

GHWP LIAISON MEMBER UPDATES - **APACMed**

December 4th, 2025

ONE VOICE

We are the unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific.





The voice of MedTech

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.

APACMed Membership – 350 Members



60 Corporates



160 Start-ups



65 Associates



20 Industry Associations



Our Network and Partners

India



North & Northeast Asia



北京大学
PEKING UNIVERSITY



香港中文大學
The Chinese University of Hong Kong

SEA



Philippine Association of Medical Device
PAMDRAP
Regulatory Affairs Professionals



USTDA
U.S. TRADE AND DEVELOPMENT AGENCY



SINGAPORE
MANUFACTURING
FEDERATION
新加坡製造商總會



ANZ




Global/International




Committees & Working Groups




REGULATORY AFFAIRS
730+ Individual Members
55+ Companies



MARKET ACCESS
250+ Individual Members
40+ Companies




GOVERNMENT AFFAIRS & POLICY
250+ Individual Members
50+ Companies



HEALTH DATA
300+ Individual Members
70+ Companies



LEGAL, ETHICS & COMPLIANCE
140+ Individual Members
35+ Companies



START-UPS
100+ Individual Members
150 Companies



Working Groups
ESG | IVD | AI

RA Committee – Leadership Teams



Joaquin Lasso
SMITH & NEPHEW

Board Sponsor



Cindy Pelou
APACMed

Secretariat



Sharad Shukla
J&J



Yasha Huang
Roche



Jason Guo
Abbott



Renee Cotta
Boston Scientific

RA Committee LT



730+
Individual Members



55+
Companies



Yu Hosokai
Cook Medical



Chloe Tan
Medtronic



Kai Chang Khoo
J&J



Mandy Tam
Zeiss

SEA CoE LT



Annie Yin
Roche



Wang Ping
Resmed



Jacqui Cui
Abbott



Xiaowei Sun
Philips

China CoE LT



Aaditya Vats
Terumo



Lipi Chakhaiyar
Abbott



Kulveen Singh
Bali Philips

India CoE LT



Leslie Kim
Stryker



Jiyoung Ahn
Boston Scientific



Mandy Kim
J&J



Seungmi Han
Roche

Korea CoE LT



TuningMartini
Roche



Yani Lina
BD



Wirda Nelly
J&J



Iri Anggraini
Abbott



Indonesia LT



Liza Pajarillo
Alcon



Julie Odarbe
GE Healthcare



Jaymie Gulle
Abbott



Audrey Santa Ana
QuidelOrtho



Philippines LT



Trang Ngo Thu
J&J



To Hoa Truong
Roche



Thu Ha Pham Thi
Siemens



Hieu Nguyen
Philips



Vietnam LT



Min Liew
Terumo



Panawan Ratanapreukskul
J&J



Tanyatom Hirunsethada
Medtronic



Phithakthorn Khanittha
Boston Scientific



CLM Lead

Thailand LT



Victor Tan
Intuitive Surgical



Wai Lan
Stryker



SINGAPORE
MANUFACTURING
FEDERATION
新加坡製造商總會

Singapore LT



Yean Ting Ong
Roche



Bob Yew
Medtronic



Malaysia LT

RA Committee's vision, missions and tools

Spearheading regulatory excellence to build trust,
enable innovation and improve patient outcomes in our region and beyond.

REGULATORY CONVERGENCE

Promote harmonization across various
international markets

REGULATORY RELIANCE

Leverage the work done elsewhere to
be more effective and increasing
speed to market

REGULATORY AGILITY

Advocate for flexibility to
accommodate emerging innovative
technologies and advancements

PREDICTIVE INTELLIGENCE

STRATEGIC ADVOCACY

REGULATORY CAPABILITY BUILDING

2025 Engagements & Activities

REGULATORY CONVERGENCE

- Participation in GHWP Academy Training in Chongqing, CIMDR Event in Suzhou
- 1-1 Engagements with APAC Authorities: China NMPA, Hong Kong MDD, India CDSCO, Indonesia MOH, Macau ISAF, Malaysia MDA, Philippines FDA, Singapore HSA, Taiwan FDA, Vietnam IMDA
- Review and contribution to public-consultation processes on regulatory drafts and guidances



REGULATORY RELIANCE

- Half Day Reliance Workshop for MedTech Manufacturers
- Closed-door Reliance Workshop co-organized with Singapore HSA, Malaysia MDA and Thai FDA
- Reliance Trainings Sessions during 28th GHWP annual meeting, to the MedTech Association in Kenya, during engagements with NRAs
- Finalising our public APAC Regulatory Reliance Tracker
- Help connect NRAs to partner on reliance activities
- Advisor to the GHWP CERP Group



REGULATORY AGILITY

- APACMed Regulatory Affairs Summit in India, focusing on AI/ML Regulations, Cybersecurity, Change Management and PCCP
- Training workshops on SaMD, AI-ML Regulation and CM with Vietnam IMDA and Malaysia MDA
- Close collaboration with CDSCO on their latest Draft SaMD Guidelines
- Joint white paper with GHWP on Regulatory Pathways for Innovative Medical Devices
- New position paper on SaMD Regulations and training with HSA Singapore and TGA Australia

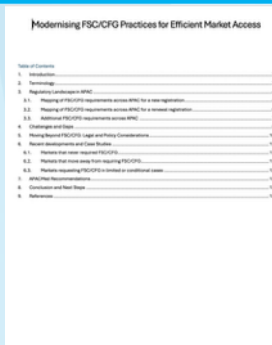


Our resources

SaMD Regulation



FSC



PMS & PMV



IVD, LDT, RUO Regulations



RWE to regulate MD



E-Labeling



Risk-based Change Management





Thank you!

If you have any questions, please contact Cindy at cpelou@apacmed.org

