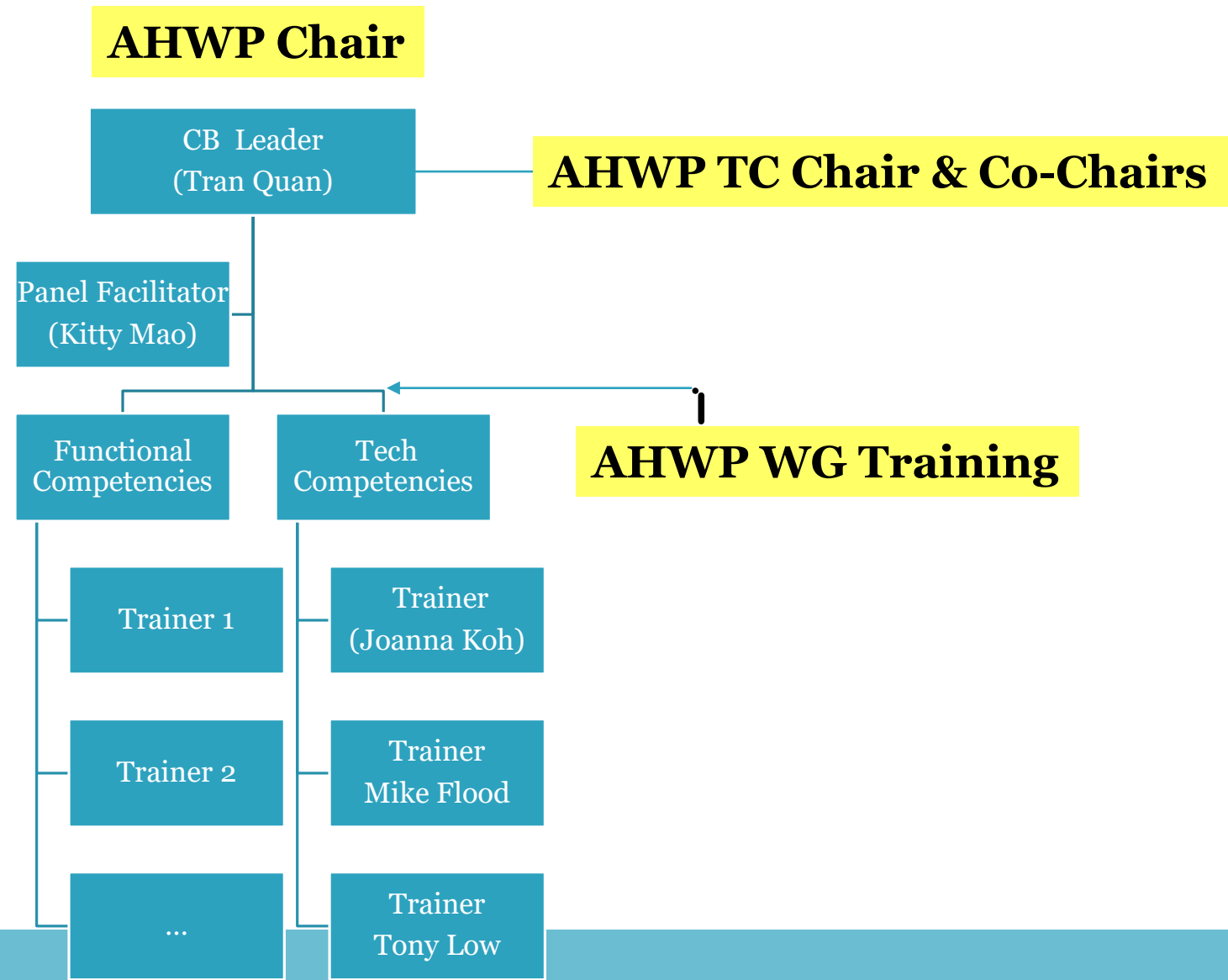


Formalization of Capacity Building Structure

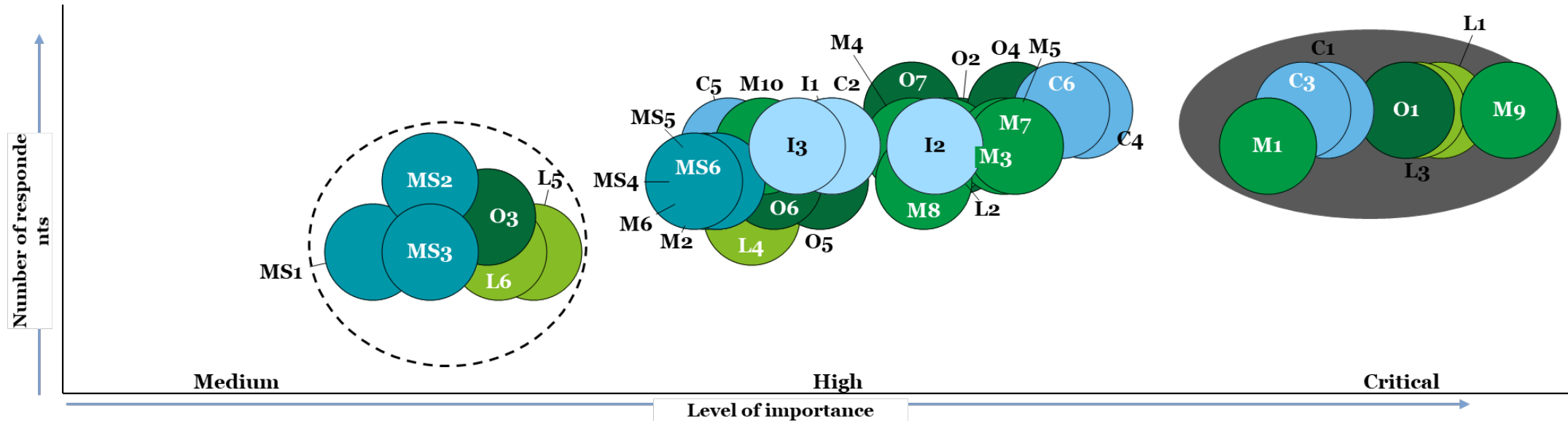


Capacity Building Trainer Panel Proposal

– Structure



AHWP Competency Framework



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

Functional Competencies
 Functional Tech Competencies

Regulator / Industry

Work Group trainings

Each WG nominate 2 candidates

CB Panel Selection Proposal - Approval



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



Regulator/
Industry



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

Thank You!