

2018

Asia Pacific Medical  
Technology Association

# Annual Report

The APACMed 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

APACMed ASIA PACIFIC  
MEDICAL TECHNOLOGY  
ASSOCIATION



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# The Rise of MedTech in Asia Pacific

Asia is a region of stark contrasts and constant demographic change, home to approximately 4.5 billion people, some 60% of the world's population.

With its 48 countries all rapidly evolving their political, economic, and healthcare systems, Asia can be a challenging region to operate in, presenting a steady flow of surprises, frequently, difficulties.

Asia is on the rise in MedTech just as it is in other industries.

Today the region already represents 23% of the global market. By 2023, Asia will eclipse Europe to become the second-largest regional market, after the United States, and demographic transformations show no signs of slowing down.

Indeed, across the region, we are observing an unprecedented baby boom juxtaposed with an increasingly ageing society, with healthcare needs likely to rise exponentially as a result.

## Significant Needs And Growing Demand For Healthcare In APAC



### Large Population

Some 60 % of the population, nearly 4.5 billion people, live in APAC



### Urbanisation

69% of "Mega-cities" in the world (cities with population of greater than 10 million) are in APAC



### Ageing Society

By 2025, APAC will have 1.1 billion people older than 50 years of age, more than 2X the EU population today



### Baby Boom

Each year ~ 65 million babies are born in APAC



### Affordability

By 2025, more than 50% of APAC, or 2 billion people, will be in the consuming class<sup>1</sup>



### Morbidity

APAC accounts for nearly two-thirds of the global disease burden from major chronic respiratory diseases<sup>2</sup>

**References** 1. With income greater than \$3,600. 2. Measured as disability-adjusted life years (DALYs) lost to COPD, asthma, and lung cancer. **Source:** IHS Economics (2015); World Bank; McKinsey Insights

Rapid urbanisation continues to be on the rise, as the region counts an overwhelming proportion of the worlds’ mega-cities.

By 2025, it is estimated that over half of the region’s population will be in the consuming class, emerging as connected, informed, and empowered citizens demanding access to affordable and high-quality healthcare.

APAC will become the second-largest regional market for Medtech, contributing 35% of the growth over the next six years.

In light of this, Asia will continue to be the major growth engine among global MedTech markets, contributing 35% of total incremental growth (Figure 1).

Ultimately, the steady rise in the demand for healthcare in the region is likely to override short-term dislocations at country or sub-regional level.

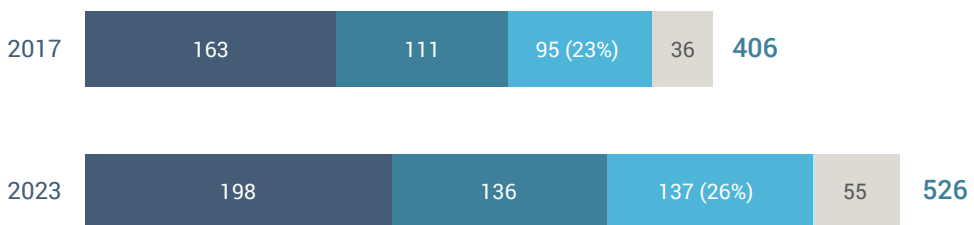
The region is also increasingly recognised as a hub for product technology innovation as well as for its innovative business models and unique healthcare ecosystem.

What is clear is that Medtech players can thrive amid the challenging and complex external environment in Asia, step up on innovation, commercial and strategic capabilities, and embrace the next wave of growth in the region. This requires agility, innovation, and long-term commitment to stay abreast of trends in this fiercely competitive market.

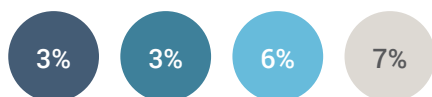
As the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific, APACMed is committed to enable its members make sense of these new realities and navigate the region’s complexities.

The Association endeavours to be the collective voice of its members, enabling them to actively shape the multifaceted healthcare agenda across the region.

Figure 1. MedTech Market Size by Region, US \$ Billions



CAGR 2017-23



Legends:



Source: HRI; McKinsey analysis

Sources [“The rise and rise of MedTech in Asia: How to thrive in the world’s fastest growing market”](#), by Amit Argawal, Florian Ten and Kevin Y Wu, McKinsey & Company (2018) [Paper presented at the MedTech Forum 2018] • [“MedTech in Asia: Committing at Scale to raise the standards of care for patients”](#), McKinsey & Company (2015)

## About the Asia Pacific Medical Technology Association (APACMed)

The APACMed mission is patient centric and calls for new creative partnerships among key stakeholders in the healthcare and medical technology ecosystem.

Our key stakeholders include but are not limited to clinicians, governments, regulators,

payers, healthcare providers, patient advocacy associations and academia.

We aim to achieve our mission through focused initiatives and activities addressing the needs of the diverse healthcare markets in the region relating to access, innovation and collaboration.



### Access

We strive to improve access to high quality healthcare for patients, by working in close collaboration with regulators, policy makers, healthcare providers, payers and patients to develop policies and put forward recommendations which ensure optimal care pathways for patients, from diagnosis to treatment.



### Innovation

We promote a cost-effective, value-based approach to healthcare in Asia Pacific by demonstrating the value of innovative medical technologies in improving quality of care, and healthcare outcomes.



### Collaboration

We provide a platform for knowledge exchange and engage with all stakeholders to raise awareness of, and develop new and unified solutions that meet the demands of diverse and complex healthcare markets in Asia Pacific.

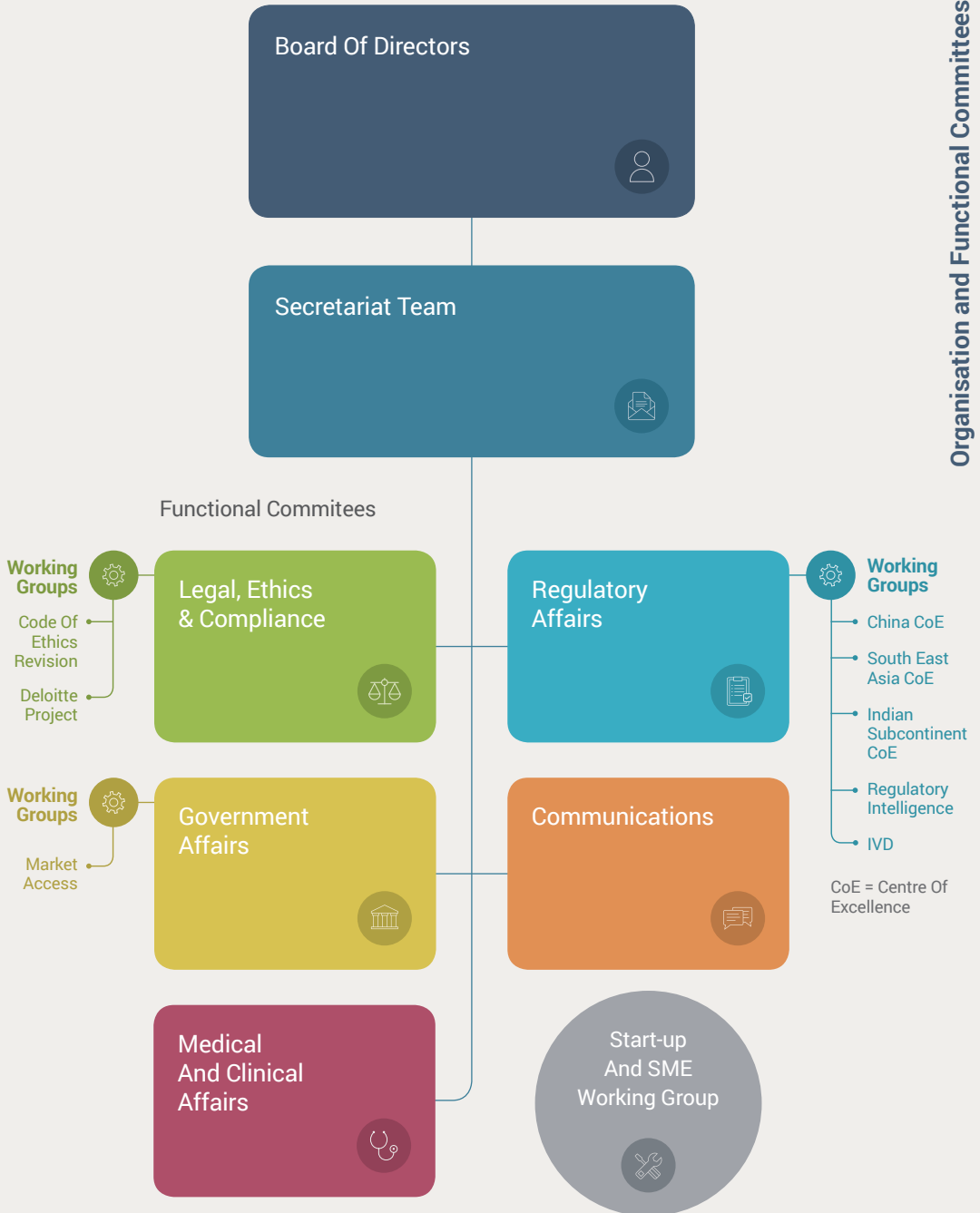
APACMed Strategic Pillars

Addressing the growing demand for healthcare in Asia Pacific requires a different kind of innovative thinking from all stakeholders in our economies.

This means that patients, policymakers, payers, healthcare workers, hospital administrators, medical technology and pharmaceutical

industries need to collaborate differently to solve the region's common health care challenges.

The Association partners with all key stakeholders to meet the growing health care needs and expectations of stakeholders and improve healthcare outcomes in Asia Pacific.





**Vladimir Makatsaria**  
Chairman, APACMed

Company Group Chairman, Asia Pacific, Johnson & Johnson Medical Devices Companies  
Chairman Johnson & Johnson China



**Anna Maria Braun**  
Vice-Chairman, APACMed

President, Asia Pacific  
and Member of the  
Management Board,  
B.Braun Melsungen AG.



**James Lim**  
Treasurer, APACMed

Executive Vice President  
and President, Greater  
Asia Becton Dickinson  
& Co.



**Hideo Arase**

Managing Director,  
Terumo Asia Holdings  
Director & Senior  
Executive Officer,  
Terumo Corporation



**Ian Burgess**

Chief Executive Officer,  
Medical Technology  
Association of Australia



**Francois Fournier**

Senior Vice President &  
Managing Director, Asia  
Pacific, Smith & Nephew



**Andrew Frye**

Senior Vice President  
and President APAC,  
Baxter Healthcare



**Chris Lee**

Senior Vice President  
and President, Asia  
Pacific, Medtronic



**Graham McLean**

President, Asia Pacific,  
Stryker



**Rajkumar Narayanan**

Region President,  
Asia, Alcon



**Sanjay Prabhakaran**

President, Asia Pacific,  
Hologic



**Harvinder Singh**

Divisional Vice President,  
Asia Pacific and Japan,  
Abbott Vascular



**Warren Wang**

Senior Vice President  
and President, Asia  
Pacific, Boston Scientific

## APACMed Functional Committees

## Legal, Ethics &amp; Compliance

**Chair****Campbell Clark**

Vice President, Legal & Compliance, APAC, Medtronic

**Vice Chair****Ana Garcia Bello**

Vice President, Law, Medical Devices Group Asia Pacific, Johnson & Johnson

**Benjamin Kwak**

Vice President, Compliance Officer and Senior Legal Counsel, Asia Pacific, Zimmer Biomet

**David Rosenzweig**

Ethics & Compliance Officer Asia Pacific, Abbott

## Regulatory Affairs

**Chair****Dominik Reterski**

Vice President Quality and Regulatory Affairs Asia Pacific, Medtronic

**Vice Chair****Miang Tanakasemsub**

Regional Head of Regulatory Affairs, Asia & Russia, Alcon

**Jason Guo**

Director Regulatory Affairs, Quality & Compliance, Abbott

## Government Affairs

**Chair****Shakilla Shahjihan**

Senior Regional Director, Government Affairs, Abbott

**Vice Chair****Hitendra Joshi**

Head of Government Affairs and Market Access Asia Pacific, B. Braun

**Lars Jandt**

Head of Public & Government Affairs Asia, Fresenius

**Rajeev Nandan**

Head of Market Access and Government Affairs, Alcon India

## Communications

**Chair****Joanna Ng**

Regional Head, Communications, Asia Pacific, B. Braun

**Vice Chair****Jasmine Chng**

Corporate Communications Director, Align

**Richard Sumich**

Head of Communications & Public Affairs, Medical Devices Group Johnson & Johnson

## Medical &amp; Clinical Affairs

**Chair****Dr. Makoto Sugita**

ASPAC Integrated Team for Medical Affairs, Clinical and Regulatory, Medical Devices Group Asia, Johnson & Johnson

**Vice Chair****Dr. Eng Hooi Sian**

GM Regional Medical & Scientific Affairs, B Braun

**Dr. Hsien-Hsien Lei**

Vice President, Medical & Scientific Affairs Asia Pacific, Medtronic

Outgoing Regulatory Vice Chair:

**Jack Wong,**

Head of Regulatory Affairs, Asia Pacific, Baxter

Outgoing Medical & Clinical Affairs Chair:

**Dr. Laurent Metz,**

HEMA Lead, Medical Devices Group, Asia Pacific, Johnson & Johnson



Only three years after its official launch in 2015, the Asia Pacific Medical Technology Association (APACMed), marked a historic milestone in 2018, [enrolling its 100th member organisation!](#)

The Association ended the year with a total of 122 member organisations including:

43

Corporate Members

09

Industry Association Members

31

Associate Members

39

Start-up &amp; SME members

## Membership Categories

## Descriptions

<b>Corporate Members</b>	Companies manufacturing and conducting R&D in innovative medical equipment, devices or in vitro diagnostics.
<b>Industry Association Members</b>	National associations representing the interests of the medical technology industry in any country in Asia Pacific.
<b>Associate Members</b>	Service providers (e.g. consultants, CRO's, recruiters), investors, distributors, contract manufacturers.
<b>Small &amp; Medium Enterprise (SME) Members (non-voting)</b>	Companies manufacturing and/or conducting R&D in medical technology with annual sales less than US\$50 million.

## Hear more from our New Members!

**Julie Tay**

Senior Vice President & Managing Director, Asia Pacific, Align Technology

# align

Align Technology is a global medical device company with industry-leading innovative products such as Invisalign clear aligners, iTero Intraoral scanners, and OrthoCAD digital services that help dental professionals achieve the clinical results they expect and deliver effective, cutting-edge dental options to their patients.

“As a global medical device company, Align Technology supports APACMed’s mission to improve the standards of care for patients and shape the future of healthcare in Asia Pacific. Align Technology has always set the bar for continuous innovation to bring new and better solutions to doctors and their patients. As the demand for medical advancement in the region grows, we share the same belief in strengthening our partnerships with regulatory and government bodies to improve access to health and the standard of care in Asia.”



**Kevin O'Reilly**  
President, Oncology  
Systems, APAC  
at Varian Medical  
Systems

## varian

Varian Medical Systems' manufactures tools that harness the power of X-ray energy to benefit patients, and has pioneered developments in the fields of radiotherapy, radiosurgery, X-ray tube technology, digital image detectors, cargo screening, and non-destructive testing.

"Varian Medical Systems is dedicated to combining the ingenuity of people with the power of data and technology to achieve new victories against cancer. We are thrilled to have joined APACMed, which offers an exciting opportunity for Varian to advance these values through collaboration across the range of stakeholders that impact patient care."



**Dr Sandeep Shah**  
CEO, Tarilian Laser  
Technologies



Tarilian Laser Technologies delivers unique solutions to the medical and consumer healthcare markets based upon its proprietary and internationally patented opto-electronic sensor which delivers continuous, and highly accurate blood pressure reading and flow, similar to the output generated from an internal invasive arterial line used in intensive care.

"TLT are proud to have joined APACMed. From my experienced global perspective, APACMed is an outstanding Medical Technology Trade Association; and one which has a powerful forward role in supporting SMEs in the new world order within the MedTech Industry - as the global shift to the Asia-Pacific Region magnifies. The scope and power of APACMed's activities, including regulatory affairs, government policy and key commercial support activities are extremely relevant to all SMEs operating within the Asia-Pacific Region and. This is indeed an exciting time of dramatic change for APACMed and its SME member".



**Toh Yanling**  
CEO, NephTech

## NephTech

NephTech is a medical technology company dedicated to providing patients and dialysis centres an evidence-based approach to vascular access surveillance and management. Vascular access is end stage renal disease patient's lifeline, as it allows removal of body waste through hemodialysis, without which patients do not survive beyond several days.

"APACMed is a unique platform that has brought together industry players from the MedTech scene in Asia Pacific. With NephTech's aspirations for regionalisation, we are thankful for the industry network and insightful conversations with APACMed members. This has provided us great opportunities to learn and share with key decision makers, to grow and develop the region's healthcare."

## Benefits of Membership



Be part of a collective voice focused on improving the standards of care, driving access and collaboration, and shaping the future of healthcare in Asia Pacific.



Join regular workshops, seminars, CEO Roundtables and other networking events.



Participate in Functional Committees and Working Groups with senior-level executives from the largest companies in the industry.



Demonstrate your commitment to the highest standards of ethics by signing on to our industry Code of Conduct that guides ethical interactions with healthcare professionals.



Benefit from exclusive market insights and analysis from APACMed Knowledge Partners.



Receive timely information providing early warning about regulatory and policy developments in the region and guidance on how to deal with them.



Participate in the annual Asia Pacific MedTech Forum, the industry's most impactful gathering of people and ideas in the region.



Stay informed – Receive the APACMed Members-only e-Newsletters.



Access extensive resources on our Members-only section on the website.



For SME's – Benefit from networking with your much larger industry peers. Join tailored workshops on IP protection, regulatory strategy, capital raising, commercialisation, market entry and more.



Get special rates on registration for APACMed events, including the annual MedTech Forum conference.

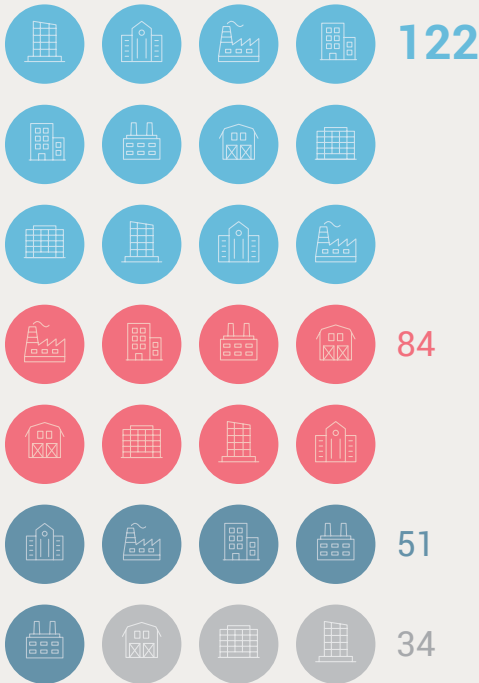


Display your organisation's logo on the APACMed web site.



Join to shape the association, the industry and the future of healthcare in Asia Pacific.

### Number of members



#### Legends:

- 2015
- 2016
- 2017
- 2018

### Committees



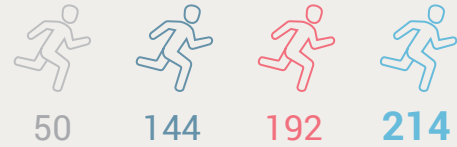
**05** with over 200+ representatives



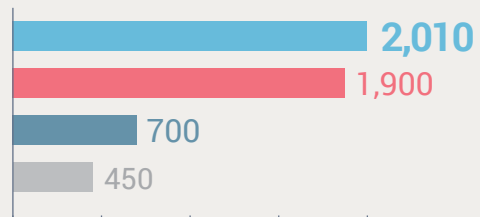
Press coverage

**30+** original articles

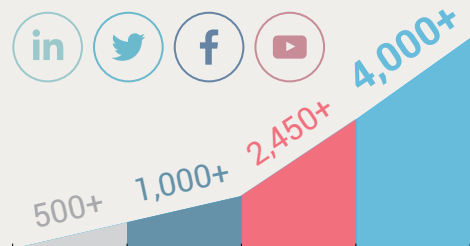
### Number of active committee participants



### Number of delegates attending events



### Social media followers



### Board members



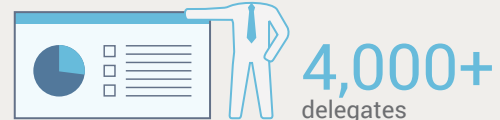
An increase from 09 board members in 2015

### Secretariat team



An increase from 02 personnel in 2015

### Events, workshops and conferences



- Corporate Members



● SME Members



● Associate Members



● Industry Members





Vladimir Makatsaria

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# Foreword by APACMed Chairman

Vladimir Makatsaria

Dear APACMed Members,

2018 was, in many ways, a year of great change and uncertainty across the world. This was certainly true in Asia Pacific and in healthcare, where we continued to adapt to a complex regional landscape, while working to harness the potential of disruptive innovations to address vast unmet patient needs.

In these times it is even more critical to speak with one industry voice – to build trust and to raise awareness of the role of innovation in developing life enhancing technologies and therapies for patients.

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technologies and therapies for patients.

As the only regional MedTech Association addressing patient needs in Asia Pacific, we play a central role in rethinking how to address the needs of a diverse population, how to partner with new players in healthcare, embrace digitisation and support advances in the regulatory environment. Over the past years we have achieved a lot in these areas, but of course our work will never be finished.

As I conclude my final term as Chairman of APACMed, I reflect on the privilege it has been to serve alongside my fellow Board Members since the creation of the association.



I am humbled by the trust and commitment of our member organisations, big and small, and all the individuals who volunteered their time and brought endless energy and experience.

I would like to thank all my colleagues and friends who have contributed to APACMed.

I would also like to recognise the pivotal role of our CEO Fredrik Nyberg in growing and developing the Association and the Secretariat team of now seven dedicated, multidisciplinary staff.

I would also like to welcome Harjit Gill as she takes on the leadership of the association and develops it further to support the needs of our members and our patients across the region.

I look forward to witnessing the next phase of growth!





Fredrik Nyberg

# CEO Report

Fredrik Nyberg

Dear Colleagues and Friends,

As the Association enters its fifth year of existence, I am proud to reflect on the great achievements of 2018, which will no doubt stand APACMed in good stead for the next chapter of its growth.

This year, we teamed up with a group of MBA Students from Singapore Management University (SMU) to formulate plans for APACMed's growth strategy, which include education and training for members and dedicated activities for our start-up/ SME members and mid-tier companies. Indeed, as an industry association, we are committed providing value and remaining relevant to all member organisations, and are, as ever, grateful for the individual and collective contributions of our members to advance critical issues across our industry. We look forward to bringing you our 2019 Strategic Plan and look

forward to another year of active engagement with you all.

In 2018, our Secretariat continued to grow and diversify, and we are delighted to have seven nationalities represented within the team. We welcomed our Director, Regulatory Affairs, Yasha Huang who brings with her a wealth of experience, and most recently worked within the China FDA.

Darwin Mariano joined us as Senior Director, Government Affairs after leading the Public Affairs function for Sanofi in South East Asia. Thanks to them, synergies have been forged between the Regulatory and Government Affairs Committees, and this year was without a doubt the most significant one to date in terms of advocacy impact across the region.

In addition, two new working groups were created this year. A Market Access group, which will be held under the aegis of the Government Affairs Functional Committee, and will be dedicated to market access, HEOR, pricing and reimbursement issues. In order to reflect our growing start-up and SME membership base, an independent working group was also created, and the founding members met late this year.



these, APACMed has been working with Deloitte Life Sciences throughout 2018 with a view to develop a web-based solution for the administration of MedTech industry grants to HCPs and HCOs. Progress on this platform is now well underway, and we hope to launch Wave 1 of this pilot project in Q1 2019. Do watch this space for more updates!

On the events front, we held many more successful events this year, such as the Asia Pacific MedTech Forum, which saw record attendance with over 750 delegates, including, for the first time, a significant number of health care providers from Singapore and further afield.

As ever, I would like to offer my sincere thanks to all APACMed members as well as Functional Committee members, for their unwavering commitment and enthusiasm. They are important ambassadors for our Association, and through their involvement in advocacy, or their support in sponsoring our events, truly play a part in advancing APACMed's mission.

In addition to this dedicated group we are facilitating for the start-up community, 2018 marked the kick off of APACMed's partnership with MedTech Innovator the premiere non-profit start-up accelerator that identifies and supports emerging medical technology start-ups through customized corporate mentorship and funding opportunities. Together, we launched [MedTech Innovator Asia](#), a programme aiming accelerate the growth of the most promising medical device, digital health, and diagnostic start-ups in the region. Applications opened at the end of 2018, and we look forward to connecting with start-ups in 2019 as we embark upon a number of pitch events across the region!

On the Legal, Ethics and Compliance front, 2018 was a year of transition, as the revision to the APACMed Code of Ethical Conduct for Interactions with Health Care Professionals came into force on 1st January, eliminating the direct sponsorship of HCPs to third party educational events. Business Leaders, Heads of Compliance, Healthcare Professionals, Healthcare Organisations and Event Organisers, have all had to find their feet during this time, which has naturally brought about some challenges on the ground. In order to address

Sincere thanks to all APACMed members as well as our Functional Committee leaders. They are important ambassadors for our Association, and through their involvement in advocacy, or their support in sponsoring our events, truly play a part in advancing APACMed's mission.

I would also like to take this opportunity to thank our outgoing Chairman, Vladimir Makatsaria for his leadership over the last four years. It has been an honour to work alongside him, and the rest of the Board. Vladimir was instrumental in first articulating the need for a region wide Association. What started as an exciting idea discussed amongst peers and trusted friends blossomed into the Association we see today.

On behalf of the entire APACMed Community, I wish Vladimir all the best in his new endeavours, and we look forward to working with a new Chairman and new Board of Directors in 2019.

The revision of the APACMed code of Ethical Conduct to eliminate direct sponsorship of Health Care Professionals (HCPs) to attend or speak at Third Party Educational Events (TPE) came into force on 1st January 2018.

This decision was taken by the APACMed Board in 2016, in order to align with international industry guidelines, and further enhance regional standards in Asia Pacific. This should be seen a great achievement for the Association, and a significant leap from its inception in 2015, when no overarching industry code existed.

Over the last year, members of the APACMed Legal, Ethics and Compliance Committee (notably Campbell Clark (Medtronic), David Rosenzweig, and Cornelia Kunze (both Abbott),

Ana Garcia Bello (Johnson & Johnson), and Benji Kwak (Zimmer Biomet) alongside CEO Fredrik Nyberg and Communications Director Emilie Rapley, have been the driving force behind our collaboration with Associate Member Deloitte Consulting.

Indeed, we are delighted to announce that 2019 will see the launch of a pilot, web-based solution, which aims to effectively 'match' grants provided by the MedTech Industry to institutions and HCPs across a two key markets in the region: Singapore and Malaysia. A series of workshops will be held throughout Q1, which all members from the compliance and commercial functions are welcome to join. Please contact our secretariat for more information and join us to cocreate this exciting solution!



## Asia Pacific MedTech Business Ethics & Compliance Meeting 2018, October 2018, Singapore

This year's annual gathering of regional MedTech Legal & Compliance Community was organised by APACMed and brought together 83 participants. Our sincere thanks to Campbell Clark, APACMed Legal/ Ethics and Compliance Committee Chair, and VP, Legal & Compliance, APAC, Medtronic for hosting the event and driving the agenda.

Thanks as well all the members of the Committee who contributed to shaping the agenda, and a special mention to Geeta Thakerar, Geeta Thakerar Consultancy Services, for her significant contributions to the process, and for organising an insightful panel discussion.

Programme highlights included:

- Compliance at times of Crisis, Control Risks
- Association compliance updates
- Update on regional legal/compliance developments: Baker & McKenzie, Sidley Austin, Nishith Desai Associates
- TPEC grants to healthcare institutions, Deloitte

### Interactive Session: Evolution, Capability, & Capacity Building for Compliance Officers

Moderated by: Geeta Thakerar, Founder, Geeta Thakerar Consultancy Services

- **Gareth Lee**  
Vice President, Legal & Compliance, Asia Pacific, Cardinal Health
- **Clara Tan**  
Managing Director, Emerging Asia, Cardinal Health
- **Ash Raivadera**  
Head of Private Practice, South Asia, Major, Lindsey & Africa
- **Yuet Ming Tham**  
Life Sciences Partner, Sidley Austin, Hong Kong



## Promoting Regulatory Convergence: APACMed Regulatory Work across the region

Part of the impetus behind the creation of the APACMed in 2015, was the need to help MedTechs navigate the increasingly complex and fragmented regulatory landscape. The work of APACMed is driven by dynamic and engaged group of 100+ senior regulatory professionals who work within the Functional Committee, in close collaboration with our Director of Regulatory Affairs, Yasha Huang.

Yasha joined the Secretariat in March 2018, and previously held the role of Principal Staff Member within the former China Food and Drug Administration (CFDA) based in Beijing, where she was actively involved in global governance and stakeholder engagement.

Much of the regulatory advocacy efforts across the region coalesce around three interdisciplinary Centres of Excellence, covering: China, South East Asia, the Indian Sub-Continent. Separate Working Groups are dedicated to regulatory intelligence (RI) and in-vitro diagnostics (IVD).

Through its Centres of Excellence and Working Groups, APACMed has successfully engaged members and fostered its networks at the local level across the region.

Our 2018 Annual Report aims to provide an overview of Regulatory Activities carried out throughout the year.

### Our Regulatory work is underpinned by three Strategic Imperatives:

01

Promote **regulatory convergence** in collaboration with government agencies, industry associations, academia and other stakeholders.

02

Build and support a strong regulatory workforce for MedTech industry and regulators, and drive **capacity building** initiatives in partnership with various stakeholders.

03

**Advocate** for policies that promote patient access to innovative technologies that advance patient outcomes.

For more details and information, please contact Yasha Huang, Director, Regulatory Affairs: [yhuang@apacmed.org](mailto:yhuang@apacmed.org)

## APACMed's Regulatory Convergence Initiatives



**Regulatory Harmonization Steering Committee**  
Life Science Innovation Forum

In 2015, APACMed became Industry Coalition Lead of the Asia Pacific Economic Cooperation Regulatory Harmonisation Steering Committee (APEC RHSC). APEC RHSC represents 21 Member Economies and is tasked by APEC Ministers to achieve convergence on regulatory approval procedures for medical products by 2020.



**IMDRF** International Medical Device Regulators Forum

APACMed is actively involved in the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonisation and convergence.



**ASEAN Medical Device Committee (AMDC)**

APACMed is actively engaged with the ASEAN Medical Device Committee (AMDC), which serves as a platform to bring together ASEAN regulators and industry stakeholders to harmonise and shape the future of medical device regulations across Southeast Asia.



**Asian Harmonization Working Party**

In 2016, APACMed became Official Liaison Member of the Asian Harmonization Working Party (AHWP), a voluntary group of regulators and industry members, representing 30 Member Economies across Asia and beyond.

Over the last two years, APACMed has established itself as a key player on the international regulatory scene.

## ● High Level Meetings and Training

### APEC - RHSC Meeting, February 2018, Singapore

On 10-11 February, APACMed CEO Fredrik Nyberg and Regulatory Affairs Committee Southeast Centre of Excellence Chair Nishith Desai attended the APEC-RHSC meeting in Singapore, representing the MedTech industry as the industry coalition member.

### International Medical Device Regulators Forum (IMDRF), March 2018, Shanghai, China

On 20 – 22 March, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang were invited to attend the Open Stakeholders Forum of the 13th IMDRF meeting along with over 300 regulators and industry representatives. As well as engaging with regulators and member companies, APACMed also took part in the Cyber Security Workshop organised by Global Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) and held side meetings with GMTA member associations including AdvaMed, MedTech Europe, MITA, and COCIR.

### ASEAN Medical Device Committee (AMDC) Meeting, April 2018, Singapore

On 5 April, APACMed CEO Fredrik Nyberg gave a presentation about the Association to an audience of regulators and industry representatives, then set the scene for a presentation on Digital Health. Following the meeting, the APACMed Secretariat together with the Regulatory Affairs Committee submitted an official letter to express a keen interest in becoming AMDC's preferred industry partner, in order to better engage regulators across 10 ASEAN countries. The APACMed Secretariat and member companies also held side meetings with U.S. Department of Commerce, AdvaMed, and SMF MTIG.



### APEC - RHSC Meeting, August 2018, Brisbane, Australia

On 22-24 August, APACMed CEO Fredrik Nyberg, RA Committee Chair Dominik Reterski and Regulatory Affairs Director Yasha Huang attended the APEC-RHSC meeting, representing the MedTech industry as the industry coalition member together with AdvaMed and JIRA. Discussion was held with Co-Champions of Medical Device PWA, regulators from US FDA, Korea MFDS, and Japan PMDA, as well as academia partners.



### International Medical Device Regulatory Forum, September 2018, Beijing, China

On 17-18 September, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang attended the Open Stakeholder Day of the 14th IMDRF meeting with an AI session, the GMTA UDI workshop, and the joint GMTA/DITTA meetings.

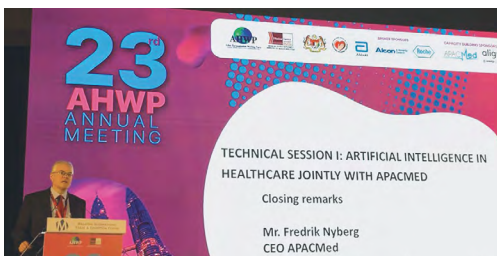


The meeting was attended by regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation, Singapore, South Korea and the United States of America (USA), as well as international organisations, academia, healthcare providers and industry representatives totaling about 450 people.

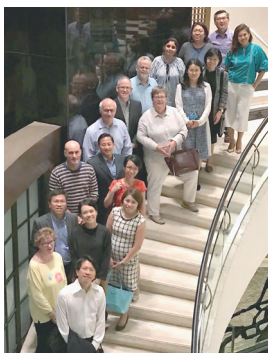


### Asian Harmonization Working Party Annual Meeting, October 2018, Kuala Lumpur, Malaysia

On 22-25 October, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang attended the 23rd AHWP annual meeting in Kuala Lumpur, Malaysia, as capacity building sponsor.



The event was opened by Malaysia's Minister of Health YB Datuk Seri Dr. Dzulkefly Ahmad. APACMed hosted a half-day AI workshop and also presented the initial findings AHWP-APACMed-Deloitte project on MedTech regulator's competency framework.



The event was attended by 200+ government and industry representatives from AHWP member economies.

Side meetings were held with US Department of Commerce,

AdvaMed, AMMI, SMF MTIG with regards to public-private collaboration and industry-wide initiatives.

### ASEAN Medical Device Committee (AMDC) Regulator Training, December 2018, Bangkok, Thailand

On 3-7 December, APACMed was invited to co-organize the AMDC regulator's training, industry training, and public-private forum in Bangkok, Thailand, attended by 60+ regulators and 100+ industry experts from ASEAN countries.



On 6 December, APACMed RA Committee Chair Dominik Reterski pitched on behalf of the MedTech industry at the AMDC closed-door session to MedTech regulators from 9 ASEAN countries regarding future engagement proposal.







## Asia Pacific Medical Device Regulatory Summit, October 2018, Singapore

For the third year running, APACMed organised a very successful closed-door event for Regulators and the MedTech Regulatory Community.

Attended by 84 delegates, the meeting saw an exceptional line up of speakers and guests from international organizations, regulatory authorities, regional harmonization initiatives, academia:

- **International Organization:**  
The World Health Organization (WHO);
- **Regulatory Authorities:** Ministry of Health, Indonesia; Pharmaceuticals and Medical Devices Agency, Japan; Ministry of Food and Drug Safety, Republic of Korea; Medical Device Authority, Malaysia; Health Sciences Authority, Singapore; Thailand Food and Drug Administration;
- **Regional Harmonization Initiatives:**  
Asian Harmonization Working Party (AHWP), ASEAN Medical Device Committee (AMDC); Asia-Pacific Economic Cooperation Regulatory Harmonization Steering Committee (APEC RHSC);
- **Industry Associations:** Europe (MedTech Europe), China (CCCMHPIE), India (MTai), Australia (MTAA), Thailand (THAIMED), Japan (JFDA), Malaysia (AMMI), Philippines (PAMDRAP), Singapore (SMF-MTIG).
- **Academia Partners:** Duke Margolis Centre For Public Policy (former Commissioner, USFDA); Duke-NUS Medical School Centre of Regulatory Excellence (CoRE) (Former CEO, Singapore HSA);
- **Law Firms:** Nishith Desai Associate (India); Ropes & Gray (China).



Themes addressed during the event ranged from country deep dives to address challenges in new regulation implementation; regulatory convergence and regional/local solutions; building a sustainable talent pipeline for regulatory professionals, as well as challenges in regulating cutting-edge Medical Technologies.



Special thanks to leadership of RA Committee Chair and Vice Chairs: Dominik Reterski, Miang Tanakasemsub, Jason Guo as well as the outgoing Vice Chair Jack Wong.

Photos of the event can be found on the [APACMed Website](#), and full details of the programme and speakers can be found [here](#).

## APACMed Capacity Building and Advocacy Activities

Thanks to the combined efforts our Regulatory Affairs Committee volunteers and the Secretariat, APACMed made inroads across key markets in 2018.

### ● Market Activities



#### China

In March 2018, the new Ministerial-level agency, the State Administration for Market Regulation (SAMR), was established incorporating responsibilities from the previous China Food and Drug Administration (CFDA), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), State Administration for Industry and Commerce (SAIC), as well as anti-trust and intellectual property functions from other Ministries. Considering the uniqueness of medical products, a separate national drug and medical device regulatory authority, the National Medical Products Administration (NMPA) was set up as a Vice Ministerial-level affiliation to SAMR, overseeing registration and inspections of pharmaceuticals, cosmetics, and medical devices.

Throughout 2018, APACMed contributed to public consultations of multiple key regulations solicited by the Chinese government, including:

- [Draft Amendments to Decree 680 \(24 Jul 2018\)](#);
- [Provisions for Import Medical Device Agents \(2 Sept 2018\)](#);
- [Guidance documents for post market surveillance including the Periodic Risk Assessment report \(Dec 2018\)](#).
- [In December, APACMed was invited, for the first time ever by the Center for Medical Device Evaluation \(CMDE\) of NMPA to attend the Expert Consultation meeting for the Draft Technical Guidance for Animal Studies in Clinical Evaluation in Beijing, China.](#)

In December, APACMed was invited by the Center for Medical Device Evaluation (CMDE) of NMPA to attend the Expert Consultation meeting for the Draft Technical Guidance for Animal Studies in Clinical Evaluation in Beijing, China.

#### China International Medical Device Regulatory Forum, September 2018, Fuzhou, China

On 13-16 September, as co-sponsor of the event, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang attended the 9th CIMDR, organised by China Center for Food and Drug International Exchange (CCFDIE) and supported by Center for Medical Device Evaluation (CMDE) of National Medical Products Administration (NMPA, previously known as CFDA).



The event brought together over 1000 delegates, from both government and industry in China and further afield. Fredrik Nyberg, CEO of APACMed met with the First Deputy Commissioner of National Medical Products Administration (NMPA) as VIP speaker and co-moderator for Plenary session on Day 1; Yasha Huang the Regulatory Affairs Director moderated the Clinical Evaluation session on Day 3. APACMed delegation also had a fruitful discussion with the leadership of CCFDIE about future collaboration.



## India

In July, APACMed submitted an official letter to Central Drugs Standard Control Organization (CDSCO) on public notice regarding medical devices as drugs in Section 3 (b) (iv) of DCA 1940, advocating for a single-window clearance and seamless transition strategies for the new regulation to ensure better access to patients.

In November, APACMed submitted letters to CDSCO and BIS to request for meetings and partnership.

In December, APACMed met with CDSCO officials to discuss collaboration and also had discussion with colleagues from AdvaMed, MedTech Europe, and MTal on future efforts in promoting standard harmonisation.



PAMDRAP leadership team, discussing the implementation and transition strategies for the medical devices Administrative Order, the CSST Pilot Project, local performance evaluation as well as capacity building initiatives.



## Thailand



In July, an APACMed delegation had a meeting with Thailand FDA and THAIMED in Bangkok to discuss trends and impact in the new regulation implementation.

In October APACMed met with Thailand FDA several times to plan for the MedTech Forum & Regulatory Summit, as well as the 7th AMDC meetings & trainings.



## Philippines

In October, APACMed was invited by the Philippines Food and Drug Administration (FDA) to attend the public hearing of draft IVD regulation in Manila. A position letter on the same regulation was then submitted to the Philippines FDA by the APACMed IVD Working Group.

In November, an APACMed delegation met with the Chief of Staff, Philippines Food and Drug Administration (FDA), together with the



## Vietnam

In June, APACMed sent a position letter to Department of Medical Equipment and Construction (DMEC) of Ministry of Health, providing comments and recommendations (aligned with other trade associations) regarding the Draft Amendments to Decree No. 36/2016/ND-CP on medical device administration.

In July, APACMed delegation met with Director General of DMEC and the representative from Legal Department of Ministry of Health in Hanoi, together with local industry group EuroCham-MDDSC, discussing the Draft Amendments to Decree No. 36 and sharing regional benchmarking experiences.

In August, as a follow-up action, APACMed sent an official letter to DMEC jointly by RA and GA committee, providing a written summary of the



APACMed proposals, as well as a draft letter addressed to higher-level government agencies (Government Office, Ministry of Justice, and Ministry of Health)

In October, during the AHWP economy updates, DMEC announced:

- A smooth transition to the new regime by extending the transition period by one year, until 1st January 2020 for the registration of Class B, C, and D products;
- Business continuity for MedTechs, thanks to the approval of the auto renewal till 31 Dec 2019, for existing import licenses (as per Circular 30);
- A faster speed to market for imported products, thanks to the implementation of a fast track approach;
- In addition, post-marketing surveillance, IVD regulation, and CSTD will be further harmonized.

## ● Projects

### Competency Framework for Medical Technology Regulators, joint project by APACMed, Deloitte and AHWP.



In 2017, the Asia Pacific Medical Technology Association (APACMed), in collaboration with Deloitte, published a white paper [“Competency Framework for Asia Pacific MedTech Regulatory Professionals”](#), which focused on regulatory professionals in the industry. This paper was launched at the beginning of 2018.

Later in 2018, to expand this initiative from industry professionals to regulators, APACMed and Deloitte partnered with the regional regulatory harmonisation entity, the Asian Harmonization Working Party (AHWP),

to identify the Competency Framework for medical technology regulators.

This project was built on primary research and secondary research, with the latter leveraging the valuable work of the World Health Organization (WHO), the Global Harmonization Task Force (GHTF), the Asian Harmonization Working Party (AHWP), etc.

For the primary research, the project team jointly conducted surveys among both regulatory authorities and companies within the Medical Technology (MedTech) sector (including medical devices, in vitro diagnostics, and digital health, etc.) in July and August 2018. These surveys were designed to identify the competencies (knowledge, skills, and behaviours) necessary to bolster the performance capabilities of MedTech regulators.

MedTech regulators from thirteen (13) AHWP economies responded to the survey, including Chile, Chinese Taipei, Hong Kong SAR of China, Indonesia, Kingdom of Saudi Arabia, Malaysia, People’s Republic of China, Philippines, Republic of Korea, Sultanate of Oman, Tanzania, Thailand, and Vietnam.



This year was an exciting one on the Government Affairs front, and many significant advancements were made across the markets of the region. In June, the Secretariat appointed Darwin Mariano, Senior Director, Government Affairs, to support the work of the Government Affairs Committee.

Originally from the Philippines, Darwin was most recently Head of Public Affairs ASEAN at Sanofi, and specialises in policy shaping and analysis, market access and expansion, industry affairs and engagement, as well as strategic stakeholder relations.

### The Mission of the Government Affairs Committee is twofold:

01

To promote awareness among governments and key influencers of the positive impact of the MedTech industry on health in the region;

02

To position the MedTech industry as a partner and stakeholder to appropriately inform and shape health policy.

For more details and information, please contact Darwin Mariano, Senior Director, Government Affairs: [dmariano@apacmed.org](mailto:dmariano@apacmed.org)

## Promoting awareness among Governments and Key Influencers of the positive impact of the MedTech Industry

Advocacy wins for an Association like ours are often the result of sustained efforts of our Regulatory and Government Affairs colleagues.

### ● Collaborations with National Trade Associations

#### Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP)

In August, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang met with President of Philippine Association of Medical Device Regulatory Affairs (PAMDRAP) in Singapore, to discuss regulatory changes in Philippines concerning both Medical Device and IVD industry.

In November, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang were invited by CCCMHPIE to attend the first overseas Belt & Road Initiatives healthcare event organised by China's Ministry of Commerce in Jakarta, Indonesia. Fredrik spoke at the China-ASEAN Healthcare Cooperation Program and had a meeting with President of CCCMHPIE to discuss future collaboration.

#### China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

In September, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang had a meeting with Vice President of our new Association Member CCCMHPIE in Beijing. CCCMHPIE is the leading and most influential national trade association in China with a mission to promote the international trade and cooperation in medicinal and health products.

#### Association of Malaysian Medical Device Industries (AMMI)

In November, the APACMed team had a meeting with Malaysian member association, AMMI, sharing experiences in training and capacity building activities.



#### The Association of Entrepreneurs for Laboratory and Health Equipment (GAKESLAB)

In November, APACMed CEO Fredrik Nyberg and Regulatory Affairs Director Yasha Huang met with Gakeslab Board members in Jakarta, Indonesia, to discuss recent regulatory changes as well as procurement policies.

## ● Projects

### Asia Pacific MedTech Investment Index

Since July 2018, APACMed in collaboration with the Asian Institute of Management based in Manila, has been working to launch the first ever Asia Pacific Medical Technology Index that seeks to identify criteria, opportunities, gaps and challenges that influence med-tech industry investment throughout the region, particularly focusing on the following countries Australia, the People's Republic of China (PRC), India, Indonesia, Japan, Malaysia, Philippines, Thailand, Vietnam, Singapore, and South Korea.

We look forward to publishing this in the first half of 2019.



### Accelerating Market Access for a maturing MedTech Industry in APAC

In August 2018, in collaboration with IQVIA, the Asia Pacific Medical Technology Association (APACMed) held a breakfast meeting to discuss the challenges around market access for MedTechs.

The White Paper [“Accelerating Market Access for a Maturing MedTech Industry in APAC”](#) was published after the event, sharing insights into creating market access enabled organisations.

Indeed, market access can no longer be understood through the narrow lens of pricing and reimbursement, without taking into consideration other elements such as regulatory, supply chain & channels, training & education, stakeholders & KOL management and financing. Thus, market access is defined here as “bringing of products or solutions to the right patient at the right price points in a timely manner through the efficient enablement of registrations, reimbursement, listing, training and supply”.



### “Telling the Story: Medical Device Footprint in Asia Pacific”

In December 2018, APACMed launched a project with Associate Member KPMG to map the MedTech Industry Footprint across the Region. This will be the first time such data is aggregated for our industry, and we look forward to bringing you the results in Q1 2019.

## Positioning the MedTech Industry as a partner to inform and shape healthcare policy

### ● Advocacy



#### India

### Trade Margin Controls

Following the publication of a concept note on trade margin controls for medical devices in June 2018 by NITI Aayog, the Government of India's think tank, APACMed submitted a position paper opposing the expansion of indiscriminate price controls and supporting a cap on trade margins based on price-to-trade, instead of landed costs. This came after an earlier high-level visit from medical technology industry executives to India to highlight the value of innovative medical technology and the importance of a level playing field to ensure Indian economic competitiveness.

APACMed continued to engage with Indian government officials throughout the year at various fora including World Health Organization meetings in Delhi and Visakhapatnam (more details below).



#### Malaysia

### Draft Halal standards for Medical Devices

Following continuous advocacy on the part of APACMed and our industry association member, Association of Malaysian Medical Industries (AMMI), the Malaysian Government has acknowledged the difficulties in the implementation of the draft halal standards for medical devices. In a meeting with a senior official from the Ministry of Health, Malaysia's Council of Rulers reportedly agreed with the view that the standard was “difficult to implement.”

Despite this, the Malaysian Investment Development Authority (MIDA) informed the industry in late 2018 that the draft standard

was approved by the Industry Standards Committee (ISC) chaired by Department of Islamic Development (JAKIM). AMMI, APACMed and other industry groups continue to engage with the Malaysian government on the issue, highlighting the difficulties in the implementation of such a standard, and its likely impact on Malaysian patients' access to life-saving medical technology.



## Vietnam

### New Cybersecurity Law

On June 2018, the Vietnamese National Assembly passed the Law on Cybersecurity (the "Cybersecurity Law"), which is due to come into effect on January 1, 2019.

It seeks to regulate data processing methods of technology companies that operate in Vietnam amongst other things. One of the major concerns relates to potential mandatory data localisation and requirements for companies serving end users to establish a physical presence in Vietnam.

APACMed wrote to the Ministry of Public Security, asking that medical device and medical technology companies be exempt from the coverage of the Law, and requesting further clarification in the compliance requirements. The Secretariat will continue to closely monitor this issue, and will follow up in 2019.

### ● High Level Meetings and Conferences

#### Visit to ASEAN Secretariat, October 2018, Jakarta, Indonesia

Following a meeting to present updates from the medical technology industry before partners at the European Chamber of Commerce in Indonesia (Eurocham Indonesia), Darwin Mariano, APACMed Senior Director for Government Affairs also paid a courtesy call to Sylvia Laksmi Sardy, Senior Officer in charge of medical devices at the Association of South East Asian Nations (ASEAN) Secretariat, together with Terry Song, Chairperson of the APACMed Southeast Asia Centre of Excellence.



Objectives of the courtesy call included, among others, APACMed's efforts to deepen and strengthen partnership with the ASEAN.

#### 71<sup>st</sup> Session of the Regional Committee of WHO South-East Asia Region (SEARO), September 2018, Delhi, India

Member countries of WHO South-East Asia Region met from 3-7 September to discuss priority health issues in the Region. Health ministers and senior officials from the 11 Member countries participates in the meeting of the highest policy making body of WHO in the Region. "Universal Health Coverage is at the core of Sustainable Development Goal 3 and can be a very powerful tool for social, gender and economic equity," said Mr J P Nadda, India's Minister of Health and Family Welfare, inaugurating the Seventy-first session of the WHO Regional Committee for South-East Asia.



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The year 2018 is also the 40th anniversary of the historic Alma-Ata Declaration, and due to our collective efforts, the Region is better prepared, and is accelerating progress toward the shared global vision of health for all through universal health coverage, he said.

Delegates discussed existing and new opportunities for improving access to essential medicines, vaccines and medical products both within WHO South-East Asia Region and beyond, as one of the key initiatives towards universal health coverage. APACMed will continue to work in close collaboration with WHO and attend regional and global events.

### **69<sup>th</sup> Session of the World Health Organization Regional Committee for the Western Pacific, October 2018, Manila, Philippines.**

Held from 8-12 October 2018 in Manila, Philippines, the meeting of the Western Pacific Regional Office of the World Health Organization ended with the election of a new regional director, several new regional frameworks and actions plans, and a reminder that amid recent health successes, the region still has much to do to improve health systems and eliminate deadly diseases.

Delegates discussed, among others, how hospitals are essential to healthcare systems and how the efficiency and effectiveness of healthcare systems are affected by hospitals. Work areas for the Western Pacific (WPRO) regional committee included a new Regional Framework for Control and Elimination of NTDs (neglected tropical diseases), which health leaders endorsed, along with the Regional Action Framework on Improving Hospital Planning and Management in the Western Pacific.

The week long meeting in Manila also discussed countries' progress against communicable and non-communicable diseases but a significant part of this year's discussions centered on hospital management and the use of digital health, such as telemedicine, issues that WHO directors said have clear links to universal health coverage.

More information is available on the [WHO Western Pacific Region Website](#).



### **4<sup>th</sup> World Health Organization Global Forum on Medical Devices, December 2018, Visakhapatnam, India**

On 13-15 December, the APACMed team (Darwin, Yasha & Emilie ) attended the [4<sup>th</sup> WHO Global Forum on Medical Devices](#) in Visakhapatnam, as a GMTA member. The theme of this event was "Increasing Access to Medical Devices". Major topics covered were:

- [Essential in vitro Diagnostic List \(EDL\)](#)
- [Classification and nomenclature of medical devices \(ICMD\)](#)
- [Priority medical devices \(PMD\)](#)

The conference was attended by over 1000 delegates from more than 90 countries. With limited industry seats, the conference was attended by a mix of the regions' health ministers, representatives from government/public institutions, academia, UN agencies, and healthcare providers. APACMed managed a MedTech industry association booth with GMTA peers, had fruitful side meetings with WHO Medical Device Lead about future engagement in capacity building, as well as peers from AdvaMed, MedTech Europe, ISPOR.

10 Jan	[Webinar] Competency Framework for Asia Pacific MedTech Regulatory Professionals (Deloitte) <b>Attendees: 28</b>	01 Aug	IQVIA & APACMed MedTech Mornings: Accelerating Market Access in APAC <b>Attendees: 81</b>
30 Jan	APACMed Virtual Town Hall <b>Attendees: 46</b>	15 Aug	APACMed Quarterly Networking Evening <b>Attendees: 62</b>
23 Feb	AGM and Networking Drinks <b>Attendees: 60</b>	30 Aug	Asia Pacific Workshop for MedTech Start-ups and SMEs <b>Attendees: 115</b>
06 Mar	[Webinar] Indian Medical Device Industry <b>Attendees: 62</b>	 <p>2018 ASIA PACIFIC <b>MEDTECH FORUM</b> TECHNOLOGY IN HEALTHCARE EMPOWERING PATIENTS, DRIVING OUTCOMES #APMTF2019</p>	
16 Mar	APACMed Dupont Packaging Seminar <b>Attendees: 37</b>		
17 May	APACMed Quarterly Networking Event <b>Attendees: 74</b>	08 10 Oct	Asia Pacific MedTech Forum 2018 <b>Attendees: 758</b>
30 May	MedTech HR Summit 2018 <b>Attendees: 56</b>	11 Oct	APACMed Regional Ethics & Compliance Meeting <b>Attendees: 83</b>
13 Jun	MedTech Meetup for Start-ups @ BASH <b>Attendees: 125</b>	11 Oct	APACMed Regulatory Affairs Summit <b>Attendees: 84</b>
21 Jun	Hong Kong Networking Event <b>Attendees: 49</b>	22 Oct	Workshop on AI in MedTech @ AHWP Regulatory Meeting <b>Attendees: 250</b>



# APACMed Annual General Meeting

February 2018, Conrad, Singapore



This third annual General Meeting, attended by 60 delegates, saw the election of a new Board of Directors.

In addition to the presentation of the 2018 APACMed Strategy and plan, an insightful panel discussion was held on **“The Connected Future of Patient Care”**.

Moderated by Dr Loke Wai Chiong, Executive Director, Healthcare Sector Leader, Deloitte South East Asia, the panel comprised:

- **Adjunct Assistant Professor Eric Wong**  
Group Chief Clinical Informatics Officer,  
National Healthcare Group
- **Mr Linus Tham**  
Group Chief Information Officer,  
Parkway Pantai
- **Dr Tan Teck Jack**  
Chairman & Medical Director, Northeast  
Medical Group & United Primary  
Care Network

Photos of the Annual General Meeting are available on the [APACMed website](#).



## DuPont Packaging Educational Seminar, March 2018, Novotel, Singapore

This event was attended by nearly 40 delegates. Aimed at healthcare technology professionals, engineers and researchers. The half day seminar explored the current developments in the medical packaging field.



## MedTech HR Summit, May 2018, Andaz, Singapore

Under the theme “Managing Organisational and People Challenges in the Digital Age”, the event brought together over 56 attendees comprising of business leaders and senior HR practitioners from 23 leading organisations.

Featuring 5 sessions and 8 speakers and panelists, the summit addressed critical areas such as digitization in the healthcare space; developing global leaders and building digitally sustainable organisations.

Opened by Fredrik Nyberg CEO, and Chairman Vladimir Makatsaria, other speakers included:

- **Meng Zhang**  
Vice President and General Manager, Tencent Healthcare Informatics Center
- **Ulrika Hagle**  
Managing Director, Global MedTech Practice, Korn Ferry

Opening presentations were followed by a dynamic panel discussion around the theme “Building Digitally Sustainable Organisations”, moderated by Scott Hensarling, Senior Client Partner, Korn Ferry, and featuring:

- **Julie Tay**  
Senior Vice President & Managing Director, Asia Pacific, Align Technology
- **Vincent Chan**  
Regional General Manager, APAC (Japan, Asia & India), Carestream
- **Guy Woollard**  
Vice President of HR, APAC, Stryker
- **Eugene Lam**  
Regional HR Director, APAC, Kimberly Clark

A full report is available for APACMed members on the [members only section of the website](#).



### **MedTech Meetup for Start-ups, June 2018, BASH, Singapore**

In collaboration with SG Innovate, APACMed hosted a meet up for MedTech startups@BASH, which attracted 75 delegates.

A panel of eminent speakers convened to share their views on “Building tomorrow’s leading MedTech firms”.

Attended by 72 delegates, the meeting was a useful launchpad for the formation of an APACMed Start Up and SME Working Group. The first meeting took place in December 2018, and it is expected members will work on a detailed plan for 2019.



### **APACMed Members Networking Event, June 2018, Hong Kong**

APACMed organised its second members’ networking event in Hong Kong earlier this year. Sponsored by our member BTG, the event brought together over 40 participants and included a very insightful presentation by Hong Ma, Executive Director of NorthHead (Public Affairs Consultancy) on “Navigating Medical Device Policy and Market Trends in China”.





### APACMed & IQVIA MedTech Morning, August 2018, Singapore

Under the theme “Accelerating Market Access for a Maturing MedTech Industry in APAC”, this breakfast brought together over 80 delegates for lively discussions around the central theme of market access.

A joint white paper was published following the event; this can be downloaded from the [APACMed Website](#).

The open address was given by Kah Yean Neo, Senior Vice President, A\*Star ETPL, on “Accelerating market access for a maturing MedTech industry in APAC”.

A panel discussion was held around the theme: “The path to successful commercialization in APAC – is it time for companies to recalibrate their market access strategies?” and was moderated by Eliza Chong, Associate Director, MedTech Asia Pacific, IQVIA. Speakers included:

- **Qi Li**  
Senior Director, Regulatory Affairs, MedTech Asia Pacific, IQVIA
- **Virginia Priest**  
Head of Health Economics and Reimbursement, AMEA, Boston Scientific
- **Kenneth Tan**  
Managing Director South East Asia, Hong Kong, Macau & Korea, Varian Medical Systems



### MedTech Start-up and SME Workshop, August 2018, Marina Bay Sands, Singapore

APACMed held its fourth MedTech Start up and SME Workshop last August in Singapore. The event, held in conjunction with Medical Fair Asia at Marina Bay Sands aimed to provide practical, hands-on guidance and deep insights to help MedTech start-ups and SMEs transition from the bench to prototyping.

Experts shared their insights on navigating clinical trial requirements & product validation, and provided updates on regulatory approval, commercialisation and post-market surveillance.

The event attracted 103 delegates and APACMed’s presence at the Medical Fair Asia Conference was also a great opportunity to engage with a wide audience.

The full programme and speaker list are available on the [APACMed Website](#).



**Asia Pacific MedTech Forum, October 2018, Suntec International Convention & Exhibition Centre, Singapore**

This year's MedTech Forum was the most successful to date! With a record attendance of over 750 delegates from some 25 countries, this year's event was also momentous in that we successfully engaged both healthcare providers and start-ups from across the region.

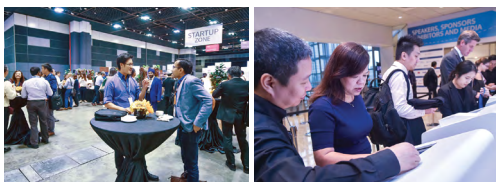
The event totaled 84 speakers, and six dedicated tracks running across two days; we were honoured to welcome Kevin Lobo, Chairman and CEO of Stryker and Ashley McEvoy, Worldwide Chair, Medical Devices for Johnson & Johnson, who, respectively, opened day one and day two of the MedTech Forum.

**Well over 700 delegates from 25 countries attended Asia Pacific MedTech Forum 2018 in Singapore!**

In addition, nearly 30 start-ups from seven countries across the region had the opportunity to showcase their solutions at our vibrant Start-up Zone, with some of these sharing the story of their entrepreneurial journey.

We were also proud to officially launch MedTech Innovator Asia, and we look forward to connecting with all our members interested in taking part in this exciting initiative.

Sincere thanks to all our Forum sponsors and partners without whom this record-breaking Forum would not have been possible!



Special thanks, as well, to all those whose contributions significantly shaped and enhanced the event; from providing us with guidance on the agenda, to putting us in touch with speakers, to taking part in our many sessions, as panelists or hosts.



And of course, Shakilla Shahjihan, Senior Director, Government Affairs, Abbott, deserves a special mention – thank you for a tremendous job as our event MC over the course of the two days!

**Re-live the excitement of the Forum!**

- The event Highlights Report is now available for [download](#) from our website.
- The event Highlights video can be viewed on our [YouTube Channel](#).
- The MedTech Forum [Photo Gallery](#) can be accessed on our website

## MedTech Forum Start-up Zone

We had around 30 start-ups exhibiting cutting-edge technologies and solutions, from telemonitoring technology from Indonesia, to a novel orthopaedic implant from Hong Kong and a blockchain company from South Korea.



Many thanks to all our members, speakers and partners who attended the Welcome Reception, at Dallas Bar & Restaurant (8 October) and the MedTech Social Night at Monti- 1 Pavilion (9 October). This was an opportunity to officially thank APACMed Chairman Vladimir Makatsaria, who will be stepping down and leaving the region to pursue a global role within Johnson & Johnson early 2019.



We were honoured to host our Association Members at our first Asia Pacific MedTech Industry Association Dinner on 10 October.



This is the first time APACMed convened the MedTech Industry Associations from Singapore, Malaysia, Indonesia, Thailand, Australia, India, China, Korea and Japan. Between us we represent over 8,000 MedTech companies across Asia Pacific!

## Launch of MedTech Innovator Asia

The Asia chapter of this accelerator programme was officially launched by CEO Paul Grand at the Medtech Forum.

Find out more in our press release and the [Business Times](#) article.

Applications for start-ups will open late November 2018. More information will be provided directly to our Start-up and SME Members. The APACMed Secretariat will also be issuing a guidance document for our Corporate and Associate members who may have an interest in becoming sponsors and join judging panels.

Please contact Gabriel Sim, Director, Business Development, for more information: [gsim@apacmed.org](mailto:gsim@apacmed.org)





## APACMed Engagements

## January

Meeting with Malaysian Government at Standards Malaysia Office to discuss Halal Certification of Medical Devices (in collaboration with AMMI, EU Chamber of Commerce, American Chamber of Commerce)

**Kuala Lumpur, Malaysia**

## February

Kick off Meeting with SMU MBA Students for APACMed Growth Strategy Project

**Singapore**

## March

Third APACMed Annual General meeting  
New Board of Directors is elected

**Singapore**

## January

APACMed attends General Assembly of Global Medical Technology Alliance (GMTA) and European MedTech Forum, organised by MedTech Europe

**Brussels, Belgium**

## February

APACMed attends APEC Regulatory Harmonisation Steering Committee (RHSC) Meeting

**Singapore**

## March

APACMed CEO and RA Director attend the 13th IMDRF meeting, DITTA Cybersecurity Workshop and GMTA/DITTA meetings

**Shanghai, China**

## January

APACMed CEO speaks on panel at "Patient Experience Asia Summit"

**Singapore**

## February

APACMed meets Duke University Margolis Centre for Public Health Team

**Singapore**

## April

APACMed meets with US Department of Commerce

**Singapore**

## February

Official dialogue meeting between APACMed CEO and CEO of Health Sciences Authority (HSA) Singapore

**Singapore**

## February

APACMed CEO takes part in NHIC Evaluation Panel IC2

**Singapore**

## April

APACMed Secretariat attends 6th ASEAN Medical Device Committee (AMDC) Meeting

**Singapore**

April

APACMed CEO attends  
China Medical Equipment  
Fair as an invited VIP

**Shanghai, China**

July

APACMed CEO attends  
APEC SME Business Ethics  
Forum

Meetings held with Japan  
Federation of Medical  
Devices (JFMDA)

**Tokyo, Japan**

August

APACMed CEO and RA  
Committee leadership  
attend Asia-Pacific Economic  
Cooperation Regulatory  
Harmonization Steering  
Committee Meeting (APEC-  
RHSC) as industry coalition  
member (alternate)

**Brisbane, Australia**

April

APACMed CEO joins  
MedTech Strategist  
Innovation Summit and  
takes part in the MedTech  
Innovator Judging Panel  
(Dublin Pitch Sessions)

**Dublin, Ireland**

July

APACMed delegation meets  
with Thailand FDA and  
THAIMED

**Bangkok, Thailand**

August

APACMed CEO presents a  
MedTech Business Brief to  
approx 70 visiting start-ups  
part of the High Commission  
of Canada and EU Business  
Delegations to South East Asia

**Singapore**

May

APACMed CEO invited to  
attended ASEAN Conference  
2018

**Singapore**

July

APACMed delegation meets  
with Director General of DMEC  
and the representative from  
Legal Department of Ministry  
of Health in Hanoi, together  
with local industry group  
EuroCham-MDDSC

**Hanoi, Vietnam**

August

APACMed CEO meets  
with President of Philippine  
Association of Medical Device  
Regulatory Affairs (PAMDRAP)

**Singapore**

June

APACMed CEO presents  
at Association of Malaysian  
Medical Industries (AMMI)  
Annual Meeting

**Penang, Malaysia**

August

APACMed CEO takes part  
in the interview panel for  
the Singapore Stanford  
Biodesign 2019 Candidate  
selection

**Singapore**

September

APACMed delegation attends  
the International Medical  
Device Regulatory Forum  
(IMDRF) as a GMTA member.  
Side meetings are held with  
CCCMHPIE Leadership and other  
stakeholders

**Beijing, China**

## September

APACMed delegation attends the 9th CIMDR, organised by China Center for Food and Drug International Exchange (CCFDIE) and supported by Center for Medical Device Evaluation (CMDE) of National Medical Products Administration (NMPA, previously known as CFDA).

APACMed CEO meets with the First Deputy Commissioner of National Medical Products Administration (NMPA) and leadership of CCFDIE about future collaboration

**Fuzhou, China**

## October

APACMed attends 23rd Asian Harmonisation Working Party Meeting and organises half-day AI workshop as part of the AHWP Technical Session

**Kuala Lumpur, Malaysia**

## October

APACMed meets with Thailand FDA to plan for the MedTech Forum & Regulatory Summit, as well as the 7th AMDC meetings & trainings

**Kuala Lumpur, Malaysia**

## October

Asia Pacific MedTech Forum 2018 followed by Regulatory Summit and Compliance Meeting

**Singapore**

## November

APACMed CEO invited to speak on surgical robotics at Singapore International Robo Expo 2018

**Singapore**

## September

APACMed CEO attends AdvaMed MedTech Conference and Global Medical Technology Alliance (GMTA) Annual Meeting

**Philadelphia, United States**

## October

APACMed is represented at the Western Pacific (WPRO) Regional Meeting of the World Health Organization (WHO)

**Manila, Philippines**

## November

APACMed delegation visits the Chief of Staff, Philippines Food and Drug Administration (FDA), together with the PAMDRAP leadership team

**Manila, Philippines**

## September

APACMed is represented at the South East Asia (SEARO) Regional Meeting of the World Health Organization (WHO)

**New Dehli, India**

## October

APACMed meets with ASEAN Secretariat to discuss future engagement

**Jakarta, Indonesia**

## November

APACMed Head of Government Affairs speaks at Duke NUS CoRE- NIHA (NUS Initiative to Improve Health in Asia) Digital Health Forum

**Singapore**

## APACMed Engagements

### November

APACMed CEO attends Medical Technology Association of Australia (MTAA) Annual Conference

**Sydney, Australia**

### November

APACMed CEO joins Singapore Stanford Biodesign Strategic Planning Exercise

APACMed CEO moderates a panel at the BME IDEA Biomedical Engineering, Innovation, Design and Entrepreneurship Alliance annual conference

APACMed CEO speaks at Stanford Biodesign Thought Leaders Series on Diabetes

**Singapore**

### November

APACMed delegation attends ChEXPO ASEAN 2018

Side meetings are held with Gakeslab and CCCMHPIE

**Jakarta, Indonesia**

### November

APACMed team hosts meeting with Malaysian member association, AMMI, to share experiences in training and capacity building activities

**Singapore**

### December

APACMed co-organises 7th ASEAN Medical Device Committee (AMDC) Meeting. Trainings for AMDC regulators and industry representatives from the region are facilitated by APACMed

**Bangkok, Thailand**

### December

APACMed Delegation attends 4th WHO Global Forum on Medical Devices and discusses capacity building collaboration with WHO officials

**Visakhapatnam, India**

### December

APACMed meets with CDSCO officials to discuss collaboration. Meetings with AdvaMed, MedTech Europe, and MTal are held to explore future efforts in promoting standard harmonisation

**Visakhapatnam, India**

## APACMed Secretariat Team



### Fredrik Nyberg

Chief Executive Officer

### Darwin Mariano

Senior Director, Government Affairs

### Yasha Huang

Director, Regulatory Affairs

### Gabriel Sim

Director, Business Development

### Emilie Rapley

Director, Communications

### Clement Chung

Operations Manager

### Wen Li Cai

Executive Assistant

## APACMed Partners

Knowledge Partner:

**McKinsey & Co.**

Talent Partner:

**Korn Ferry**

Auditor:

**RSM Chio Lim LLP**

Tax Advisor:

**Deloitte & Touche LLP**

Corporate Secretary:

**Dentons Rodyck & Davidson LLP**

Public Relations:

**Spurwing Communications**

# Annual Report 2018

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚太医疗技术协会) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific.

APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory convergence.

Learn more about the association at [www.apacmed.org](http://www.apacmed.org)

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**APACMed** ASIA PACIFIC  
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ASSOCIATION

