Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

APACMed
The voice of MedTech

GHWP LIAISON MEMBER UPDATES

APACMed

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Agenda

- APACMed Overview
- White and positions papers for advocacy on key RA topics
- Capability Building activities
- Engagements with international regulatory bodies and authorities
- Recent Highlights in RA

ONE

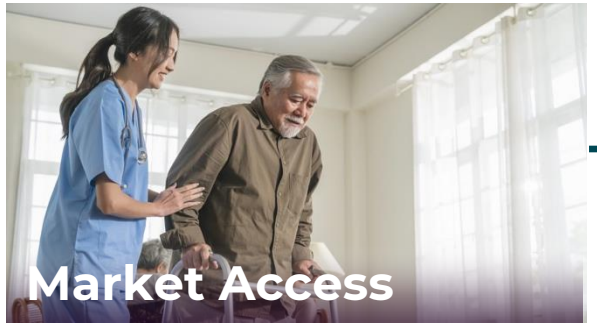
Voice

The unifying voice for the medical devices, in-vitro diagnostics and digital health industry in APAC.

Mission

To improve the standards of care for patients in APAC through strategic collaborations with MedTech stakeholders.

Committees & Working Groups



APACMed

RAC – Leadership Team

Paul Tan
ABBOTT
RA Committee
Board Sponsor

Cindy Pelou
APACMED
RA Committee
Manager

Gunjan Verma
APACMED
RA Committee
Advisor

Devya Bharati
APACMED
RA Committee
Associate

600+ Individual members

60+ Companies

Miang Tanaka.
J&J VISION
RA Committee
Chair

Yasha Huang
ROCHE DGN
RA Committee
Vice-Chair

Jason Guo
ABBOTT
RA Committee
Vice-Chair

James Chan
VARIAN
RA Committee
Vice-Chair

Marianne Yap
ALCON
RA Committee
Vice-Chair

RAC – Our Vision and Objectives

Accelerating Market Access

By advocating for harmonized regulations, regulatory reliance, and fit-for-purpose frameworks for emerging technologies, reducing approval times and enhanced patient access.

Building Capabilities

By providing capability-building programs and regulatory intelligence to equip professionals with the skills and tools needed to navigate complex regulatory landscapes efficiently.

Being a Trusted Partner

By building long-term, sustainable relationships with all MedTech Stakeholders, enabling trust in interactions through knowledge-sharing and dissemination, with the ultimate objective of ensuring patient safety.

White and positions papers for advocacy on key RA topics

Regulating SaMD

Regulating Health Data

Electronic Labelling

PMS & PMV

IVD, LDT, RUO Regulations

Risk-based Change Management

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Capability Building activities

We developed a **Harmonized Regulators Curriculum** (LINK HERE):
standardized training curriculum based on the competency framework for MedTech Regulatory officials to initiate capability development processes

We developed an **E-learning Hub**: on demand self-paced training videos, based on different stages of product lifecycle

We **train and collaborate with Regulators** in APAC:

- Workshop on IVD regulation with Vietnam IMDA
- Workshop on Change Management with Malaysia MDA
- SaMD Regulatory Panel Discussion with HSA, MDA, MFDS, PMDA, TGA
- PPCP Panel Discussion with HSA, MDA, MFDS, PMDA, TGA

Engagements with international regulatory bodies and authorities

Regional SaMD Roundtable

AMDC in Yogyakarta

RA Forum in Singapore

Workshop with MDA Malaysia

Indonesia MOH

Thai FDA

IMDA Vietnam

Philippines FDA

CDSCO India

Sri Lanka NMRA

Engagements with international regulatory bodies and authorities

We are Industry Coalition Lead of the Asia Pacific Economic Cooperation Regulatory Harmonisation Steering Committee (APEC RHSC)

We are a member of the WHO Network for Regulatory Systems Strengthening

We participate in the International Medical Device Regulators Forum (IMDRF) Conferences and collaborate on the conference agenda

We are GHWP Industry Liaison Partner

We are a member of the GMTA

We are co-organiser of the AMDC annual meetings, especially the Public-Private Dialogues (PPF)

Recent Highlights in RA

REGULATORY RELIANCE

- Including change management in the SG-TH reliance program and shared lessons learned to guide others in implementing similar initiatives
- Work closely with local industry associations to ensure that the private sector is actively participating in regulatory reliance initiatives
- Foster collaboration between industry experts and regulatory authorities to address common challenges
- Establish regular communication channels with regulatory partners to address any emerging issues or challenges in reliance programs
- Facilitating a reliance pilot between Malaysia and Singapore
- Facilitating a reliance pilot between Thailand and Laos

STAKEHOLDER ENGAGEMENT

- Participation in international regulatory forums such as the IMDRF and GHWP to share insights and collaborate on global regulatory standards
- Organize networking events and roundtable discussions that bring together regulators, industry representatives, and other stakeholders to foster collaboration and information exchange
- Country missions to MDA Malaysia, IMDA Vietnam, Philippines FDA, Indonesia MOH and others
- Annual dialogue with health authorities (e.g., HSA) to discuss regulatory developments, and address industry concerns
- Partnerships with academic institutions to leverage research and expertise, contributing to capacity building and knowledge dissemination

CAPABILITY BUILDING AND ADVOCACY

- Advocated for and shaped streamlined and harmonized regulations on key topics [electronic IFU (ID), IVD (VN), Change management (MY, TH, SG), Halal policy (ID), PMS (ID), Shelf life (IN), Medical equipment registration (IN), Import control regulations (MY), GMP licence renewal (KR), Streamlining MD regulations (SL)]

REGULATORY INTELLIGENCE

- Knowledge creation & intelligence for pro- active advocacy in key markets
- Monthly regulatory intelligence bulletin
- Regular Webinars on Regulatory Updates

APACMed values GHWP's work in advancing regulatory harmonisation and convergence for medical devices, recognising the importance of fostering innovation and collaborative efforts to improve regulatory processes and global access to medical technologies.

Thank you!

For any query feel free to contact me at cpelou@apacmed.org

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