



Update: Asia Pacific Medical Technology Association

Fredrik Nyberg, CEO
AHWP Annual Meeting
December 2017



亚太医疗技术协会

APACMed: Fact Sheet

- Full name: **Asia Pacific Medical Technology Association.**
- 亚太医疗技术协会.
- Established in 2014 to provide a *unified voice of the medical technology industry* in Asia Pacific.
- Coverage: All of Asia Pacific.
- Headquarters: Singapore.
- Engage with *local medical device associations* and *companies* in Asia Pacific to jointly advance regional issues, code of ethics, and share best practices.
- For more information please visit: www.apacmed.org .

Mission Statement

“ *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.* ”



Corporate & SME Members (28 Nov 2017)

Corporate Members:



SME Members:



APACMed Regulatory Initiatives

- Centres of Excellence: China, India, ASEAN.
- International collaborations:



IMDRF International Medical
Device Regulators Forum

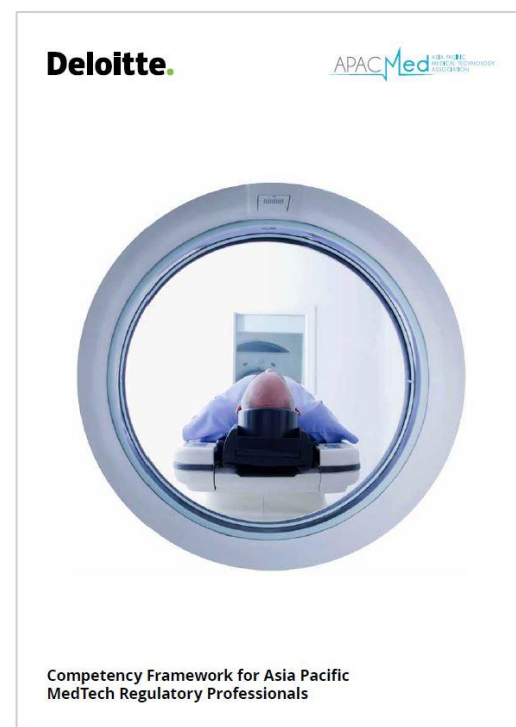


- AHWP Industry Liaison Member since 2016.
- APEC RHSC: Industry Coalition representative since 2016.
- MOU with Duke-NUS Centre of Regulatory Excellence (CoRE)
- Published reports on *“Building Regulatory Capacity for Medical Devices in Asia Pacific”* and *“Competency Framework for Asia Pacific Regulatory Professionals”*.

Reports and whitepapers



Competency Framework for Asia Pacific MedTech Regulatory Professionals



“Competency Framework for Asia Pacific MedTech Regulatory Professionals”

Competency Framework Building Blocks – “Domain”, “Competencies”

A Domain
Reflects scope of responsibilities throughout the product lifecycle

B Competencies
Documents the essential skills in each domain across Knowledge, Skills and Abilities

Functional
Specifically related to the work of the professional, including technical, scientific and regulatory aspects of medical devices

Regulatory Concept & Application
Regulatory Strategy
Pre-marketing
Post-marketing
Quality & Compliance

Knowledge
Institutional and regulatory professional knowledge

Foundational
Activities and competencies that apply to regulatory and other professions

Business Operations
Regulatory Strategy
Communication
Project Management
Project Management

Introduction to the competency framework....

A Domain
Reflects scope of responsibilities throughout the product lifecycle

B Competencies
Documents the essential skills in each domain across Knowledge, Skills and Abilities

C Professional Level
Refers to one of four professional/career levels

D Proficiency Level
Represents the ability of an individual to demonstrate competencies (B) across professional level (C)

RA Competency High Level Framework

A	Domain			
	Foundational		Functional	
	Scope of Practice			
B	Competencies			
	Knowledge Institutional and regulatory professional knowledge		Skill/Abilities Professional and interpersonal/ business-related	
C	Professional Level			
	Level I New professionals	Level II Experienced professionals	Level III Proficient professionals	Level IV Seasoned professionals
D	Proficiency Level			
	Basic	Advanced	Expert	Mastery

The next few pages provides more description of each of these building blocks and an example of how it might applied to a specific competency

Events and activities in 2017 led by our Regulatory Affairs Committee

- 23 Feb: Published report on *“Building Regulatory Capacity for Medical Devices in Asia Pacific”*.
- 30 Mar: New India medical device regulations – Webinar for APACMed members.
- 4-8 April: Regulatory Capacity Building Training held in Jakarta, Indonesia.
- 20 April: APACMed meeting with China Center for Drug International Exchange CCFDIE, Beijing.
- 3 May: Meetings with India CDSCO and MOH in New Delhi.
- 12 Jul: APACMed-Duke NUS CoRE MOU Signing Ceremony.
- 25 Jul: APACMed webinar co-hosted by Korea Ministry of Food and Drug Safety (MFDS).
- 8-9 Aug: International Medical Device Regulatory Forum hosted by MDA, Penang Malaysia.
- 16-18 Aug: CIMDR, Hangzhou China.
- 23 Aug: Breakfast Seminar: *“Recent Changes in USFDA and EU Device Regulations”*.
- 18-19 Aug: APEC RHSC, Ho Chi Minh City Vietnam.
- 7 Sep: MedTech SME Workshop.
- 3-5 Oct: Joint regulatory training programme held in conjunction with the 5th ASEAN Medical Device Committee Meeting, Surabaya, Indonesia.
- 8 Nov: Panel discussion at Asia Pacific MedTech Forum 2017.
- 9 Nov: APACMed RA Summit. Published report on *“Competency Framework for Asia Pacific Regulatory Professionals”*.
- 4-8 Dec: AHWP, New Delhi

2017
ASIA PACIFIC
7TH – 9TH NOVEMBER

MEDTECH FORUM

Theme:
“Transforming Healthcare
Through Innovation”



Attendees: 622

Speakers: 83

Sponsors: 29

Plenary ratings G/VG/E: 87.7%*

Breakout ratings G/VG/E: 78.4%*

#APMTF2017

*Post-event survey n=98

www.medtechforum.asia

APAC Med ASIA PACIFIC
MEDICAL TECHNOLOGY
ASSOCIATION

2017
ASIA PACIFIC
7TH – 9TH NOVEMBER

MEDTECH FORUM

APACMed Regulatory Affairs Summit 2017, 9 November



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MEDICAL TECHNOLOGY
ASSOCIATION

SAVE
THE
DATE

ASIA PACIFIC
MEDTECH
FORUM
2018

9 – 11 October 2018

Suntec Singapore International
Convention and Exhibition Centre

www.medtechforum.asia

APACMed ASIA PACIFIC
MEDICAL TECHNOLOGY
ASSOCIATION

Outlook for 2018 and beyond:

- Disruptive technological innovations will continue to impact the medical device sector.
- Developments in such areas as AI, 3D-printing, surgical robotics, personalized medicine will offer significant opportunities to raise standards of care for patients in both developed and developing economies.
- Multi-stakeholder collaboration, and in particular a strong industry-regulator partnership, will become increasingly important to ensure that patients have timely access to new innovations that are safe and of highest quality.

Thank you!

Follow us on social media:

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