

AHWP Update

Growing from Strength to Strength

Tran Quan

AHWP Vice-Chair (Industry)

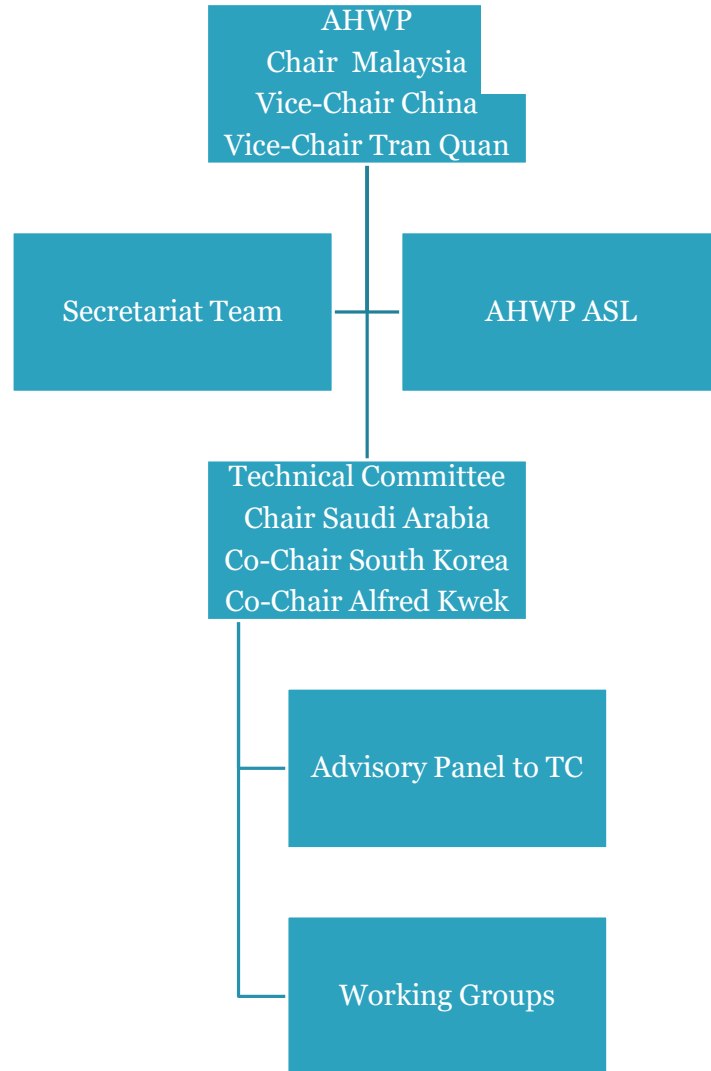
Head of APAC RAGAQA, Align

24 Oct 2018



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP New Term

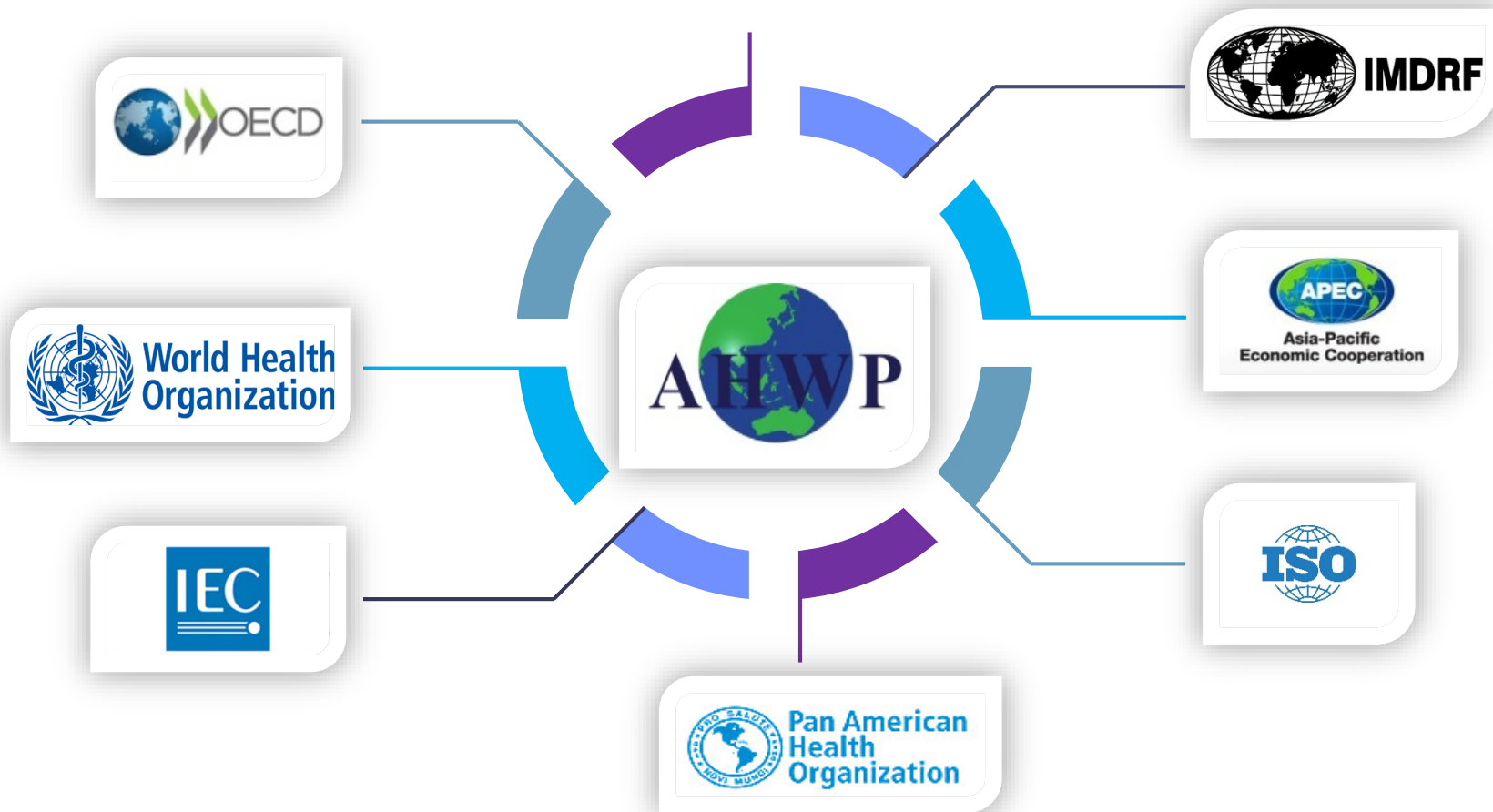


Asia Harmonization Working Party
2018 - 2020



30 Member Economies

AHWP Global Partnership



IMDRF Meeting, Shanghai
19-21 March 2018

AHWP Activities with Liaisons



AHWP Website Enhancement

New AHWP Website for Easier Access and Better Communication

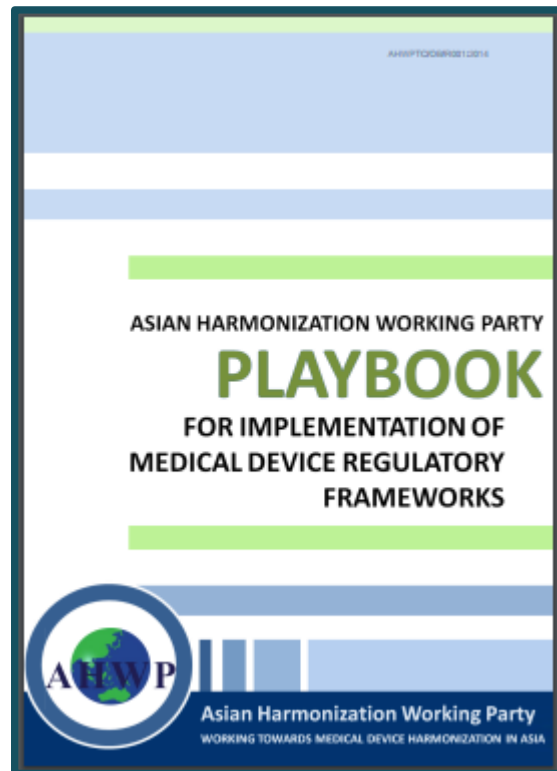
The screenshot displays the AHWP website interface. At the top left is the AHWP logo, which consists of a globe with the letters 'AHWP' overlaid. To the right of the logo is the text 'Asian Harmonization Working Party' and 'WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA'. Below the logo and text is a navigation menu with the following items: HOME, CHAIRMAN'S MESSAGE, HISTORICAL DEVELOPMENT, MEETING CALENDAR, and CONTACT. A search bar is located to the right of the navigation menu, containing the text 'Search the AHWP website.' Below the navigation menu is a large photograph of a group of people at a meeting, with the caption '20th AHWP annual meeting in Bangkok, Thailand'. To the left of the main content area is a sidebar with a 'MAIN SECTIONS-' header and a list of links: About AHWP, Member Economies, Technical Committee, News, Events Announcements, and Events. The main content area features a news item titled '19th AHWP Meeting Photos, Seoul, 18-21 Nov 2014', submitted by admin on Wed, 11/23/2016 - 14:55. Below the title is a 'test' comment and a 'Read more' button. To the right of the news item are social media icons for Facebook, Twitter, Google+, LinkedIn, and a plus sign. Below the news item is another news item titled 'STG (U&N) - Special Task Group on UDI & Nomenclature'. At the bottom of the main content area is a 'Reminder - Please prepare your VISA application for traveling to , New Delhi, India for the joining of 22nd AHWP Meeting' with an update date of 'Thu, 10/12/2017 - 16:47'. On the right side of the screenshot, a partial view of another page is visible, showing the text 'Working Party', 'HARMONIZATION IN ASIA', 'g Towards', 'al Device', 'onization', 'Asia', 'Delhi, India', 'ber 2017', and 'ni, India, 4-8'.

Our Capacity Building Journey

2014

2015 - 2017

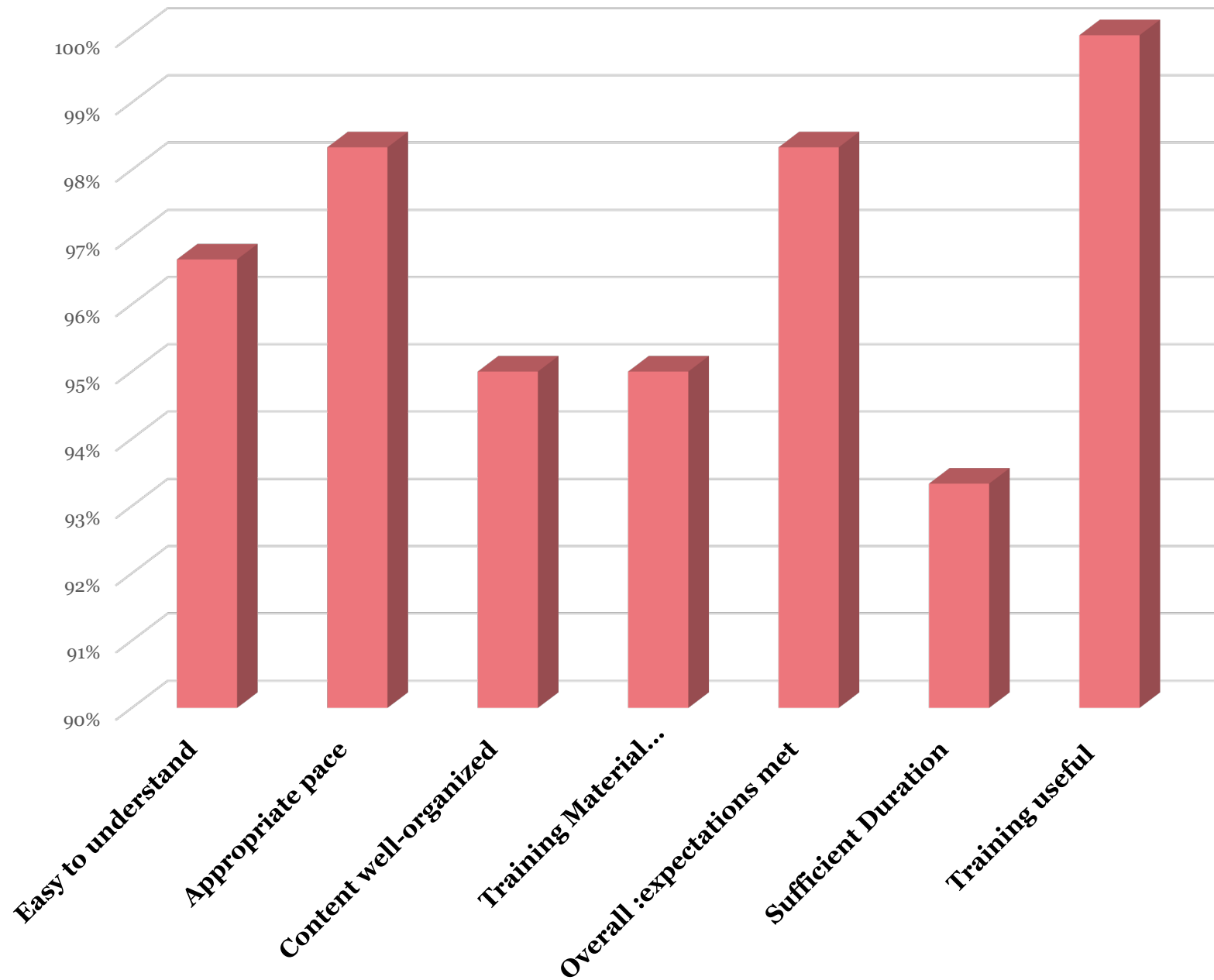
2018



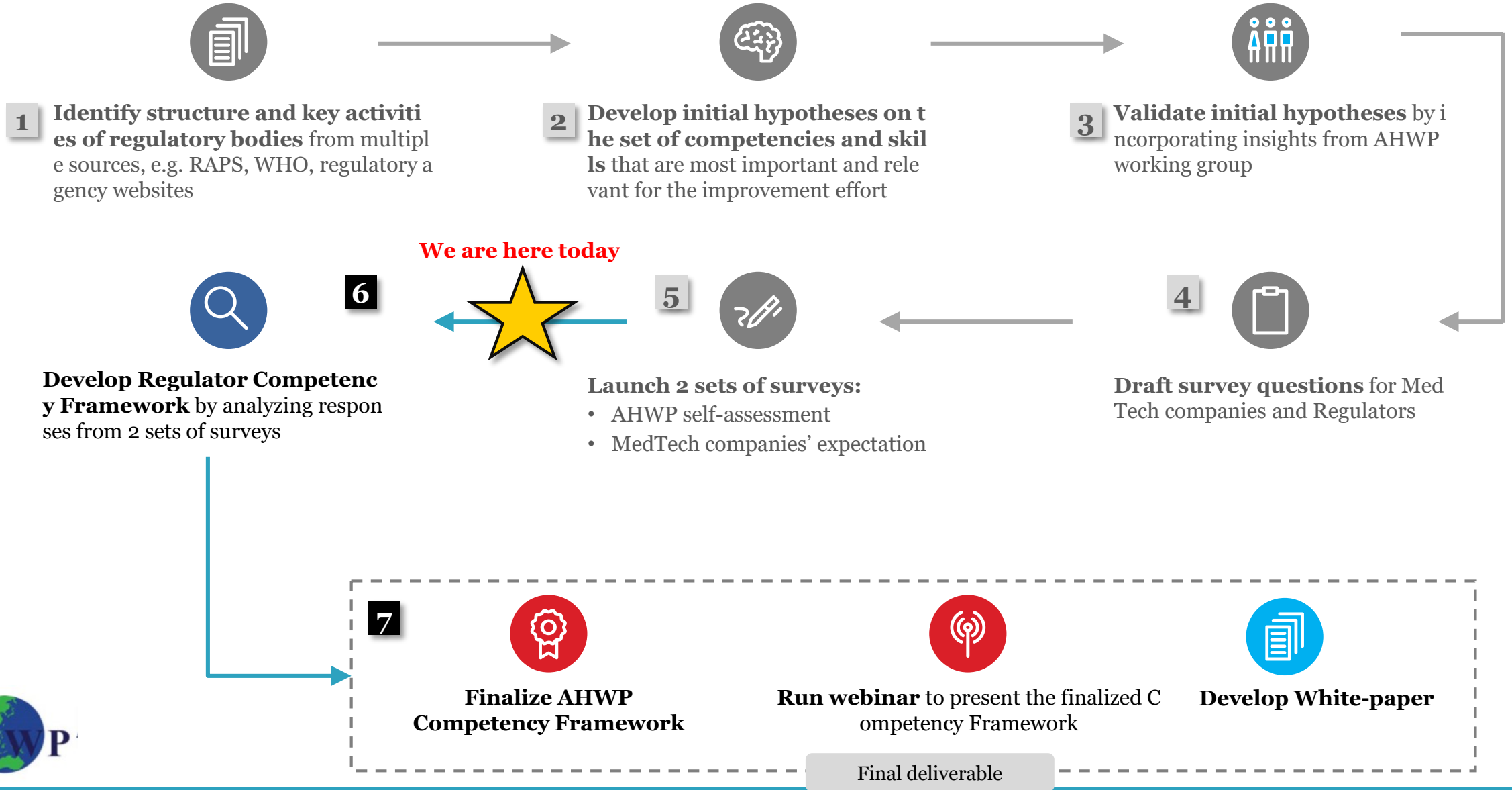
Launch Competency Framework
for MedTech Regulators

A joint initiative of AHWP, APACMed and Deloitte

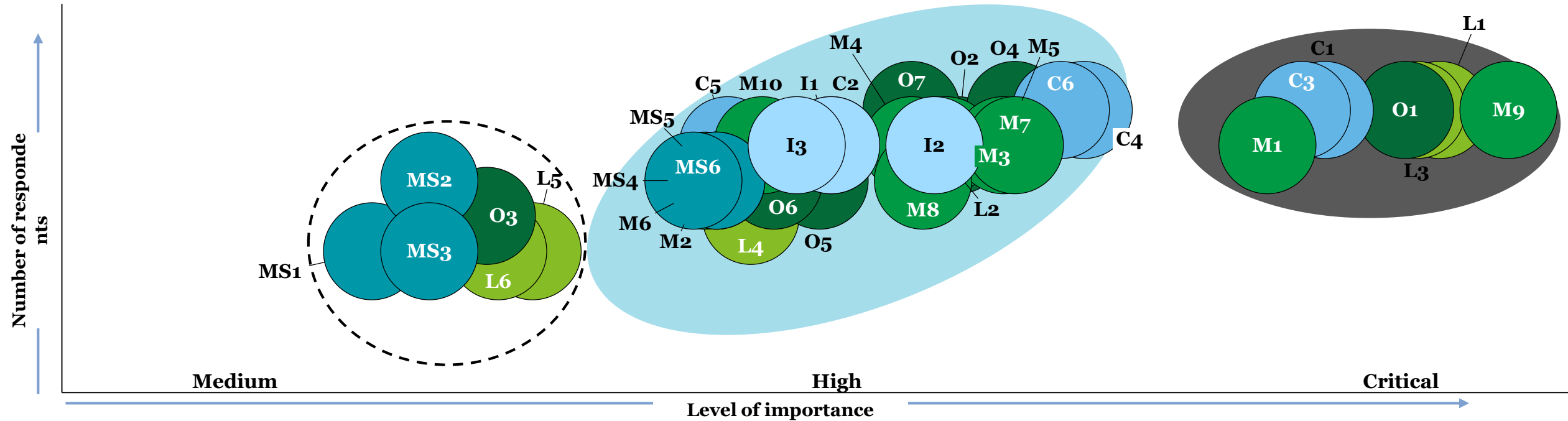
Member Economy Feedback



We are working with Deloitte using a survey based assessment



1 While foundational skills are considered as important across all economies, three distinct groups of competencies emerge across level of importance



Legal	
1	Understand & assess Legal documents (local)
2	...Legal documents (international)
3	Understand & assess Technical documents (local)
4	...Technical documents (international)
5	Understand Legislative process
6	Legal writing

Operation	
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

Communication	
1	Effective Communication
2	Public Speaking
3	Interpersonal Skills
4	Negotiation
5	Information Dissemination & Media Strategy
6	Public Education

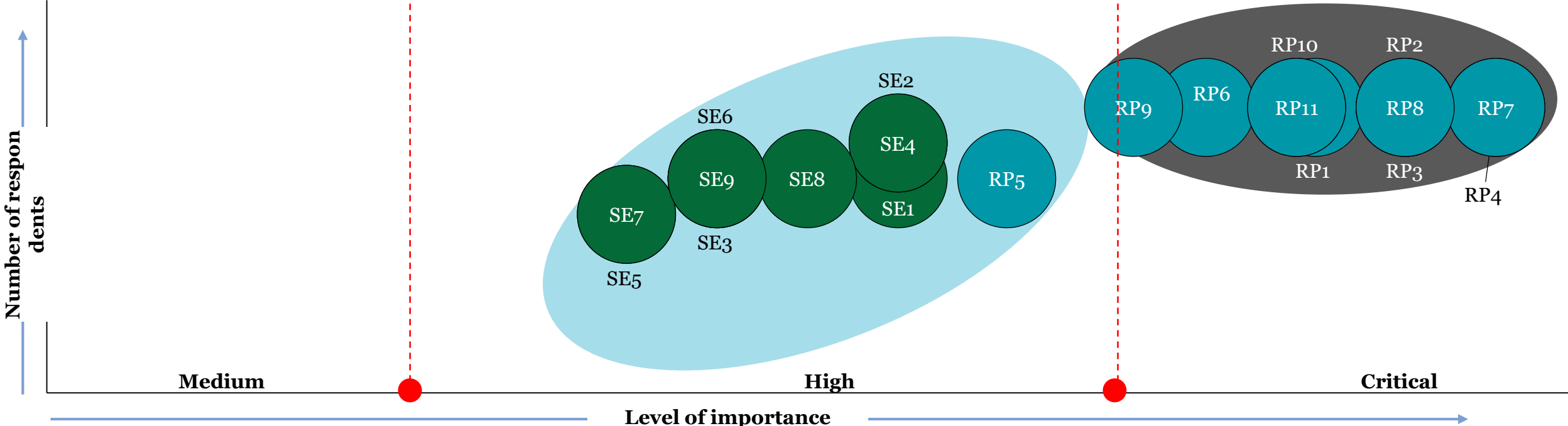
Management	
1	Quality Mgmt. system
2	Project Mgmt.
3	Risk Mgmt.
4	Crisis Mgmt.
5	People Mgmt.
6	Mentoring & Coaching
7	Training
8	Leadership
9	Good Regulatory Practice
10	Policy Analysis

Multisector partnership	
1	Foreign Languages & Culture
2	Diplomatic and Foreign Affairs Policy
3	Healthcare Ecosystem
4	Stakeholder Engagement
5	International Initiatives and networks
6	Public Health

Industry Insights	
1	Local industry landscape
2	Emerging technologies and products
3	International industry landscape

2

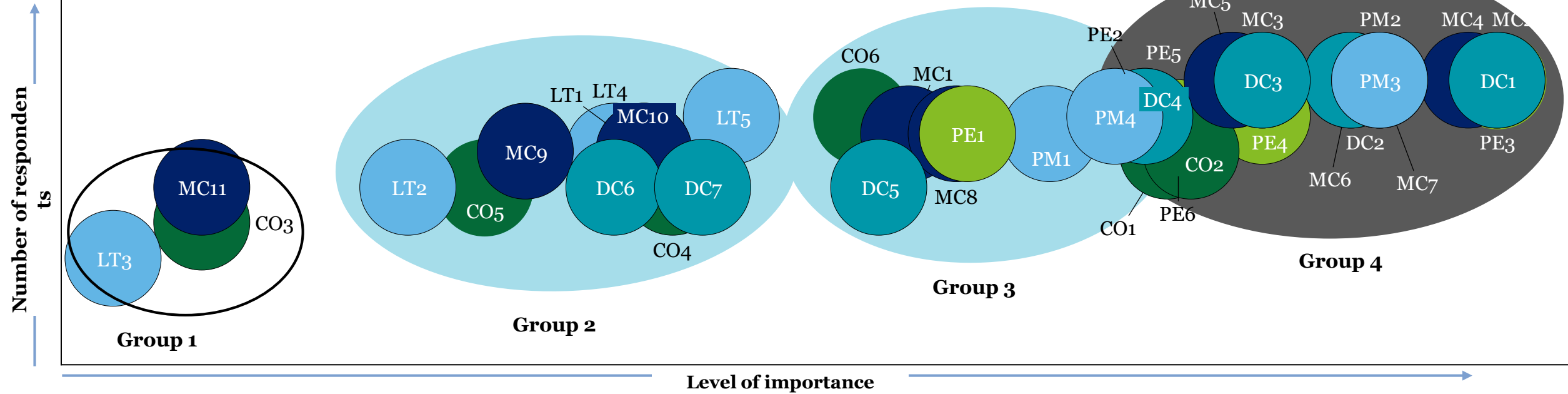
General technical skills are considered important, however capability and understanding of regulatory principles are critical



Scientific & Eng. Principles	
1	Human Anatomy and Physiology
2	Biological Science
3	Biochemistry
4	Biomaterials
5	Nanomaterials
6	Biomechanics
7	Bioelectronics
8	Radiation and Nuclear Medicine
9	Digital Technology (mobile health, tele medicine, AI, etc.)

Regulatory Principles	
1	Differences -Pharmaceuticals, General MDs & IVDs
2	Combination and Borderline Products
3	Risk Classification
4	Essential Principles of Safety & Performance
5	Device Nomenclature Systems (GMDN/UMDNS)
6	Device Labelling & Unique Device Identifier (UDI)
7	Conformity Assessment Concepts and Principles
8	Post-marketing Surveillance System
9	Supply chain integrity
10	Local Standards
11	International Standards

3 ...Skills and Capabilities required to undertake regulatory activities across Medical Device product life-cycle have been ranked across four levels of importance by member economies



Pre-Market	Clinical Oversight	Laboratory testing	Manufacturing control	Distribution Control	Post Market
1 International MD Rqmts.	1 Declaration of Helsinki & Nuremberg Code	1 Good Laboratory Practice	1 Intl. MD Rqmts. In Quality system (QS)	1 Good Distribution Practice	Intl. MD reqmts. in Post-
2 Device Registration Unit / Grouping Principles	2 ISO 14155 Clinical Investigation of MD for Human Subjects.	2 Laboratory Quality Management System	2 GMP (loc.)	2 Quality System auditing skills	1 marketing Surveillance
3 Submission Dossier Format and Content	3 Good Clinical Practice (ICH)	3 Occupational Health and Safety Standards	3 GMP(Intl.)	3 Risk Management principles	2 Risk Management principles
4 Declaration of Conformity Rqmts.	4 Good Clinical Practice (Local)	4 Relevant local test standards	4 QS auditing skills	4 Import/export regulations (loc.)	3 Advertising & Promotional Regulation
5 Device Change Management	5 Clinical Evaluation (Evidence Based)	5 Relevant international test standards	5 Loc./Intl. standards	5 Import/export regulations (Intl.)	4 Supervision on reprocessing of single-use medical devices
6 General Device Safety & Performance	6 Statistics		6 Design validation / verification methods	6 Disposal of MDs	
			7 Risk Mgmt. Principles	7 Environmental considerations	
			8 Mfg.Process & Tech.		
			9 Calibration/Metrology		
			10 Cleanroom process		
			11 Refurbishment of MDs		

& The Journey Continues

White Paper
Competency Handbook
Curriculum
Training certification

Thank You

