

APACMed Updates

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APACMed



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



Some of our recent papers & engagements

29th IMDRF 2026

REGULATORY CONVERGENCE

Position Papers



Workshops with NRAs



IVD Training with Vietnam IMDA



SaMD and PMS Training with Indonesia MOH



ASEAN Medical Device Committee

REGULATORY RELIANCE

Position Papers & Internal Resources



Workshops with NRAs



Regulatory Reliance WS 2025 with the WHO



GHWP 2025 & CERP Meetings

REGULATORY AGILITY

Position Papers



Workshops with NRAs



Risk-based Change Management WS with Malaysia MDA



AI Regulations with China NMPA & Innovative Device Pathway at CIMDR



APACMed RA Summit including SaMD and risk-based Change Management



2026 Outlook: Regional Priorities Driven by APACMed

29th IMDRF 2026

Regulatory Reliance

- Regulatory Landscape
- White Paper Report
- Joint GHWP CERP Paper
- ASEAN training

Risk-Based Change Management

- Regulatory convergence & predictability through capability building training for APAC Authorities

Regulatory Agility & PCCP

- Regulatory convergence & predictability through capability building training for APAC Authorities

Innovative Device Pathways

- Regulatory Landscape
- Industry Position Paper
- Engagement with APAC authorities

March 2026

Training for **Ph FDA**: SaMD, CM and PCCP

August 2026

CIMDR: Presenting on Innovative Device Pathway

October 2026

AMDC PPF: workshop to simplify and harmonise CM practices in ASEAN

April 2026

Training for **Thai FDA**: SaMD, CM and PCCP, Refurbished devices

September 2026

- **EU-MDR/IVDR**: Joint WS with MedTech Europe
- **APACMed MTF**: Innovative Device Pathways (regulators and payers)
- Training for **MDA** and CABs on CM and Alternative Pathways

December 2026

Side event at **GHWP**: Regulatory Agility Workshop



Thank You!

