

APACMed Updates

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APACMed



IMDRF International Medical Device
Regulators Forum



HSA
Health Sciences Authority

25
YEARS AND BEYOND

APACMed Members

The Asia Pacific Medical Technology Association (APACMed) is a regional trade association representing medical device and in vitro diagnostics companies across the Asia Pacific region.



Corporates



Start-ups



Service Providers



Industry Associations

Our Committees:

REGULATORY AFFAIRS
700+ Individual Members
50+ Companies

HEALTH DATA & AI
300+ Individual Members
60+ Companies

ESG Working Group
90+ Individual Members
30+ Companies

GOVERNMENT AFFAIRS
460+ Individual Members
50+ Companies

MARKET ACCESS
250+ Individual Members
40+ Companies

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



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APACMed 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

**IMDRF**

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Some of our recent papers & engagements

REGULATORY CONVERGENCE

Position Papers



- 2 new position papers with policy recommendations for UDI adoption and on refurbished medical devices

REGULATORY RELIANCE

Position Papers & Internal Resources



- New Workshop Outcome Report "From Concept To Practice: Advancing Regulatory Reliance For Medical Devices"

REGULATORY AGILITY

Position Papers



- 2 new position papers shared with NMPA, CMDE, and the Chinese Society for Drug Regulation on e-IFU and risk-based change mgmt
- 1 new position paper shared with MFDS on Korea Digital Medical Product Act

Engagements with NRAs



Deep-dive session on EU MDR/IVDR and their impact on international registrations



Workshop on Cybersecurity and International Standards for Medical Devices

Engagements with NRAs



Regulatory Reliance workshop with GHWP CERP Members in Beijing

Engagements with NRAs



Philippines FDA training on SaMD and risk-based Change Mngt and during PAMDRAP GMM



Thailand FDA training on SaMD and risk-based Change Mngt with Malaysia MDA

APACMed Events Overview 2026



JAN-MAR

- **AI Bootcamp**
- **Philippines FDA workshop:** SaMD, Risk-Based Change Management and PCCP
- **Deep-Dive Session on EU MDR/IVDR:** Joint workshop with MedTech Europe



APR-JUN

- **South Korea Healthcare Transformation Summit**
- **MedTech Talent Summit**
- **Supply Chain Summit**
- **Japan Healthcare DX workshop**
- **Thai FDA training:** Refurbished Devices and Risk-Based Change Management
- **Data Privacy & Data Localisation Workshop**



JUL-SEP

- **China CEO Forum**
- **CEO Roundtable with Invest India**
- **Cyber Security in MedTech Industry Workshop**
- **Philippines FDA workshop:** IVD, Reliance, Risk-Based Change Mngt
- **China CIMDR:** Risk-Based Change Management
- **Malaysia IMDEC:** SaMD, Risk-Based Change Management
- **APACMed MedTech Forum**
- **Deep-Dive Session on EU MDR/IVDR:** Joint workshop with MedTech Europe



OCT-DEC

- **Pakistan DRAP workshop on refurbished devices:** Joint workshop with Mecomed
- **AMDC Public Private Forum:** SaMD, Risk-Based Change Management, PCCP, UDI, Refurbished Devices
- **Regional Regulatory Agility Workshop**
- **GHWP Conference:** AI/ML, Risk-Based Change Management
- **GBA Training Workshop for Macau ISAF on Change Mngt**



Thank You!

If you have any questions, feel free to reach out to cpelou@apacmed.org



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APACMED
APAC MEDICAL DEVICE
REGULATORS FORUM
2026
10-12 NOVEMBER
SINGAPORE

