APACMed

The voice of MedTech

# GHWP LIAISON MEMBER UPDATES

**Cindy Pelou**

Lead, Regulatory Affairs, APACMed

# OUTLINE

I. APACMed Overview
II. White and positions papers for advocacy on key RA topics
III. Capacity and Capability Building activities
IV. Engagements with international regulatory bodies and authorities
V. Recent Highlights in RA
VI. Our message

# I. APACMed Overview

## WHO WE ARE

- The Asia Pacific Medical Technology Association (APACMed) represents **manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders** associated with the medical technology industry in Asia Pacific.

## OUR OBJECTIVES

- As a trade association, our mission is to **improve the standards of care for patients** through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.
- Our mission is to build and support a strong regulatory workforce for MedTech industry and regulators and drive capacity building initiatives in partnership with various stakeholders.

Transforming Healthcare
Saving Lives

# I. APACMed Overview

**350** member companies

**60** corporate members
20 of the top 30 MedTech companies worldwide

**200** startup members

**HEADQUARTERS:** SINGAPORE

**COUNTRY OFFICES:** INDIA & CHINA

## FUNCTIONAL COMMITTEES

**Regulatory Affairs**
400+ committee members

**Government Affairs & Market Access**
250+ committee members

**In-Vitro Diagnostics**
130+ committee members

**Digital Health**
300+ committee members

**Legal Ethics & Compliance**
100+ committee members

**Start-Up & SME**
250+ committee members

# I. APACMed Overview

## APACMed Board Of Directors 2023

**John Collings**
President, Asia Pacific
Stryker

**Probir Das**
Chairman
Terumo Asia Holdings

**Lam Chee Hong**
President, Asia Pacific
B. Braun

**Steve Flynn**
President, APAC
Baxter Healthcare

**Alex Gu**
Senior Vice President and
President, Greater China Region
Medtronic

**Marc Radatt**
CEO, Asia Pacific
Olympus

**Tim Schmid**
Company Group Chairman,
Medical Devices, Asia Pacific
Johnson & Johnson

**Justin Leong**
President, Asia & Latin America
ResMed

**Lance Little**
Managing Director, Asia Pacific
Roche Diagnostics Asia Pacific

**Pavan Mocherla**
Executive Vice President
& President, Greater Asia
Becton Dickinson

**Stephen Morse**
Senior Vice President &
President, Asia Pacific
Boston Scientific

**Farhana Nakhooda**
Senior Vice President, Asia Pacific
Health Catalyst

**Paul Tan Minjie**
Divisional Vice President, APAC
Abbott

**Vy Tran**
Head of Asia Pacific
Japan Region
Siemens Healthineers

# I. APACMed Overview

## RA Committee's Core Leadership

**Lance Little**
ROCHE DIAGNOSTICS
RA Committee
Board Sponsor

**Cindy Pelou**
APACMED
RA Committee
Manager

**Devya Bharati**
APACMED
RA Committee
Associate

400+ individual members

55+ companies

**Miang Tanakasemsub**
J&J VISION
RA Committee
Chair

**Yasha Huang**
ROCHE DIAGNOSTICS
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

# I. APACMed Overview

## RA Committee's Vision and Mission

**Pioneering regulatory excellence and aspiring to be the preferred partner of regulators, dedicated to optimizing patient access to medical devices.**

### 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 to emerging innovative technologies and advancements

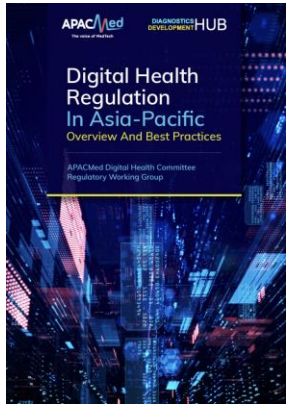
Predictive Regulatory Intelligence & Strategic Advocacy

### REGULATORY CAPACITY BUILDING

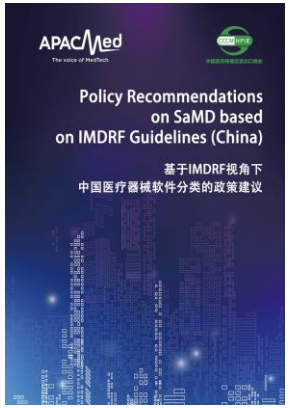
Modernize and upskill regulatory authorities' and industry's capabilities for future ready leaders

# II. White and positions papers for advocacy on key RA topics

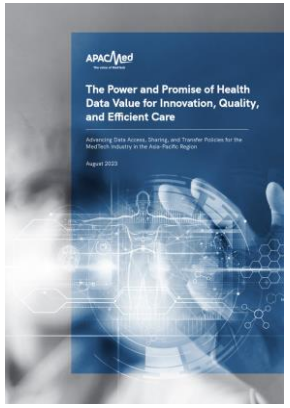
## SaMD Regulation

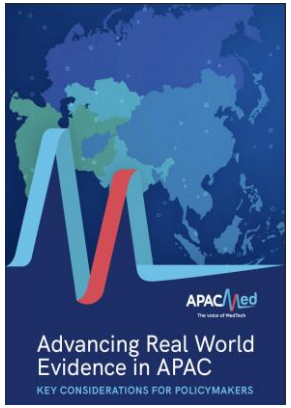





## Regulating health data




## IVD, LDT, RUO Regulations



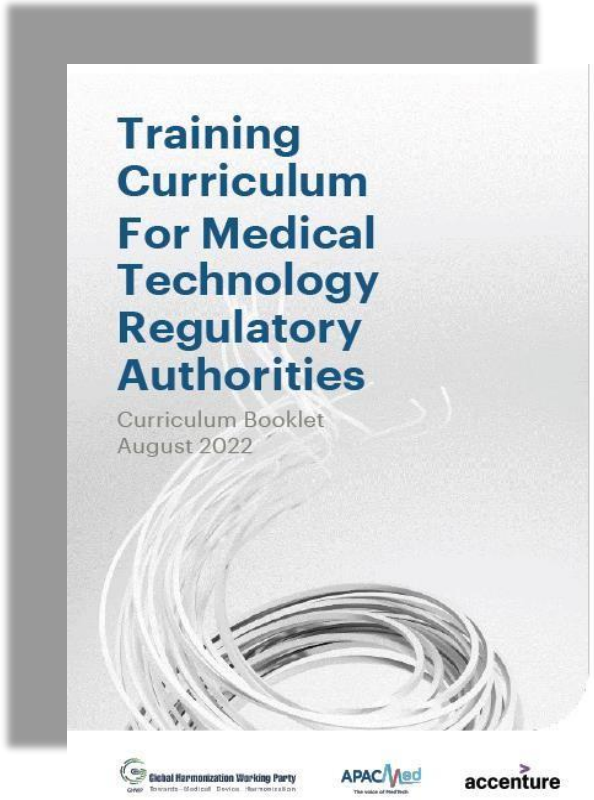
## Advocacy papers in ASEAN


# III. Capacity and 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 facilitated a **Regulatory Reliance Programme** between the Thai FDA and Singapore HSA: Singapore is now a reference country for pre-market regulations of medical devices and IVD in Thailand
- We initiated a **Regulatory Reliance Pilot** between Malaysia MDA and DRAP Pakistan for pre-market regulations
- We **train and collaborate with Regulators** in APAC:
  - Singapore HSA – Thai FDA five-days workshop on medical device regulatory framework
  - Training on EU-MDR and IVDR for Indonesia MOH
  - Training on Software as a Medical Device with Malaysia MDA
  - Training on IVD regulation with Vietnam IMDA

# III. Capacity and Capability Building activities

## Competency framework for medtech regulators




The Competency Framework for MedTech Regulators is a globally applicable tool designed to structure and prioritize essential competencies.

It enables the development of targeted training curricula for regulatory officials, facilitating standardized and effective capability development in the MedTech sector.

# IV. Engagements with international regulatory bodies and authorities

Regional SaMD Roundtable

IMDRF Sydney


GHWP Riyadh

MDA Malaysia


Indonesia MOH

Thai FDA

DMEC Vietnam

Philippines FDA

CDSCO India

Sri Lanka NMRA

# IV. Engagements with international regulatory bodies and authorities

World Health Organization

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

IMDRF International Medical Device Regulators Forum

**We participated in the International Medical Device Regulators Forum (IMDRF) 2022 Conference in Sydney or collaborating now on the 2023 agenda**

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

**We are GHWP Industry Liaison Partner**

GMTA Global Medical Technology Alliance
Innovating for a Healthier World

**We are a member of the GMTA**

AMDC
ASEAN Medical Device Committee

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

# V. Recent Highlights in RA

**REGULATORY RELIANCE**

- Partnered with the WHO to explore opportunities to expand regulatory reliance programs to other countries within APAC
- Finalized inclusion of all classes of devices in the SG-TH reliance program
- Shared insights and lessons learned from the SG-TH reliance program to guide other countries 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 on pre-market regulations between MY and PK
- Facilitating a reliance pilot between MY and SG

**STAKEHOLDER ENGAGEMENT**

- Participation in international regulatory forums such as the IMDRF 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, DMEC Vietnam & Philippines FDA
- 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

**LIVE ISSUE ADVOCACY**

- Shaped pro-industry, streamlined and Harmonized regulations on key issues [Country clinics (VN, TH), Change management (TH), Halal policy (ID), Shelf life (IN), Medical equipment registration (IN), Import control regulations (MY) etc, GMP licence renewal (KR), Streamlining medical device regulations (SL)]

**REGULATORY INTELLIGENCE**

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

# VI. Our message

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

# Thank You

For more information, please contact Cindy at cpelou@apacmed.org