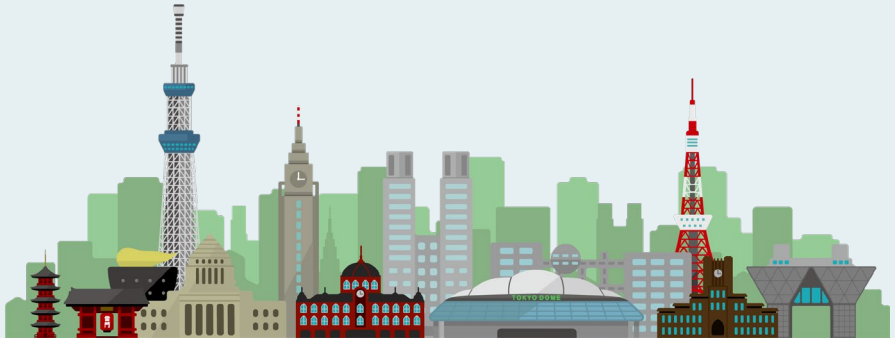
IMDRF International Medical Device Regulators Forum



APEC on the current effort of Training and Capacity Building initiatives

Muralitharan Paramasua, PhD
Chief Executive of Medical Device Authority (MDA), Malaysia

10th March 2025
Tokyo, Japan

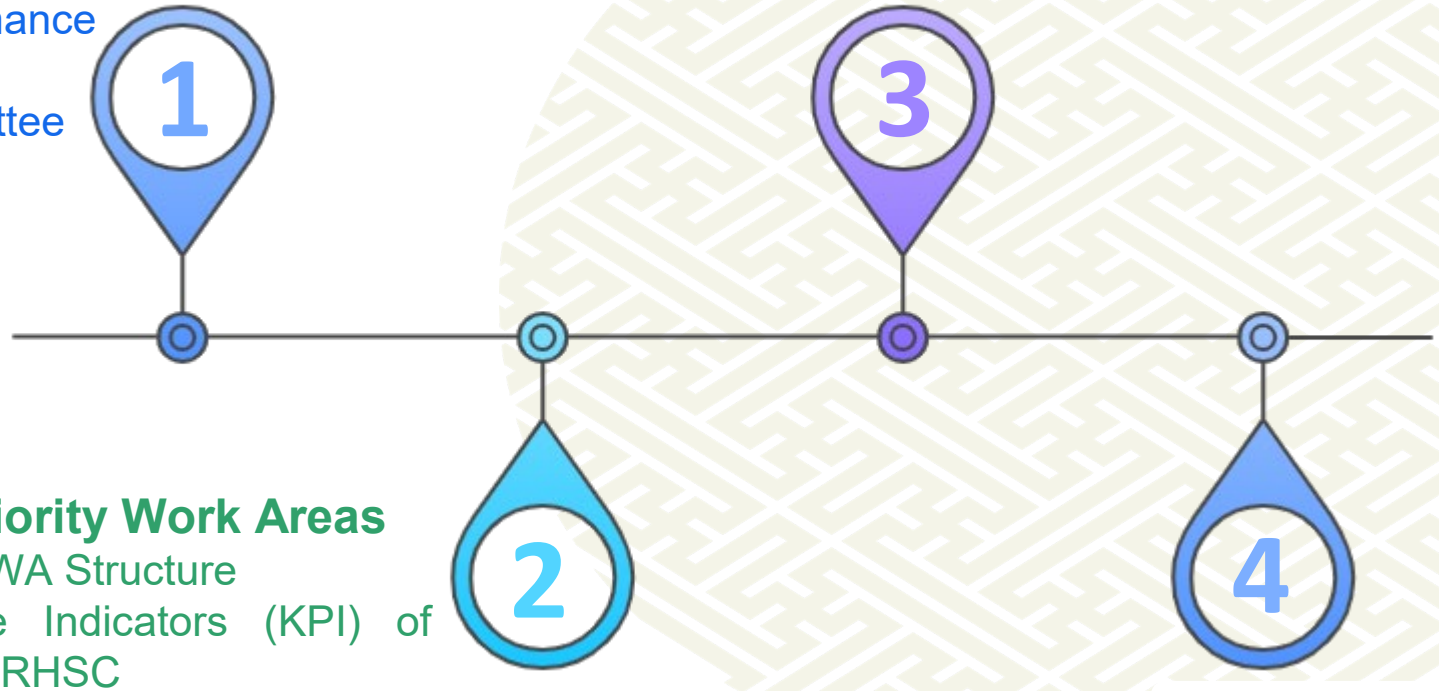
OVERVIEW

Asia-Pacific Economic Cooperation (APEC)

1. Committee on Trade and Investment (CTI)
2. Sub-Committee on Standards and Conformance (SCSC)
3. Regulatory Harmonization Steering Committee (RHSC) on Medical Products
   a. Goals, Strategies and Tactics of RHSC

Center of Excellence (CoE) Programs

Summary of CoE Activities (2024 and 2025)

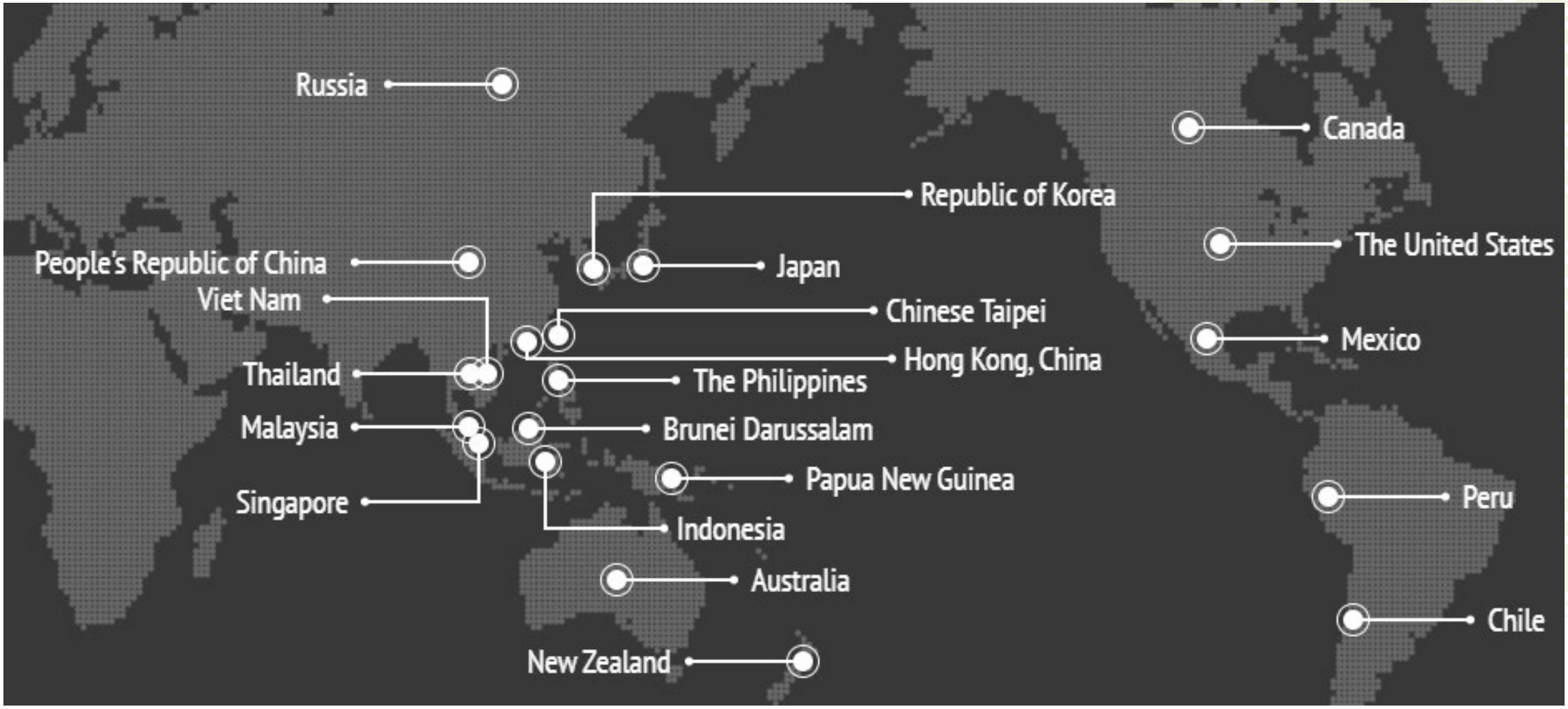


Medical Device Priority Work Areas

1. Medical Device PWA Structure
2. Key Performance Indicators (KPI) of Medical Device in RHSC
3. Medical Device PWA Roadmap
4. Medical Device PWA Core Curriculum

Next Steps

APEC 21 Economy Members



1. CTI

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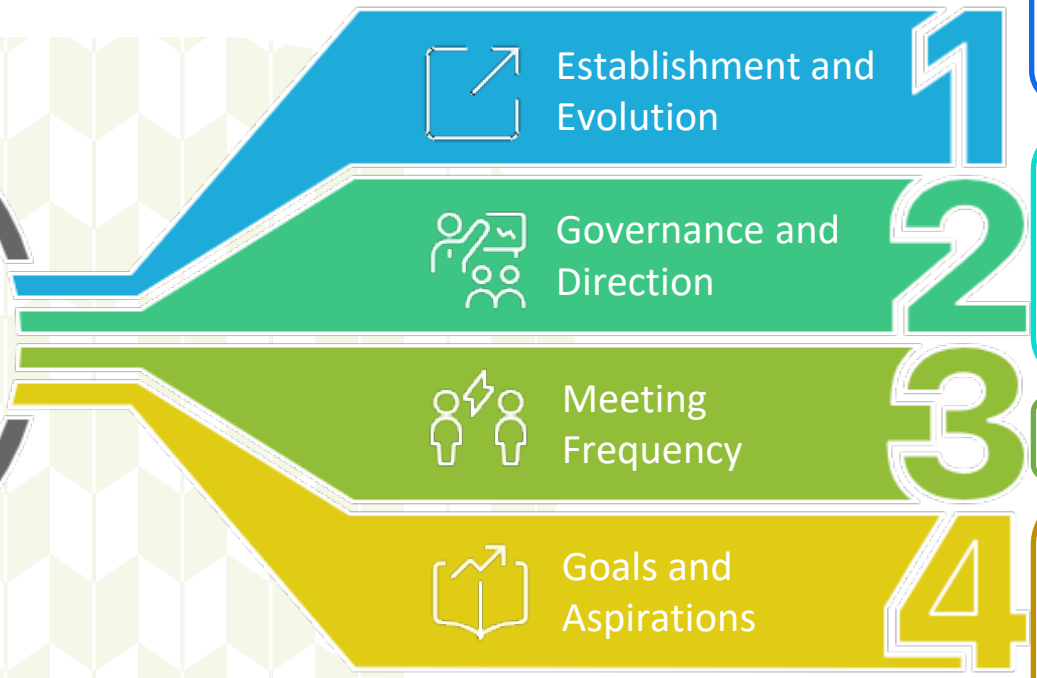
Asia-Pacific Economic Cooperation (APEC)

Committee on Trade and Investment (CTI)



- Established in November 1993
- A forum for APEC's 21 member economies to deliberate on all **trade, investment and policy issues**

- Guided by the **Putrajaya Vision 2040 (PV2040)**
- Aligned with **Aotearoa Plan of Action, APA (2021), the Bangkok Goals (2022) and the San Francisco Principles (2023)**

- 3 times a year (Senior Officials' Meetings)

- **Reduce impediments to business activity** in the areas outlined by the Osaka Action Agenda 1997 and **promote trade and investment** as stated in the APA
- Helping APEC **economies achieve free and open trade and investment while pursuing the PV2040**

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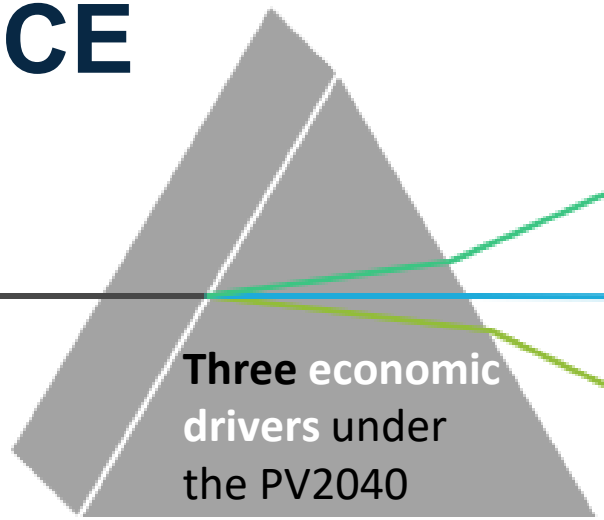
CTI GOVERNANCE

APEC Economic Leaders launched the **Putrajaya Vision 2040 (PV2040)** in 2020 and the **Aotearoa Plan of Action (APA)** in 2021



- Trade and Investment;
- Innovation and Digitalisation
- Strong, Balanced, Secure, Sustainable and Inclusive Growth.

With Peru as the host economy for **2024**, the three CTI plenary meetings in 2024 were aligned with the overall CTI work programme

- Support the Multilateral Trading System
- Aim to deepen Economic Integration in the Region
- Promote Trade Facilitation, Connectivity, Digitalisation, and Innovation
- Encourage Inclusion and Sustainability in trade practices

2. SCSC UNDER CTI

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SCSC's Role in APEC

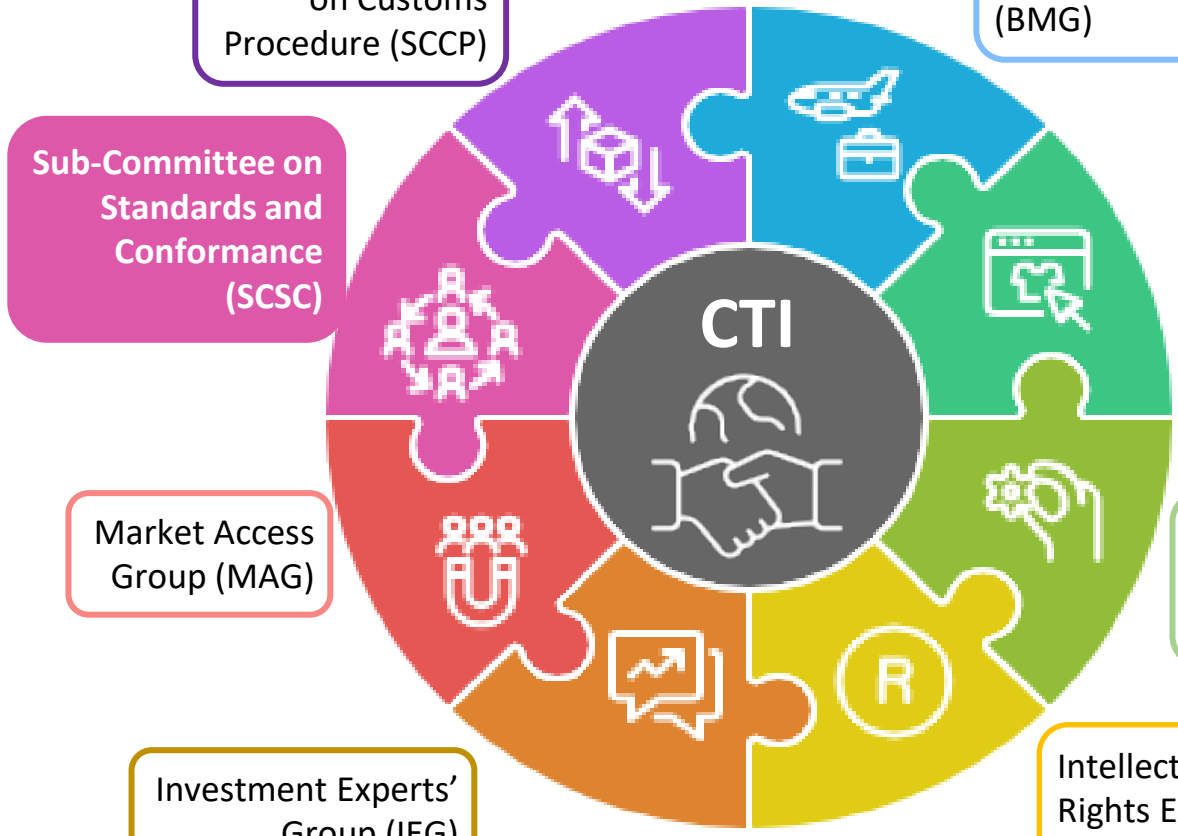
Establishment Year
1994

Purpose
Reduce trade barriers

Relationship with CTI
Assists CTI

APEC Goals
Trade liberalization

CTI Oversees 8 Sub-Groups



- Sub-Committee on Customs Procedure (SCCP)
- Business Mobility Group (BMG)
- Sub-Committee on Standards and Conformance (SCSC)
- Digital Economy Steering Group (DESG)
- Market Access Group (MAG)
- Group on Services (GOS)
- Investment Experts' Group (IEG)
- Intellectual Property Rights Experts Group (IPEG)

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SCSC Objectives

Reduce Barriers
Focus on minimizing trade obstacles through standards and conformance

Promote GRP
Encourage effective regulatory practices in standards

Regional Cooperation
Promote collaboration in line with global agreements

Education Programs
Support awareness initiatives for business capacity building

Align Standards
Ensure local standards match international benchmarks

Mutual Recognition
Foster agreements for conformity assessment

Greater Transparency
Advocate for openness in standard processes

1st economic driver "Trade and Investment"

- Reducing unnecessary barriers
- Improving economies' transparency through trade measures and policies
- Advance capacity building programmes (WTO Rules) → Transparency & notification obligations
- Promote trade and investment facilitation for all

2nd economic driver "Innovation & Digitalisation"

- Adopt new and emerging technologies
- Address challenges and barriers
- Promote e-commerce / digital trade

3rd economic driver "Strong, Balanced, Secure, Sustainable and Inclusive Growth"

- Encourage and exchange best practice policies, and promote capacity building programme

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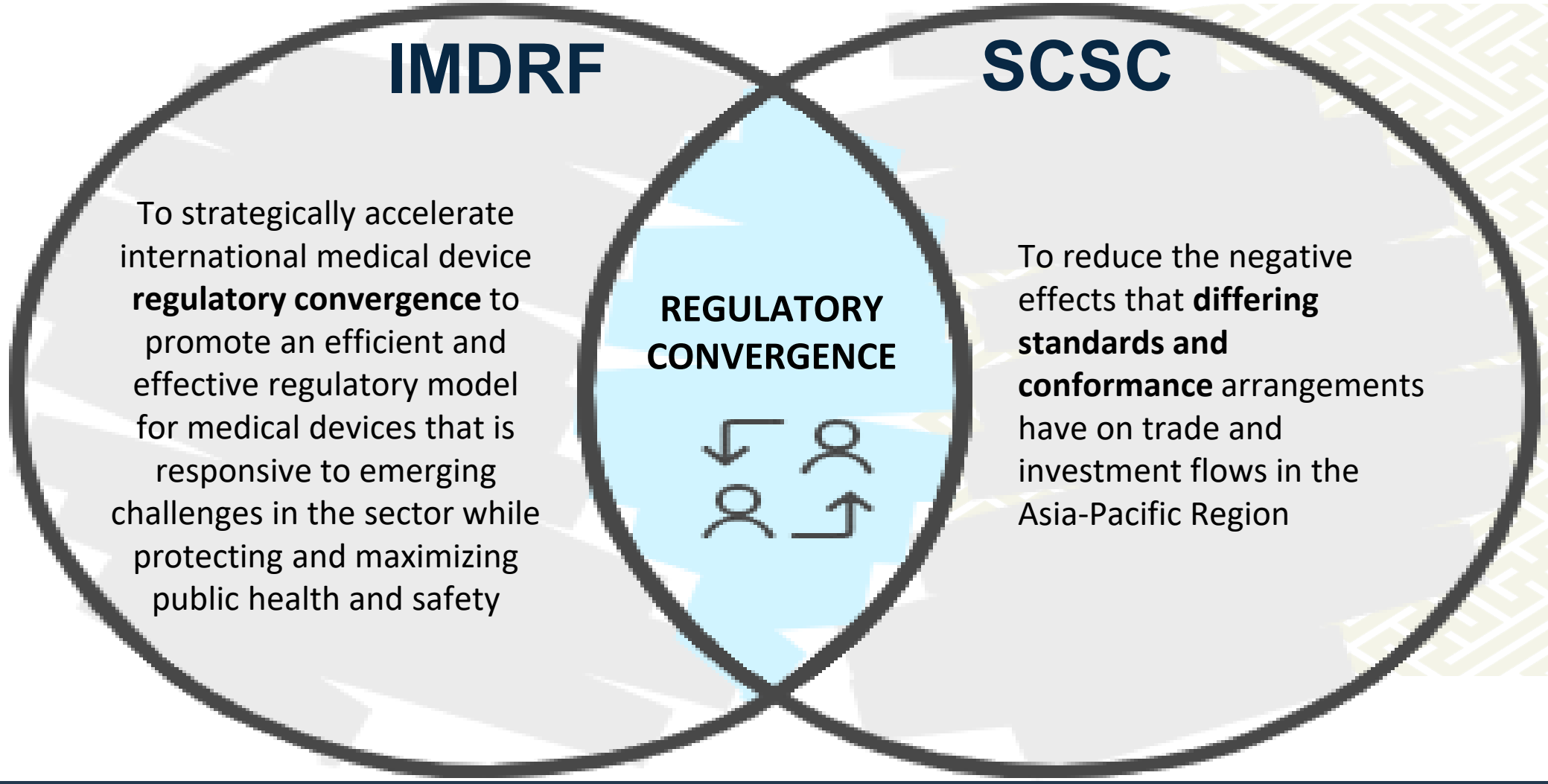
Mutual Objectives



3. RHSC UNDER SCSC

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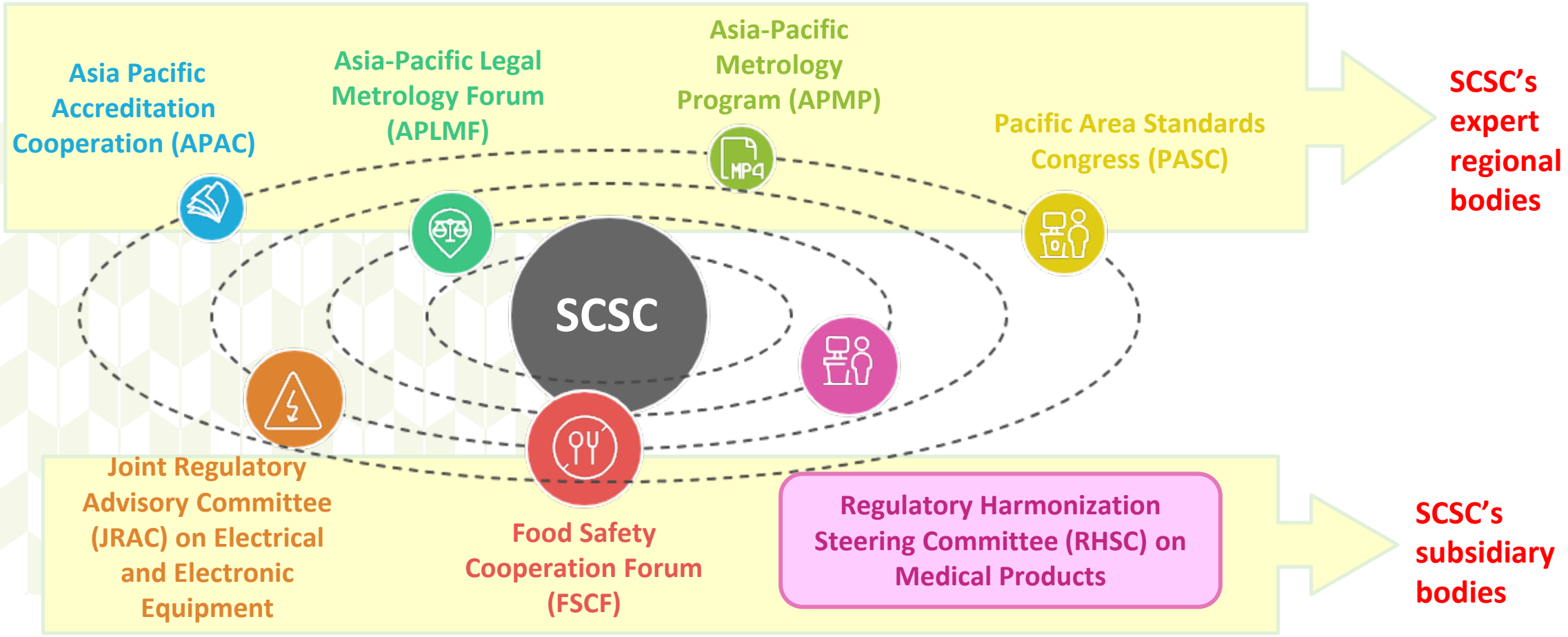
SCSC Structure



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RHSC GOVERNANCE

In March 2024, CTI endorsed the updated Terms of Reference (ToR) for the SCSC which now **incorporates the RHSC as Appendix 5 of SCSC's ToR**.

The RHSC's goal is **to promote regulatory convergence** and cooperation for medical products with the objectives of :

a. **facilitating regulatory convergence and cooperation** among medical product regulatory authorities;

b. **building human capacity in regulatory science** among medical product regulatory staff; and

c. promoting **convergence and reliance** among **regulatory policymakers in APEC.**

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Goals, Strategies & Tactics RHSC

IMDRF International Medical Device Regulators Forum

1 Goal of RHSC: Facilitate regulatory cooperation among medical product regulatory authorities

A

Strategy: Build neutral platforms for cohesion and alignment

- Action: **Convene meetings** of the RHSC twice per year
- Action: **Maintain Priority Work Areas** (PWAs)
- Action: **Create virtual spaces** for regulatory cooperation through the RHSC website and email distribution lists

B

Strategy: Build tools for regulatory information-sharing and work-sharing

- Action: **Development of template agreements**
- Action: **Developing a technical platform to facilitate information-sharing and work-sharing**

C

Strategy: Promote regulatory convergence and reliance and its tools

- Action: **Organize regular workshops** to explain and support the use of instruments of **reliance**
- Action: **Support participation in regulatory harmonization**
- Action: Explore the feasibility of developing consensus-driven joint APEC commitments and bilateral or multilateral **reliance agreements**

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2 Goal of RHSC : Build human capacity in regulatory science among medical product regulatory staff

A Strategy: Strengthen and scale APEC Training Centers of Excellence for Regulatory Science

- Action: **Support the Center of Excellence Coalition**
- Action: **Encourage consistent, long-term, and peer-to-peer Training** and **the development of peer networks for participants in person and virtually**
- Action: **Organize ad-hoc virtual and in-person workshops for Center Excellence faculty**
- Action: **Enable more regulatory staff** from more APEC economies to participate in Center of Excellence training programs by
- Action: **Measure the short- and long-term learning outcomes**

B Strategy: Maintain strategic roadmaps and core curricula to guide programming

- Action: **Review roadmaps** every 5 years at minimum, and core curricula every 2 years at a minimum

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3 Goal of RHSC : Promote political will for convergence and reliance among regulatory policymakers

A

Strategy: Explore new ways to measure regulatory convergence and its impacts

- Action: **Continue measuring progress towards regulatory convergence with proxy indicators**
- Action: **Analyze the macroeconomic case for and cost of inaction** on regulatory convergence and reliance

B

Strategy: Support policymakers seeking to establish or change legal frameworks, laws, or regulations

- Action: **Organize policy dialogues**
- Action: **Supply policymakers with guiding principles on decision-making** towards the establishment or change of legal frameworks, laws, or regulations, when needed

C

Strategy: Elevate the case for regulatory convergence and reliance, including at the highest political levels

- Action**: Issue an annual letter from the RHSC Co-Chairs to the heads of RA**
- Action: **Organize policy dialogues to discuss regulatory convergence and reliance**
- Action: **Secure continued high-level political support**
- Action: **Position APEC economies as champions of regulatory convergence and share progress with non-APEC economies**

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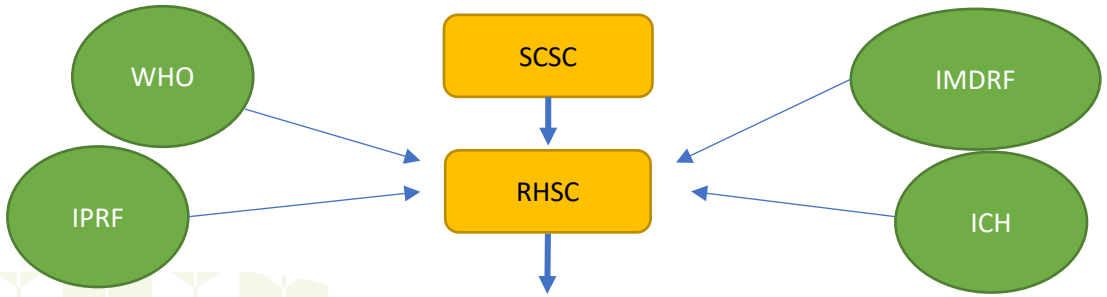
RHSC Structure



PWA 1	PWA 2	PWA 3	PWA 4	PWA 5	PWA 6	PWA 7
MEDICAL DEVICE	MRCT	PHARMACO VIGILANCE	BIOTHERAPIC PRODUCTS	ADVANCED THERAPY	GOOD REG MANAGEMENT	GLOBAL SUPPLY CHAIN
CO-CHAMPION	CO-CHAMPION	CO-CHAMPION	CO-CHAMPION	CO-CHAMPION	CO-CHAMPION	CO-CHAMPION
SUB-CHAMPION	SUB-CHAMPION	SUB-CHAMPION		SUB-CHAMPION	SUB-CHAMPION	SUB-CHAMPION
CoE / HOST INSTITUTION	CoE / HOST INSTITUTION	CoE / HOST INSTITUTION	CoE / HOST INSTITUTION	CoE / HOST INSTITUTION	CoE / HOST INSTITUTION	CoE / HOST INSTITUTION

NON-MEMBER *FORMER COE *PILOT COE

Every CoE has its own COE PROGRAM COMMITTEE

Every PWA has its own PWA STEERING COMMITTEE

CoE COALITION

5. MEDICAL DEVICE PWA

UNDER RHSC

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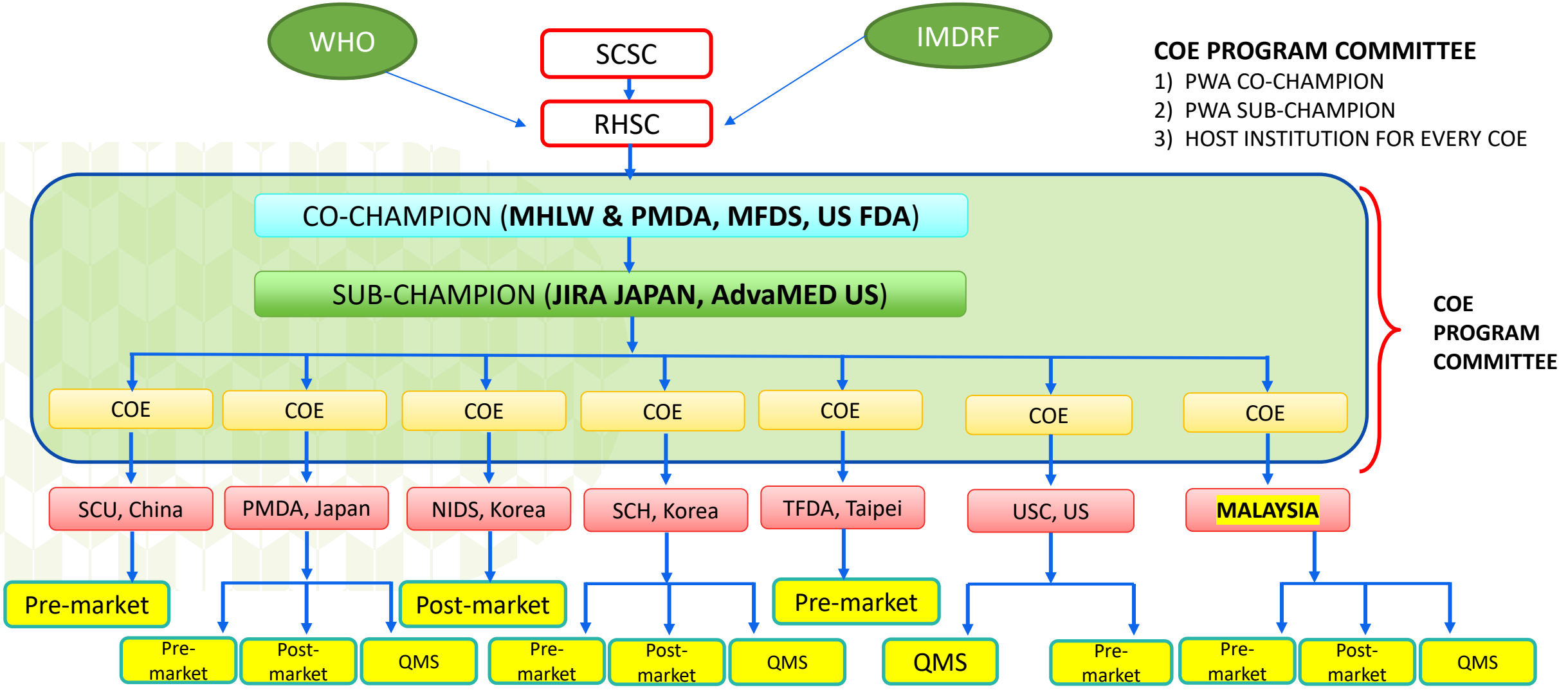
MEDICAL DEVICE PWA STRUCTURE



COE PROGRAM COMMITTEE

1) PWA CO-CHAMPION
2) PWA SUB-CHAMPION
3) HOST INSTITUTION FOR EVERY COE

COE PROGRAM COMMITTEE

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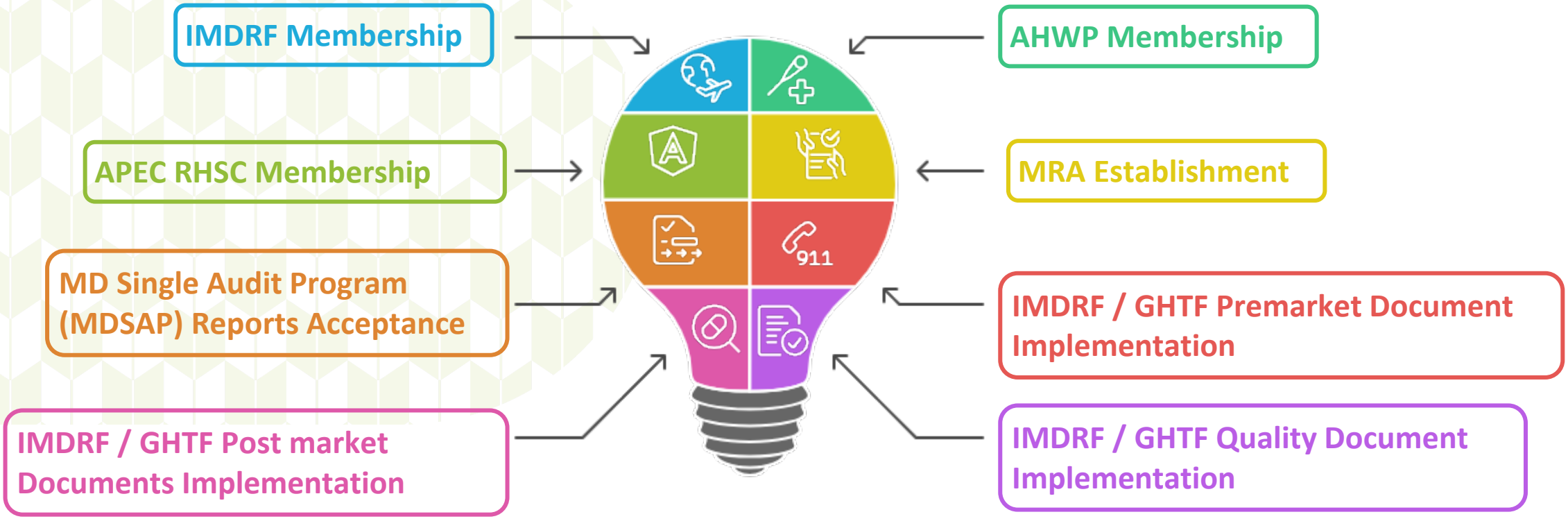
KPI in RHSC for Medical Devices

Establishment and monitoring of **eight (8) key performance indicators (KPIs)** to measure progress towards achieving **regulatory convergence for medical devices** over the last decade and on an annual basis, including:



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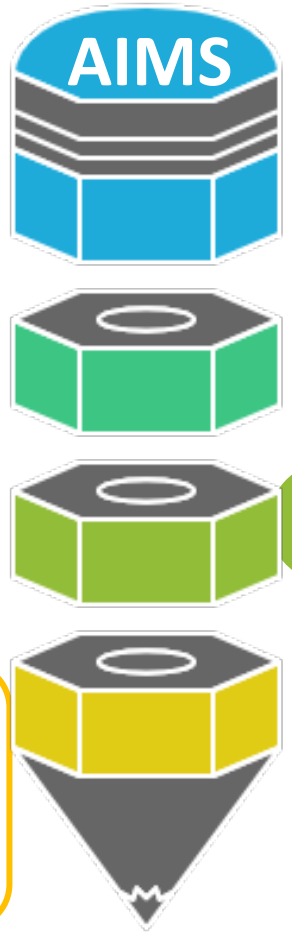
RHSC MD PWA ROADMAP (endorsed on 26/2/25)



1

Regulatory Capacity Building

Enhances regulatory knowledge and skills

2

International harmonization initiatives

Promotes global standards for MD

3

Harmonized Implementation Support

Facilitates consistent application across economies

4

Regulatory Convergence

Promotes regulatory convergence for medical device regulatory system

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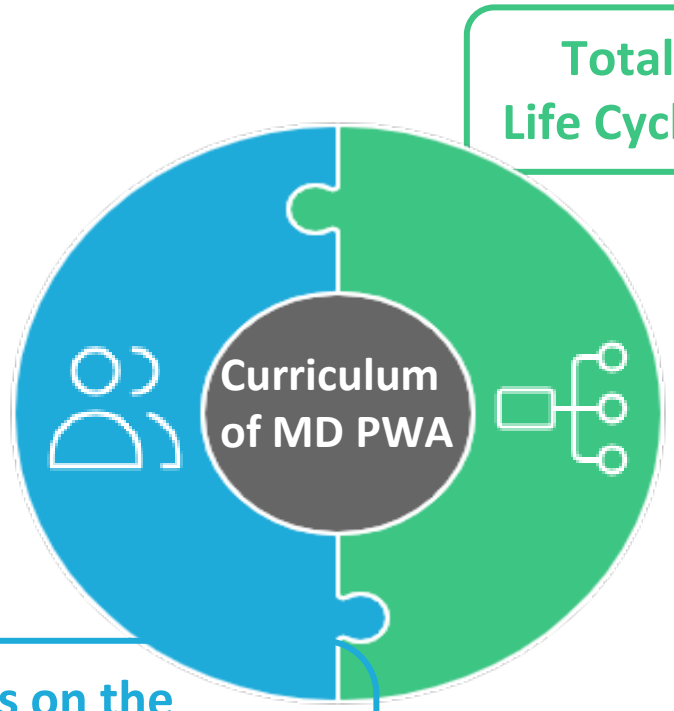
MD PWA CURRICULUM

NUMBER OF IMDRF DOCUMENT USED IN COE PROGRAM



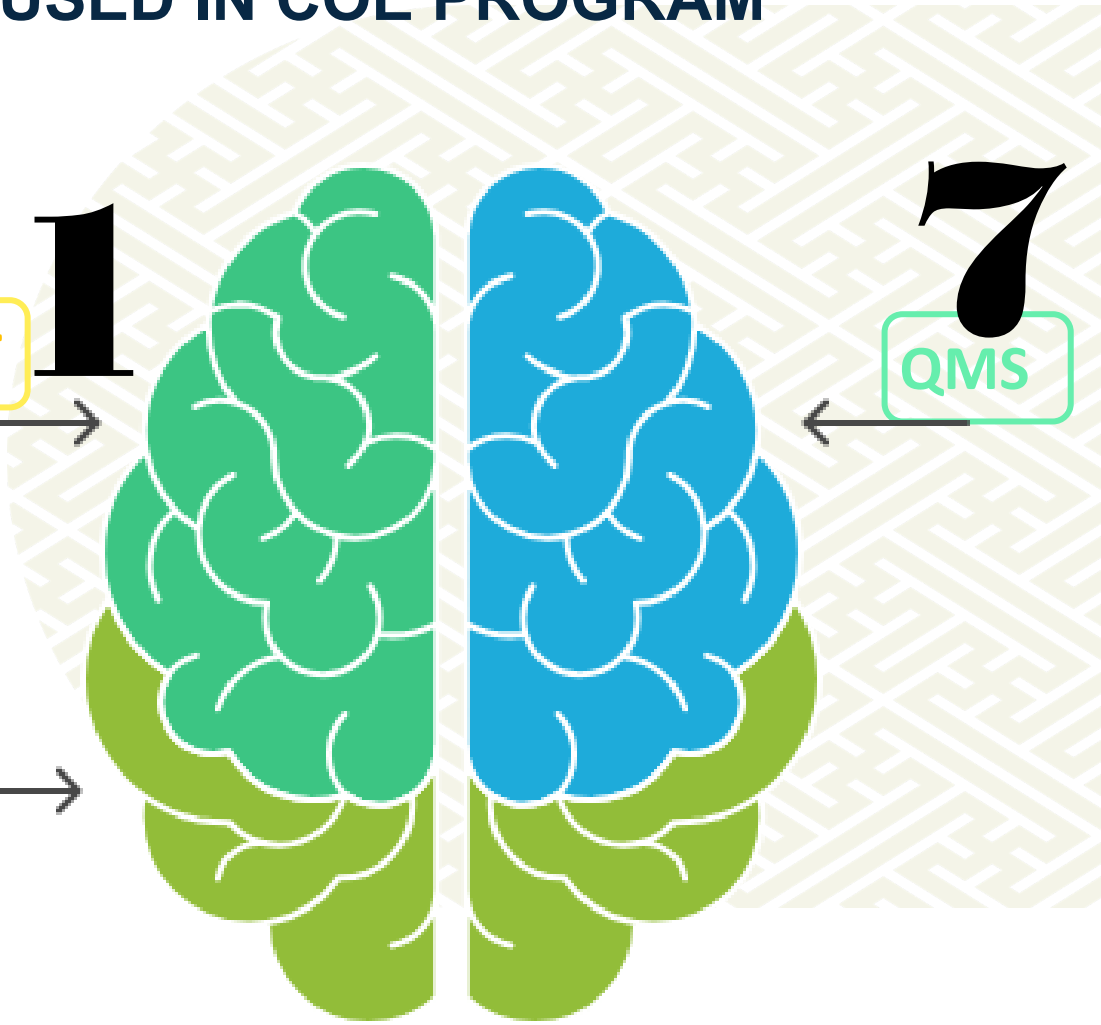
Total Product Life Cycle (TPLC)

Focuses on the GHTF/IMDRF foundational regulatory principles

POST MARKET **1**

PRE-MARKET **16**

7 QMS



EXAMPLE OF MD PWA CURRICULUM

Category	Elements	GHTF/IMDRF Documents and Standards
Pre-market	Medical Device Definitions	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (SG1/N071: 2012) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf
Pre-market	Medical Device Definitions	Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer (SG1/N055: 2009) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.pdf
Pre-market	Medical Device Classification	Principles of Medical Device Classification (SG1/N77: 2012) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf
Pre-market	Medical Device Classification	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG/N64FINAL:2021 (formerly GHTF/SG1/N045:2008)) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

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EXAMPLE OF MD PWA CURRICULUM

Category	Elements	GHTF/IMDRF Documents and Standards
QMS	Quality Management Systems and Risk Management	ISO13485: 2016 Medical devices -- Quality management systems -- Requirements for Regulatory Purposes
QMS	Quality Management Systems and Risk Management	ISO 14971: 2019 Medical Devices - Application of Risk Management for Medical Devices
Postmarket	Adverse Event Reporting	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n54r8-guidance-adverse-events-061130.pdf IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Edition 4) (IMDRF/AE WG/N43FINAL:2020) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf IMDRF/AE WG/N43FINAL: Updated Annexes https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes

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Summary of CoE Activities (2024 and 2025)

Name of institution	Economy	2024	2025 (Plan)
Sichuan University (SCU)	China	✓	
Pharmaceuticals and Medical Devices Agency (PMDA)	Japan	✓	-
Soonchunhyang University (SCH)	Korea	✓	✓
Taiwan Food and Drug Administration (TFDA)	Chinese Taipei	✓	✓
University of Southern California (USC)	United States	✓	✓

Malaysia MDA nominates to become Pilot CoE

1) Soon Chun Hyang University (SCH) APEC Medical Device CoE, Rep. of Korea

Application

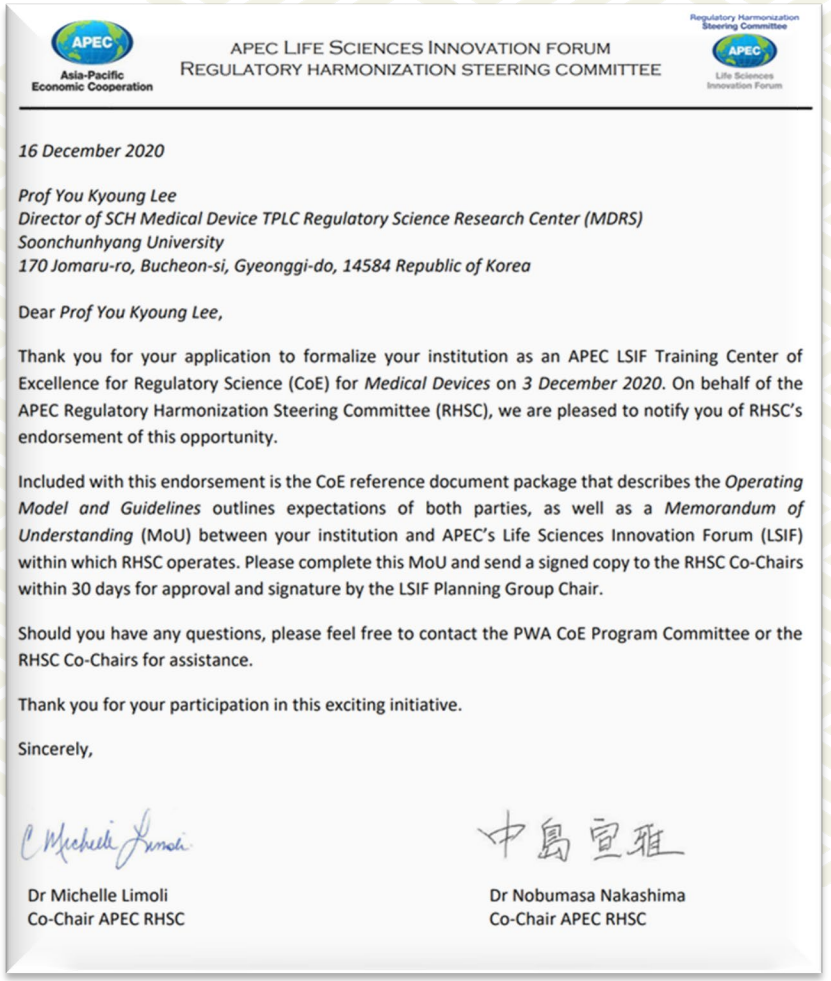
- Application for candidate CoE and CoE pilot training
- RHSC endorsed SCH pilot application (Jun 2020)

Formal CoE

- Conducted a CoE pilot training (Oct - Nov 2020)
- Recognition as a formal CoE (Dec 2020)

CoE Training

- 2021 SCH APEC MD CoE Training (Sep 2021)
- 2022 SCH APEC MD CoE Training (Nov 2022)
- 2023 SCH APEC MD CoE Training (Nov 2023)
- 2024 SCH APEC MD CoE Training (Oct 2024)



APEC Asia-Pacific Economic Cooperation

APEC LIFE SCIENCES INNOVATION FORUM
REGULATORY HARMONIZATION STEERING COMMITTEE

Regulatory Harmonization Steering Committee
APEC Life Sciences Innovation Forum

16 December 2020

Prof You Kyoung Lee
Director of SCH Medical Device TPLC Regulatory Science Research Center (MDRS)
Soonchunhyang University
170 Jomaru-ro, Bucheon-si, Gyeonggi-do, 14584 Republic of Korea

Dear *Prof You Kyoung Lee*,

Thank you for your application to formalize your institution as an APEC LSIF Training Center of Excellence for Regulatory Science (CoE) for *Medical Devices* on *3 December 2020*. On behalf of the APEC Regulatory Harmonization Steering Committee (RHSC), we are pleased to notify you of RHSC's endorsement of this opportunity.

Included with this endorsement is the CoE reference document package that describes the *Operating Model and Guidelines* outlines expectations of both parties, as well as a *Memorandum of Understanding* (MoU) between your institution and APEC's Life Sciences Innovation Forum (LSIF) within which RHSC operates. Please complete this MoU and send a signed copy to the RHSC Co-Chairs within 30 days for approval and signature by the LSIF Planning Group Chair.

Should you have any questions, please feel free to contact the PWA CoE Program Committee or the RHSC Co-Chairs for assistance.

Thank you for your participation in this exciting initiative.

Sincerely,

Dr Michelle Limoli
Co-Chair APEC RHSC

Dr Nobumasa Nakashima
Co-Chair APEC RHSC

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2024 SCH APEC Medical Device CoE Training Survey result

Participants and Participating Economies

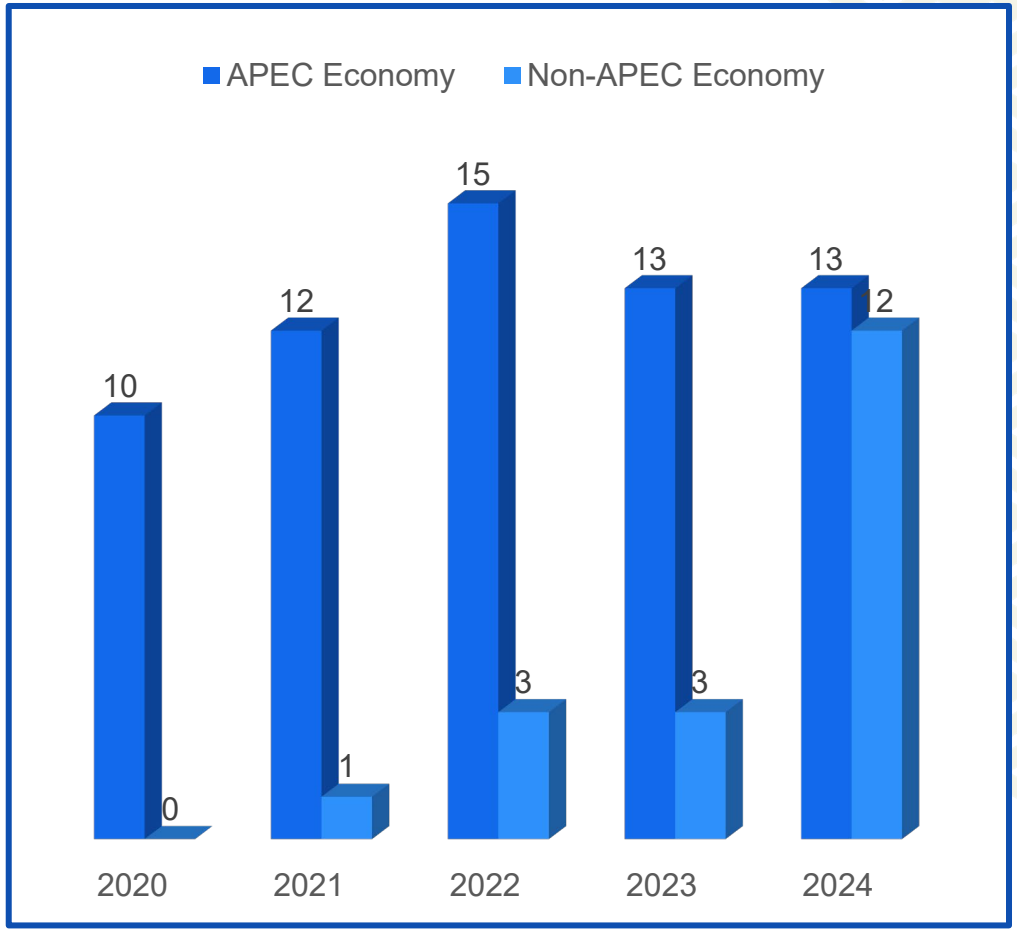
(2020) 10 economies, 130 Participants

(2021) 13 economies, 138 participants

(2022) 18 economies, 129 participants

(2023) 16 economies, 115 participants

(2024) 25 economies, 232 participants



Satisfaction Survey

Overall satisfaction 4.64

Training topics satisfaction 4.62

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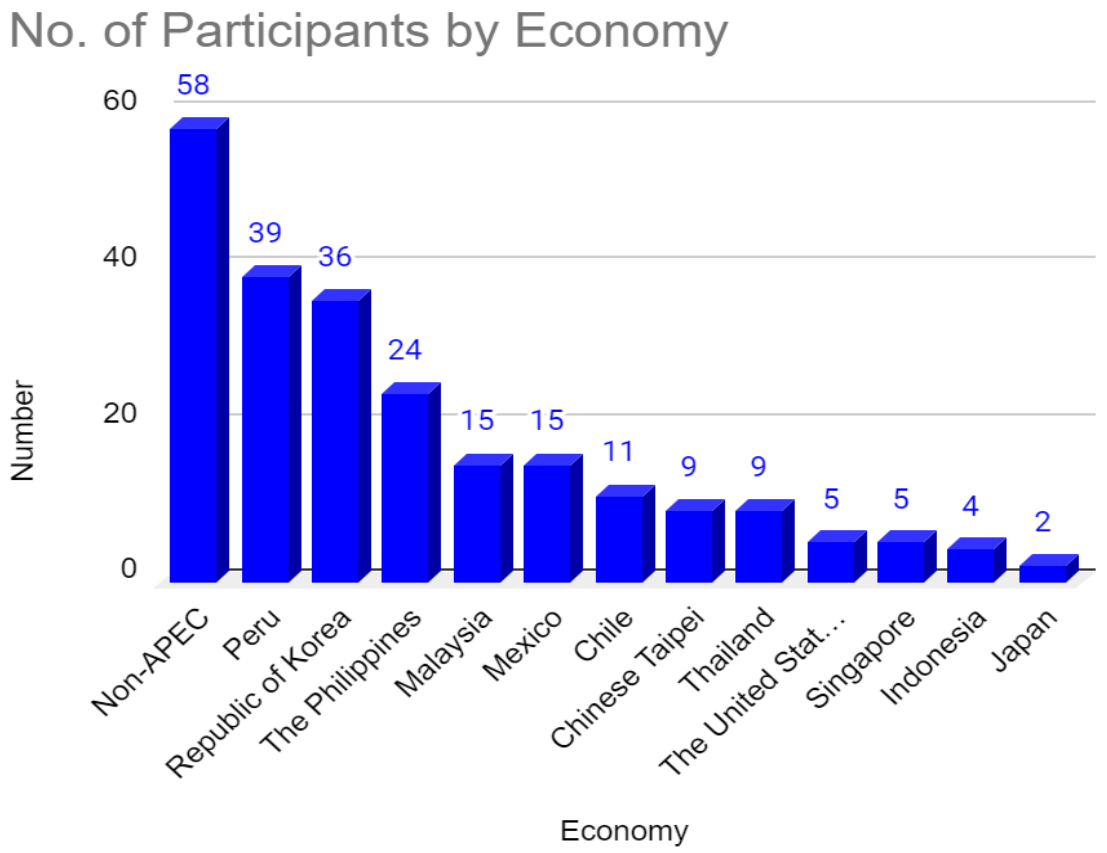
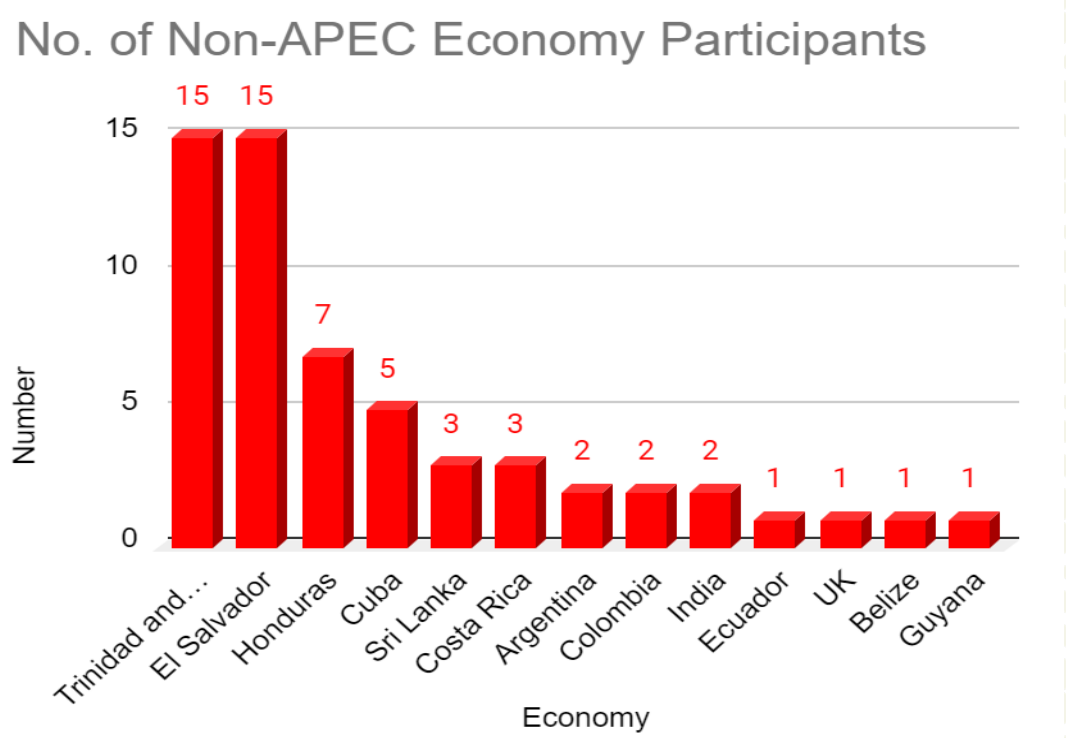
2024 SCH APEC Medical Device CoE Training
Trainees' data analysis





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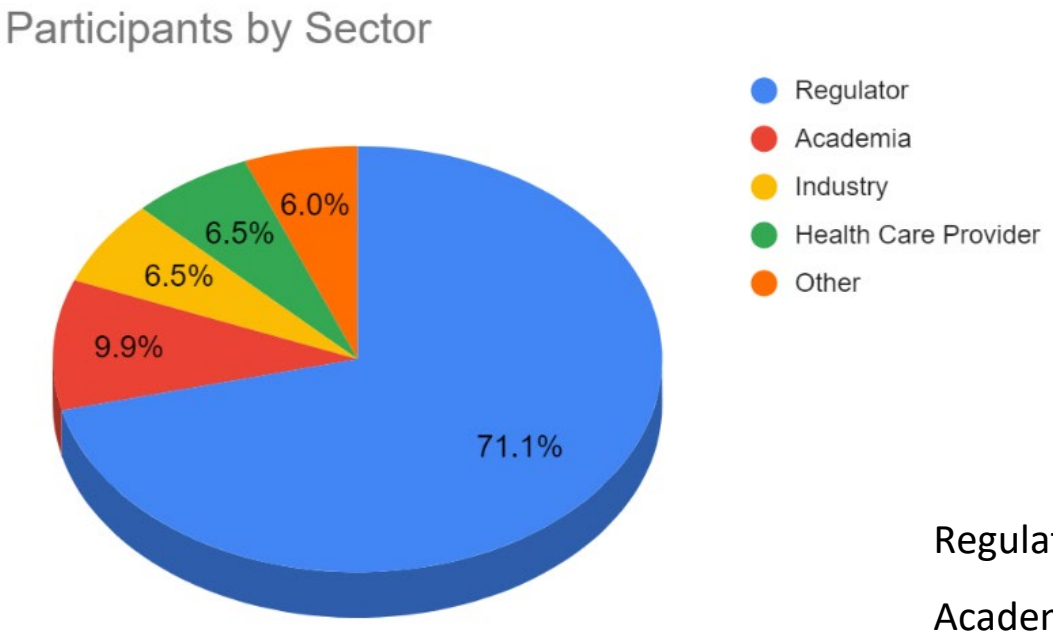
2024 SCH APEC Medical Device CoE Training
Trainees' data analysis



Regulator – 165 participants (71.1%)

Academia – 23 participants (9.9%)

Industry – 15 participants (6.5%)

Health Care Provider- 15 participants (6.5%)

ETC (International Organization, consulting company, INGO, etc.) – 14 participants (6%)

2) USC Mann DK Kim International Center for Regulator Science

Top-Line Summary

Registrations:

16 registered

7 canceled

9 on-site from 5 economies,

Speakers: 12

Areas of interest for participants:

- Case Studies of Design Control
- Risk Management
- Conformity Assessments
- Outcomes

Attendee Demographics (n=9)

- 1 Chile
- 2 Indonesia
- 2 Malaysia
- 2 Papua New Guinea
- 2 Peru

Institution	Number of Attendees
Medical Device Authority, Ministry of Health, Malaysia	1
Medical Device Authority, Malaysia	1
National Department of Health Papua New Guinea	2
General Directorate of Medicines Supplies and Drug, Peru	2
Ministry of Health, Republic of Indonesia	2
Instituto de Salud Pública de Chile	1

IMDRF International Medical Device Regulators Forum

3) PMDA-ATC

CoE Update: Medical Device PWA

KANEMATSU Miwa

Pharmaceuticals and Medical Devices Agency (PMDA)

Japan

PMDA

PMDA-ATC

Participants

Participants: 37 from 22 economies

APEC Economies		Non-APEC Economies			
Australia	4	Algeria	2	Nepal	1
Brunei Darussalam	2	Bangladesh	1	Pakistan	2
Chinese Taipei	1	Egypt	1	South Africa	2
The Philippines	1	El Salvador	2	Sri Lanka	2
Singapore	1	Ethiopia	2	Tanzania	1
Thailand	2	Guyana	1	Timor-Leste	1
		India	2	Uganda	1
		Myanmar	2	Uzbekistan	3

Program

Day 1: Lectures on the international harmonization of medical device regulations, reviews of medical devices and QMS for medical devices

Day 2: A case study on the post-market safety measures for medical devices

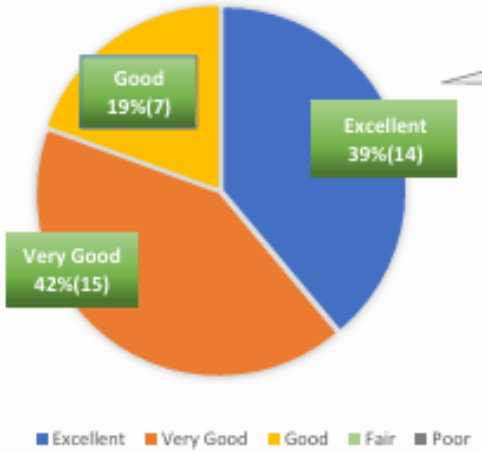
PMDA lecturers

Participants

PMDA

Satisfaction of Participants

Overall satisfaction



Comments from the participants

In general, the webinar is useful to know the area that we are not very aware of such as IMDRF terminology.

It is a great opportunity for us to learn developed regulatory system to apply this knowledge in the development of their own regulation.

A wonderful opportunity.
I got to learn a lot of things
I can implement in my economy.

What to expect

- Enhance the cooperation between IMDRF and APEC; usage of document, expand the scope of the curriculum in the capacity building program (eg; regulatory sandbox, agile regulatory governance, digitalisation)
- Promote regulatory convergence among APEC economies to facilitate the trade
- Mutual cooperation to address the issue of tariff and non-tariff (technical regulation)

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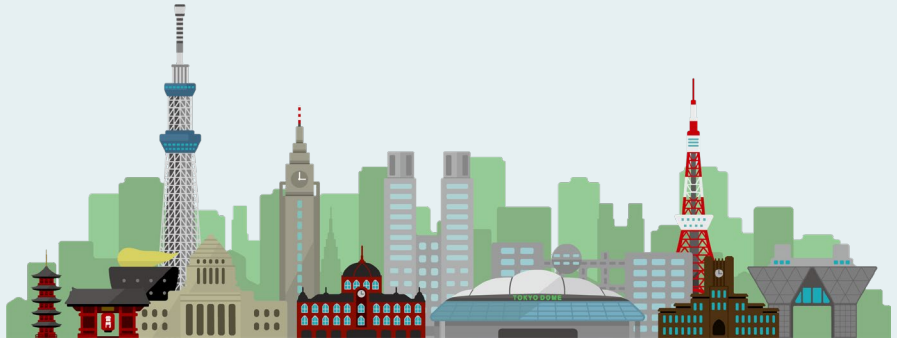

Thank you/Questions

Text style
- Bullet level 1 style
  - Bullet level 2 style
    - Bullet level 3 style

Subhead style