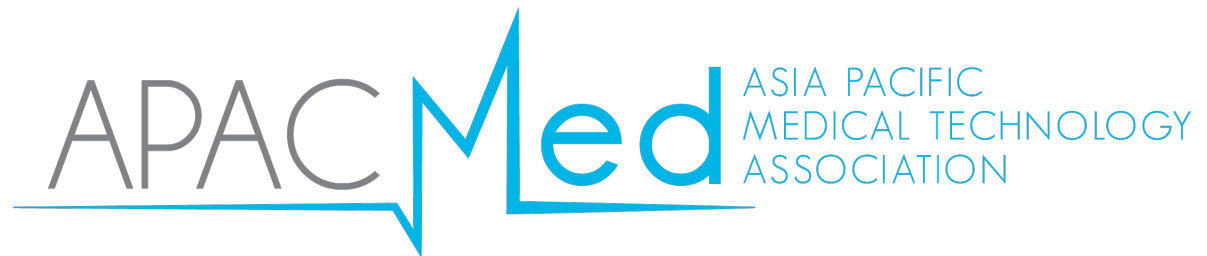




Update: Asia Pacific Medical Technology Association

Fredrik Nyberg, CEO
AHWP Annual
Meeting
25 October 2018



亚太医疗技术协会

APACMed in numbers:

- Current membership: 122
- Member representatives: 700+
- Five Committees. Eight Working Groups.
- Committee representatives: 200+
- Secretariat headcount: 7
- Board Members: 13
- Events, workshops and conferences: 3,800+ delegates
- Press coverage: 35+ original articles
- Social media followers: 3,700+

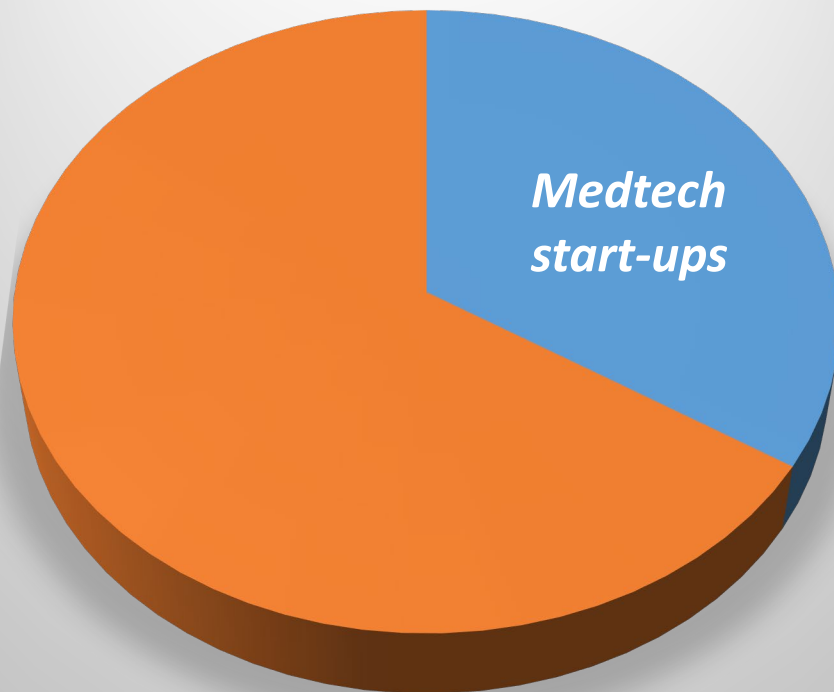
Corporate members (as of Sept 2018)

Corporate Members:



One third of APACMed members are local, Asian-headquartered start-ups

Number of member companies



advent
access

Anatomics

AxonSphere

iota medtech

Beta

privi

BETASIGHT
TECHNOLOGIES

ARTICARES

evitalz
connected to care

CareTech
services pty ltd

cognifyx

QRITIVE

GUARDANT HEALTH

Lifespans
Soft Implants for Soft Bones

AWAK
Changing Dialysis Forever

GemVCare
Your Genes • Your Gem • Your Health

MEDILOT

See-
Mode
Technologies

TeleCTG

NephTech

ROCESO
TECHNOLOGIES

EndoMaster

SG | Meditech

SensDx
SMART DIAGNOSTICS

KINEXCS
Monitor. Assist. Rehabilitate

NDR
MEDICAL TECHNOLOGY

VISWIRE

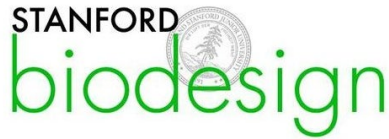
Volition

crely.ai

Healint

SINI/MED

Partnerships & Publications



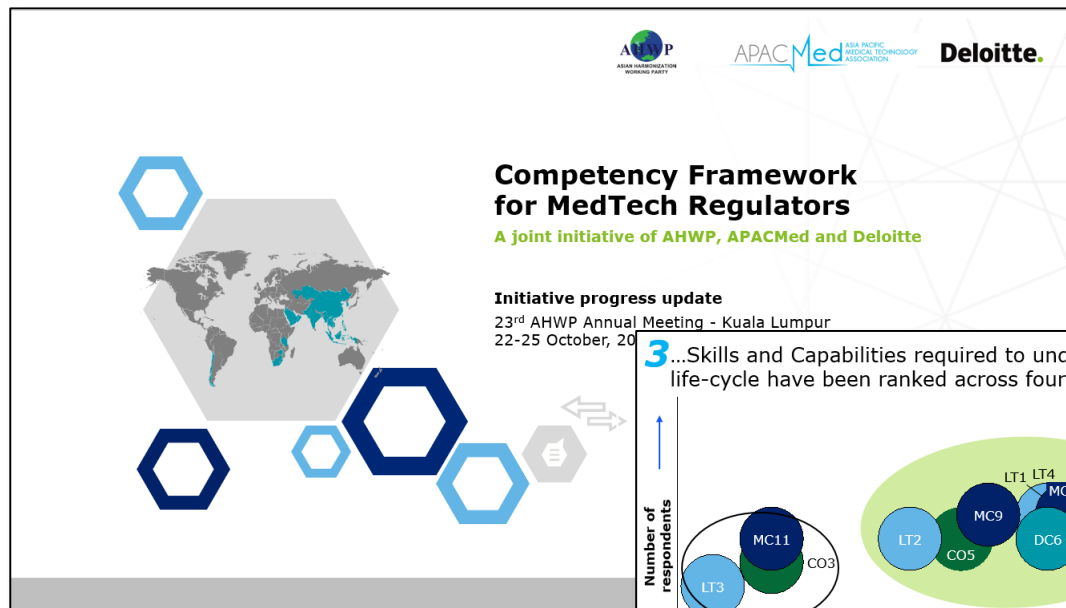
McKinsey&Company

Deloitte.

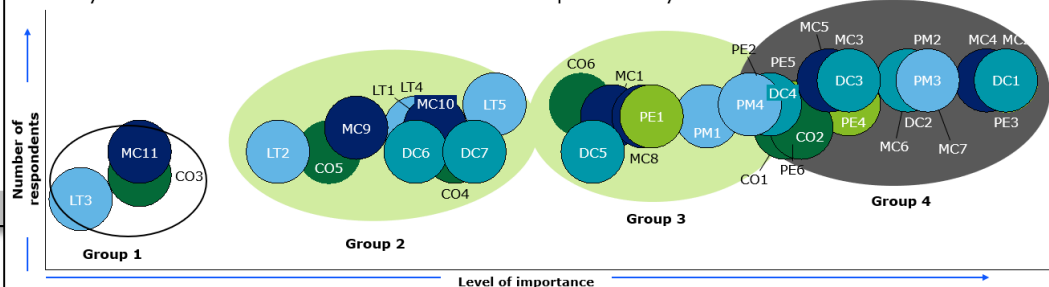


“Competency Framework for Asia Pacific MedTech Regulatory Professionals” (2017)

Collaboration in Capacity Building: Joint AHWP-APACMed-Deloitte project



3...Skills and Capabilities required to undertake regulatory activities across Medical Device product life-cycle have been ranked across four levels of importance by member economies



Pre-Market	Clinical Oversight	Laboratory testing	Manufacturing control	Distribution Control	Post Market
1 International MD Rmmts.	1 Declaration of Helsinki & Nuremberg Code	1 Good Laboratory Practice	1 Intl. MD Rmmts. In Quality system (QS)	1 Good Distribution Practice	1 Intl. MD reamts. in
2 Device Registration Unit / Grouping Principles	2 ISO 14155 Clinical Investigation of MD for Human Subj.	2 Laboratory Quality Management System	2 GMP(Intl.)	2 Quality System auditing	1 Post-marketing Surveillance
3 Submission Dossier Format and Content	3 Good Clinical Practice (ICH)	3 Occupational Health and Safety Standards	3 QS auditing skills	3 Risk Management principles	2 Risk Management principles
4 Declaration of Conformity Rmmts.	4 Good Clinical Practice (Local)	4 Relevant local test standards	4 Loc./Intl. standards	4 Import/export regulations (loc.)	3 Advertising & Promotional Regulation
5 Device Change Management	5 Clinical Evaluation (Evidence Based)	5 Relevant international test standards	5 Design validation / verification methods	5 Import/export regulations (Intl.)	4 Supervision on reprocessing of single-use medical devices
6 General Device Safety & Performance	6 Statistics		6 Risk Mgmt. Principles	6 Disposal of MDs	
			7 Mfg Process & Tech	7 Environmental considerations	
			8 Calibration/Metrology		
			9 Cleanroom process		
			10 Refurbishment of MDs		

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2018
ASIA
PACIFIC

MEDTECH FORUM

TECHNOLOGY IN HEALTHCARE:
EMPOWERING PATIENTS, DRIVING OUTCOMES

www.medtechforum.asia

Attendees: 758
Speakers: 84
Sponsors: 53





The industry's nonprofit global competition and accelerator for medical device, digital health, and diagnostic start-ups.

Our mission is to improve the lives of patients by accelerating the growth of companies that are transforming the healthcare system.



THE BUSINESS TIMES

Asia Pacific MedTech Forum sees startup accelerator programme unveiled

WED, OCT 10, 2018 - 4:11 PM

CLAUDIA CHONG ✉ chongkmc@sph.com.sg 🐦 @ClaudiaChongBT

AN accelerator programme for medical device, digital health and diagnostic startups was launched on Wednesday at the Asia Pacific MedTech Forum.

The MedTech Innovator Asia non-profit programme is the Asia edition of the US-based MedTech Innovator.

Since 2013, MedTech Innovator has reviewed over 2,500 early-stage companies from around the world and graduated 185 companies through its four-month accelerator



3rd Asia Pacific Medical Device Regulatory Summit

2018
ASIA PACIFIC

MEDTECH
FORUM

Held in conjunction with the Asia Pacific MedTech Forum 2018



3rd Asia Pacific Medical Device Regulatory Summit

2018
ASIA PACIFIC

MEDTECH
FORUM

Held in conjunction with the Asia Pacific MedTech Forum 2018

Topics included:

- Challenges in Implementation of New Regulations
– Thailand, India, EU.
- Regulatory Convergence and Regional/Local Solutions
– Indonesia, China, MDSAP.
- Sustainable Talent Pipeline for Regulatory Professionals
– Japan, Malaysia, WHO.
- Regulations of Disruptive Innovation
– Korea, Australia, U.S.

Regulatory Calendar* Q3-Q4 2018

DATE	EVENT
30 May	MedTech HR Summit 2018, Singapore (with Korn-Ferry)
13 Jun	MedTech Start-up Dialogue/Round Table @ BASH (with SG Innovate)
21 Jun	Joint APACMed-HKHMDIA seminar & networking event, Hong Kong
21-22 Aug	APEC Regulatory Harmonization Steering Committee Meeting, Brisbane
30 Aug	APACMed Workshop for MedTech Start-ups and SMEs, Singapore
13-16 Sep	CIMDR, Fuzhou
18 Sep	IMDRF, Beijing
23 Sep	Global Medical Technology Alliance AGM, Philadelphia
9-10 Oct	4 th Asia Pacific MedTech Forum 2018, Singapore
10 Oct	MedTech Industry Associations Leadership Dinner, Singapore
11 Oct	3 rd APACMed Medical Device Regulatory Summit, Singapore
22-25 Oct	AHWP AI Workshop & 23 rd Annual Meeting, Kuala Lumpur
20 Nov	CoRE Duke-NUS Joint Digital Health Symposium, Singapore
3-4 Dec	Stanford Biodesign BME-IDEA Conference, Singapore
3-7 Dec	Training @ AMDC Annual Meeting, Bangkok
13-15 Dec	4 th WHO Global Forum on Medical Devices, Vishakhapatnam, India

*Not an exhaustive list. Excludes all Committee Meetings.

Thank you!

Follow us on social media:

@APACMed



Contact details:

Asia Pacific Medical Technology Association (APACMed)

2 Science Park Drive, Ascent Tower A

#02-03, Science Park I

Singapore 118222

Tel: +65 6816 3180

E-mail: info@apacmed.org

URL: www.apacmed.org