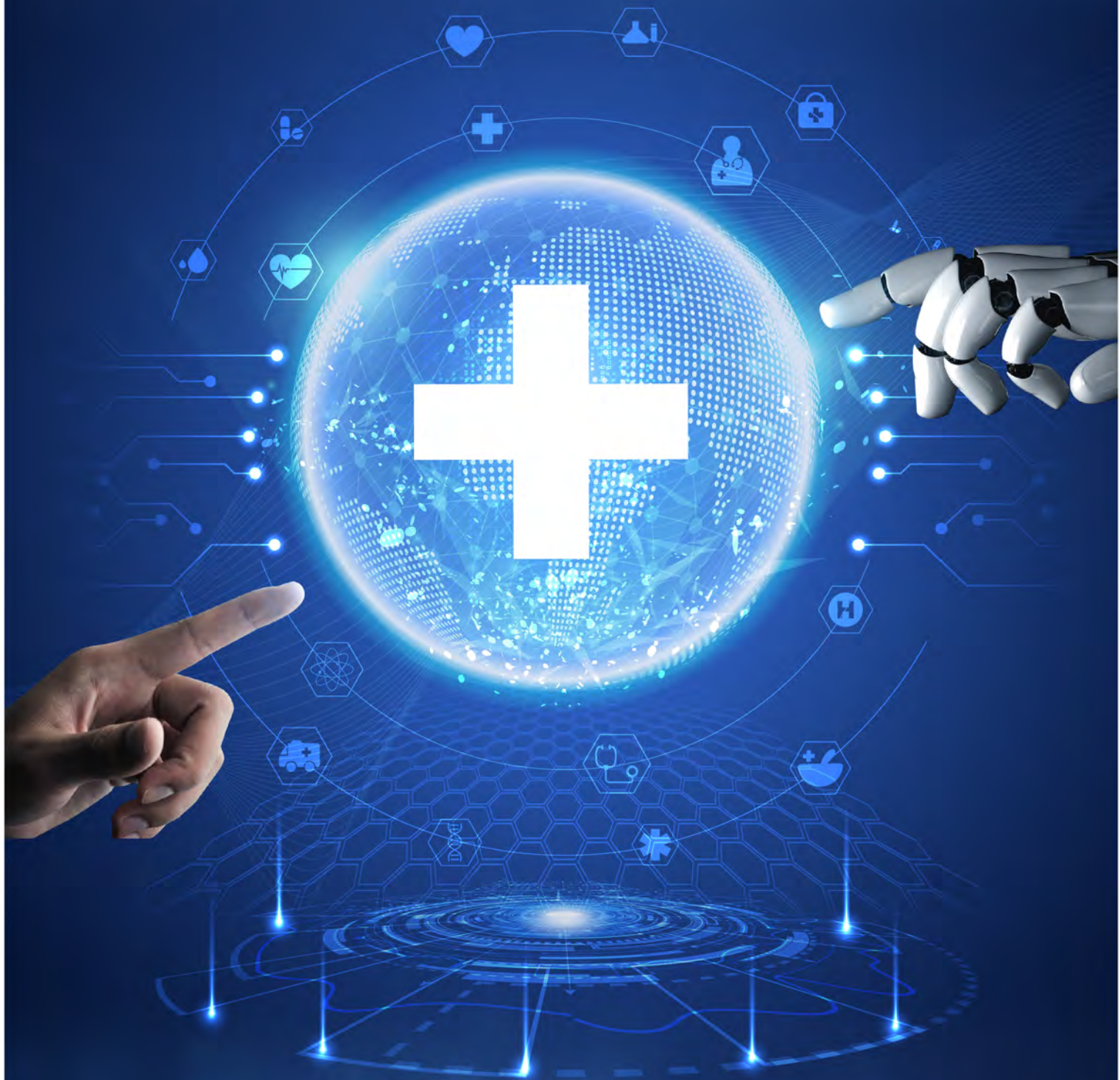


**APAC Med**  
The voice of MedTech



Transforming Healthcare  
Saving Lives



*Asia Pacific Medical Technology Association  
Annual Report 2022*

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# Asia Pacific Medical Technology Association (APACMed)

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 healthcare challenges.

By providing a unifying voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, the Asia Pacific Medical Technology Association (APACMed) works to promote innovation and impact policy that advances healthcare access for patients.

APACMed's mission is patient-centric and calls for new creative partnerships within the healthcare and medical technology ecosystem, amongst key stakeholders including clinicians, governments, regulators, payers, healthcare providers, patient advocacy groups and academia.

## Our Mission

APACMed strives to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

## APACMed Strategic Pillars



### ACCESS

We strive to improve access to high quality healthcare for patients through close collaborations with our members and the wider ecosystem stakeholders to help shape policies that truly impact the lives of patients.



### INNOVATION

We support innovative new technologies and start-ups that improve quality of care and healthcare outcomes.



### HARMONISATION

We drive common approaches aligned with international best practices and standards to promote speed to access in a safe, secure and ethical manner through the adherence of the Code of Conduct.



*"The life once I gave up upon returned. Because of the knee joint replacement surgeries, I was able to restart my life."  
Shinkichi Shoji*



## A Patient's Story: Innovations that help change lives

Shinkichi Shoji of Shimane, Japan, has always been an athlete. For decades, he was a triathlete competing almost annually in triathlons. In his later years, his interest in sailing grew and, in 2016, Shinkichi completed a solo sailing journey across the Pacific Ocean from Japan to San Francisco, California.

Although he had experienced knee pain prior to his cross-Pacific trip, it was after the physically demanding journey that had his knee condition worsened to the point where he began to worry that he might not be able to continue his physically active lifestyle. As a life-long athlete and avid sailor, he found this thought very difficult to bear.

It was then that he consulted with his healthcare provider to explore his treatment options and decided to undergo knee replacement surgery in both knees.

He recalls after the surgeries, "The life once I gave up upon returned. Because of the knee joint replacement surgeries, I was able to restart my life."

"I can continue to live and grow my dreams even more now that I have artificial knee joints."  
Shinkichi's latest dream is to complete a sailing trip around the world.



# Welcome Message

## John Collings, APACMed Chairman

*"Today, more than ever, our APACMed purpose resonates powerfully as we aim to strengthen healthcare systems for the benefit of patient access. Together, we can drive lasting positive change that will shape an environment for MedTech innovation and move us further toward our mission."*



Dear APACMed Members,

On behalf of the APACMed Board of Directors, I am pleased to present APACMed's 2022 Annual Report. 2022 was a year that brought opportunities and challenges as we continue to witness the impact of the pandemic within our industry and healthcare systems. APACMed, with our stakeholders across the Asia Pacific region, rose to the occasion by supporting members to address this dynamic, staying focused on the opportunities to further our collective mission.

APACMed's theme in 2022 was Patient Centricity, which guided our work to better involve, activate, and support patients within the region to gain access to the technology and services that MedTech can provide. Over the course of 2022, APACMed continued to promote and advocate access to high quality and affordable healthcare, whilst leveraging the value of innovation and regulatory harmonisation through recommendations including digital health reimbursement, sustainability, and market access.

APACMed also supported members to uncover new opportunities to further improve healthcare across the region and create a future for innovation. As an example, members and partners shared best practices to support patient and provider access to information and discussed how better to support remote healthcare models. In addition, we responded to the shift of MedTech innovation generation towards Asia Pacific by developing programmes to better support the community we serve. As a result, APACMed now has its own start-up community ready to share, collaborate and partner as we accelerate technology innovation and further patient impact collectively.

Today, APACMed has more than 310 member organisations ranging from large companies, start-ups, and local associations across the Asia Pacific region. From these organizations, I am incredibly grateful to the over 1,300 individuals who contribute their time, energy, and expertise within our committees. It's through their leadership that we continue to make progress against our mission.

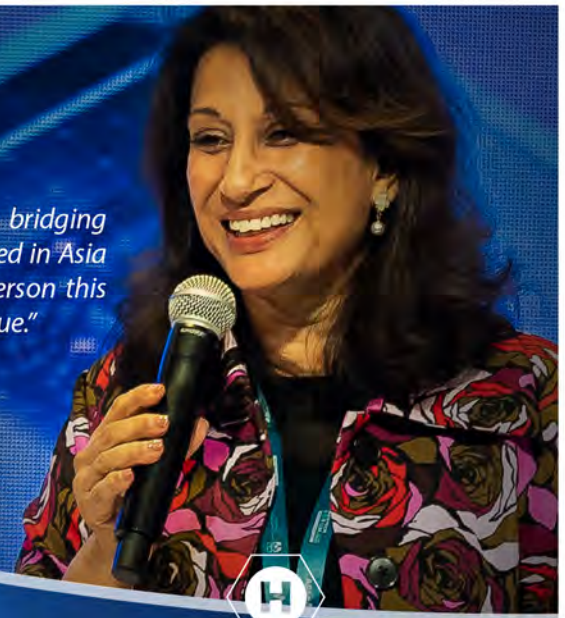
Thanks to these contributions, APACMed was able to launch 11 position papers, gather over 4,000 attendees at numerous live events, and host several public-private dialogues with key stakeholders in 2022. The impact of this has been a collective progress, ultimately making healthcare better for patients across Asia Pacific.

As we close the year and look to 2023, I would again like to thank all of our members, partners, stakeholders, and the APACMed Secretariat for their tremendous efforts to progress the MedTech industry's shared purpose of improving the lives of patients. MedTech remains critical to preserving health and well-being, improving lives and contributing to sustainable healthcare systems. Thanks to you, our momentum is strong and we are positioned for even greater and meaningful progress against our ambition in 2023.

Sincerely,  
John Collings  
Chairman  
APACMed

# In Conversation with Harjit Gill, APACMed CEO

*"The MedTech industry is poised to take a leading role in bridging pathways to provide life-saving technologies to those in need in Asia Pacific. It's been wonderful to see everyone together in person this year, and to maximise the energy from public-private dialogue."*



The MedTech industry in Asia Pacific demonstrated resilience and agility when faced with unprecedented challenges during COVID-19. As we moved past the pandemic, our industry continues to evolve to meet the shifting demands of patients and their healthcare needs. With the growing prevalence of chronic diseases, increasing adoption of innovative technologies and government policies aimed at enhancing healthcare access; the industry is poised for sustained growth, positively impacting health outcomes throughout the region.

In 2022 our focus was on patients and patient-centered care models. During the COVID-19 pandemic, we all experienced first-hand being patients and serving as caregivers. While more than one billion people in Asia Pacific still lack access to basic healthcare services and products, our collective sense as a MedTech industry remains strong in terms of cultivating public-private collaboration for policy improvements. It was incredible to see over a thousand stakeholders, from varying profiles across the ecosystem, convene at the MedTech Forum, under the theme of Patient Futures 2025, to talk about how regulations and reimbursement can continue to be enhanced so that MedTech innovations are reaching those in need around the region.

Corresponding to the above, it's been a busy year of outcomes for APACMed. A few of the major highlights for me include:

- Our membership grew 18% Y-o-Y, and we registered an official office in China
- More than 4,000 attendees joined our webinars and events throughout the year, including representatives from 31 countries at our flagship MedTech Forum
- The Regulatory Affairs Committee finalised inclusion of all device classes in the Singapore-Thailand Regulatory Reliance Programme, thereby increasing speed-to-market
- The Government Affairs & Market Access Committee continued to drive the health services initiative, including open dialogue with policymakers in Singapore and China
- The Digital Health Committee's "Value of Diagnostics" whitepaper was recognised by The Lancet Commission as part of a WHO resolution proposal, among other continued initiatives in areas such as regulation and reimbursement
- The Legal, Ethics, and Compliance (LEC) Committee held a dedicated summit for member company LEC teams to discuss the future of the profession
- In terms of our branding footprint, we saw the highest traffic in APACMed's history – 81,000+ visitors to the website (87% Y-o-Y increase) and 16,000+ followers across social media (28% Y-o-Y increase)

I would like to thank our APACMed members and stakeholders, who represent a diverse cohort of large and small organisations, from public and private sector, across a wide geography in the Asia Pacific. Your contributions have enabled us to keep the end goal in mind of improving the lives of patients. I would also like to thank the APACMed Secretariat, who work tirelessly to ensure we execute our plans for the year with utmost quality, while staying on top of the numerous live issues which need to be tackled along the way. 2023 is shaping up to be another ambitious period for APACMed, and I look forward to sharing more in due course about our plans and how you can be involved.

Sincerely,  
Harjit Gill  
Chief Executive Officer  
APACMed



## Organisation & Committees

**Board of Directors**



**Secretariat Team**



**Committees**

**Government Affairs  
& Market Access**

*250 Committee  
Members*



**Digital Health**

*318 Committee  
Members*



**Regulatory Affairs**

*350 Committee  
Members*



**Legal, Ethics &  
Compliance**

*100 Committee  
Members*



**Start-Up & SME**

*300 Committee  
Members*





**John Collings**  
Chairman, APACMed  
President, Asia Pacific  
Stryker



**Elisabeth Staudinger**  
Vice Chairman, APACMed  
Managing Board Member &  
President, Asia Pacific  
Siemens Healthineers



**James Lim**  
Treasurer, APACMed  
Executive Vice President &  
President, Greater Asia  
Becton Dickinson



**Farhana Nakhooda**  
General Manager &  
Senior Vice President, Asia Pacific  
Health Catalyst



**Steven Flynn**  
Senior Vice President and  
President, Asia Pacific  
Baxter Healthcare



**Probir Das**  
Group Executive Officer  
Terumo Corporation  
Chairman, Terumo Asia Holdings  
Chairman & Regional Representative  
Asia Pacific & India



**Lam Chee Hong**  
President, Asia Pacific  
B.Braun



**Chris Lee**  
Senior Vice President &  
President, Asia Pacific  
Medtronic



**Justin Leong**  
President, Asia & Latin America  
Resmed



**Lance Little**  
Managing Director  
Roche Diagnostics Asia Pacific



**Art Butcher**  
Executive Vice President  
& President, Asia Pacific  
Boston Scientific



**Marc Radatt**  
Chief Executive Officer  
Olympus Asia Pacific



**Tim Schmid**  
Company Group Chairman,  
MedTech Asia Pacific  
Johnson & Johnson



**Paul Tan Minjie**  
Divisional Vice President, Asia Pacific  
Abbott





## Committee Board Sponsors



**Government Affairs & Market Access**

**Paul Tan Minjie**

Divisional Vice President, Asia Pacific  
Abbott



**Digital Health**

**Elisabeth Staudinger**

Managing Board Member & President, Asia Pacific  
Siemens Healthineers



**Regulatory Affairs**

**Lance Little**

Managing Director  
Roche Diagnostics Asia Pacific



**Legal, Ethics & Compliance**

**Tim Schmid**

Company Group Chairman, MedTech Asia Pacific  
Johnson & Johnson



**Start-up & SME**

**Justin Leong**

President, Asia & Latin America  
Resmed

## Country Board Sponsors



**ASEAN**

**Lam Chee Hong**

President, Asia Pacific  
B. Braun



**CHINA**

**James Lim**

Executive Vice President &  
President, Greater Asia  
Becton Dickinson



**INDIA**

**Probir Das**

Chairman & Managing Director  
Terumo Asia Holdings



**JAPAN**

**Art Butcher**

Executive Vice President &  
President, Asia Pacific  
Boston Scientific



**KOREA**

**Chris Lee**

Senior Vice President &  
President, Asia Pacific  
Medtronic



**AUSTRALIA**

**Farhana Nakhoda**

General Manager & Senior Vice President  
Asia Pacific, Health Catalyst



**Harjit Gill**  
Chief Executive Officer



**Gabriel Sim**  
Director, Strategic Partnership  
& Start-up Programme



**Christine Tan**  
Director, Country Activation &  
Marketing



**Anirudh Sen**  
Country Lead, APACMed India &  
Director, Regulatory Affairs, Asia Pacific



**Alicia Chang**  
Country Lead,  
APACMed China



**Nishan Pillai**  
Manager, Finance & Operations



**Roberta Sarno**  
Director, Digital Health



**Glenda Teng**  
Manager, Government Affairs &  
Market Access



**Camille Moutard**  
Manager, Digital Health



**Gideon Praveen Kumar**  
Manager, Regulatory Affairs



**Cindy Pelou**  
Manager, Legal,  
Ethics & Compliance



**Benish Aslam**  
Assistant Manager,  
Government Affairs &  
Market Access



**Grace Chua**  
Manager, Marketing



**Rakesh Mistry**  
Manager,  
Business Development



**Ankit Sharma**  
Manager, APACMed India



**Shreya Bansal**  
Research Associate,  
APACMed India & Regulatory Affairs



## 18% GROWTH OF MEMBER COMPANIES

Number of member companies increased from 263 in 2021 to 310 in 2022



Number of Member Companies

## 1,318 COMMITTEE MEMBERS

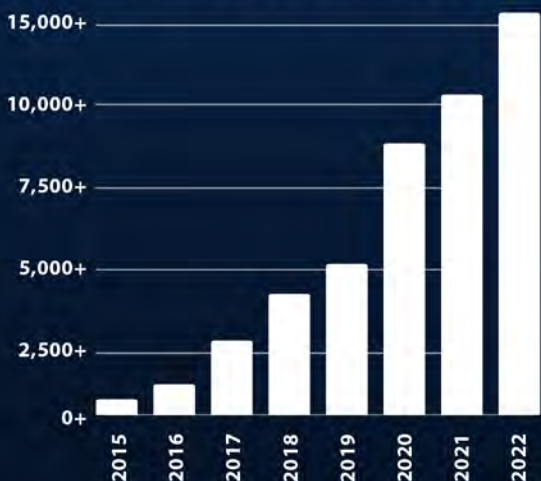
Total number of members from 5 committees in 2022



Number of Committee Members

## 28% GROWTH OF SOCIAL MEDIA FOLLOWERS

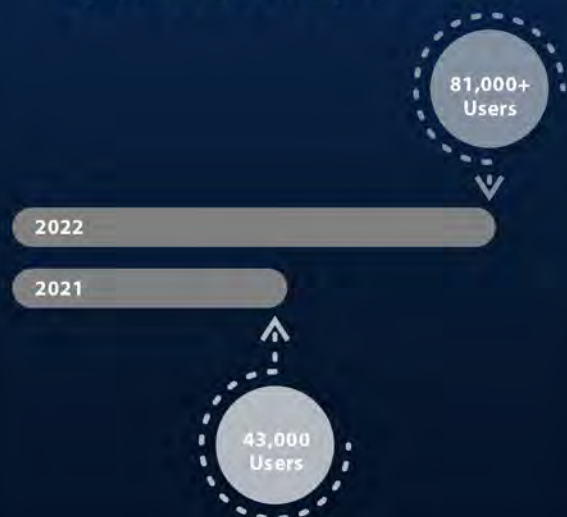
Number of social media followers increased from 12,000+ in 2021 to 16,000+ in 2022



Number of Social Media Followers

## 87% GROWTH OF WEBSITE USERS

Number of website users increased from 43,000+ in 2021 to 81,000+ in 2022



Number of Website Users

## 4,400+ DELEGATES

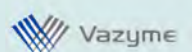
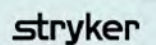
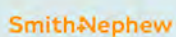
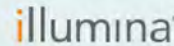
Events, Workshops and Conferences

## 11 POSITION PAPERS

Published across 4 committees



—○ Corporate Members





—○ Digital Health Members



—○ Associate Members



—○ Start-Up & SME Members





—○ Start-Up & SME Members





—○ Industry Association Members



# Government Affairs & Market Access Committee

Working with policy makers and other stakeholders across the healthcare ecosystem, in order to shape policies and processes that facilitate increased access and affordability of medical technologies for patients in the Asia Pacific region.

## Core Leadership



**Shakilla Shahjihan**  
Government Affairs Chairperson  
Divisional Vice President,  
Government Affairs,  
Asia Pacific & Japan  
Abbott



**Jane Mcmillan**  
Government Affairs  
Vice-Chairperson  
Head, Government Affairs & Policy  
MedTech Asia Pacific  
Johnson & Johnson



**Dr Sang-Soo Lee**  
Market Access Chairperson  
Senior Healthcare Economics &  
Government Affairs Director  
Medtronic North Asia  
(Korea & Japan)



**Virginia Priest**  
Market Access  
Vice-Chairperson  
Director, Health Economics &  
Market Access, Asia Pacific  
Boston Scientific



**Shivkumar Hurdale**  
Government Affairs  
Vice-Chairperson  
Director – GA/RA/QA  
India & RA Advocacy (ASPAC)  
Stryker



**Rajeev Nandan**  
Government Affairs  
Vice-Chairperson  
Head, Market Access &  
Government Affairs  
Alcon



**Alice Chu**  
Market Access  
Vice-Chairperson  
Director, Market Access &  
Medical Marketing, Asia Pacific  
Glaukos

## Country Centres of Excellence

### CHINA



**Anita Song**  
Chairperson  
Director, Health Economics,  
Policy and Reimbursement  
Medtronic Greater China



**Jenny Jin**  
Vice-Chairperson  
Senior Director, GA & QREM  
Fresenius Medical Care China



**Ning Yue**  
Vice-Chairperson  
Strategic Access Director  
Becton Dickinson China

### INDIA



**Vibhav Garg**  
Chairperson  
Director, Government Affairs  
Strategy, India Hub & ASEAN  
Boston Scientific



**Vineet Gupta**  
Vice-Chairperson  
Director, Government  
Affairs (South Asia)  
Varian Medical Systems



**Parveen Jain**  
Vice-Chairperson  
Head, Regulatory Affairs,  
Quality & Government Affairs  
Fresenius Medical Care

### INDONESIA



**Wanda Harahap**  
Chairperson  
Government Affairs Director  
Abbott Indonesia



**Wulaning Putri Sunuwati**  
Vice-Chairperson  
Head of Government Affairs &  
Business Development,  
Head of Quality Regulatory  
Siemens Healthineers Indonesia



**Lenny Santida Tarigan**  
Vice-Chairperson  
Country Market Access  
Government Affairs &  
Partnership Leader  
Medtronic Indonesia

### SOUTH KOREA



**Jongbae (JB) Kim**  
Chairperson  
Head of Health Economics &  
Market Access (Hema)  
Johnson & Johnson Medical Korea



**Alex (Sook-Young) Jeon**  
Vice-Chairperson  
Director, Public Affairs, Policy, Market  
Access, Heor and Communications  
Becton Dickinson Korea



**Nicole Kim (Se-A)**  
Vice-Chairperson  
SR, Quality Manager  
Illumina Korea

### VIETNAM



**Julia Tran**  
Chairperson  
Regional Director, Government Affairs of  
Vietnam, Thailand, Cambodia, Laos & Myanmar  
Abbott



**Nguyen Thi Li Minh**  
Vice-Chairperson  
Market Access Lead  
Baxter Vietnam



**Thuy Pham**  
Vice-Chairperson  
Market Access Lead  
Boston Scientific Vietnam





This year, over 250 industry professionals from 47 companies participated actively in knowledge sharing of best practices in policy shaping and advocacy through the Government Affairs and Market Access (GAMA) committee.

### Strategic Initiatives

In 2022, GAMA's key market-shaping initiatives were as follows:

#### MedTech Health Services

GAMA Health Services Working Group and our knowledge partner L.E.K. Consulting developed a white paper "Health Services in APAC – Opportunities, Challenges and the Path to Progress: Insights from MedTech". Over two expert panel discussions focused respectively on diabetes management and chronic kidney disease, our members invited physicians, providers and patient advocates to consider MedTech's innovations in health service delivery. Insights were consolidated into a special report: "[Chronic Disease Management: The Case for MedTech Health Services](#)," in August 2022. APACMed China GAMA CoE brought the discussion to Chinese stakeholders through a collaboration with Tsinghua University on "Health Services Beyond Hospitals", which included an Expert Dialogue in August 2022 and a post-meeting summary report in Dec 2022.

#### Value-Based Market Access

GAMA Market Access Working Group (MAWG) organised the inaugural [VBMA Symposium](#) in June 2022. Held in hybrid format, over 400 attendees participated in a lively dialogue with policymakers and key opinion leaders from the US, Europe, China, India, Australia, Thailand and South Korea on how MedTech industry can partner with health systems to drive value-based healthcare transformation. [A report was developed](#) to summarise key learnings from the symposium.



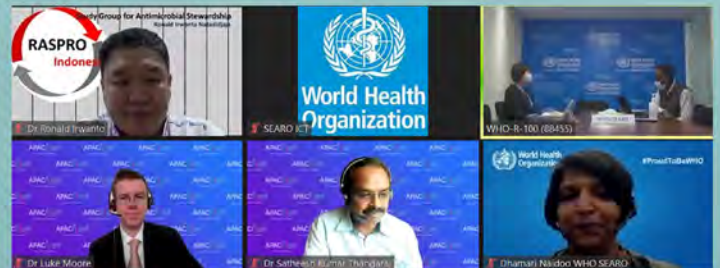
#### Capability Building through Market Access Country Spotlight Series

A series of exclusive capability building and networking sessions saw GAMA members gain insight into the market

realities from local country experts. The South Korea session in March 2022 focused on health policy and reimbursement changes with transition to a new Presidential leadership; the Australia session in June 2022 focused on policy implications under the new Prostheses List announcement.

#### Critical Role of Diagnostics in Anti-Microbial Resistance (AMR) Stewardship and COVID-19 Management

To support adoption of COVID-19 self-testing in Indonesia, APACMed GAMA Indonesia CoE facilitated a closed-door focus group discussion with the Indonesian Ministry of Health in March 2022, which was well-appreciated. A similar discussion was held in China with the Beijing Centre for Disease Control (CDC), highlighting the specific role for self-testing in the gradual re-opening of economies both in the region and globally.



To highlight the critical role of testing for AMR, APACMed GAMA was one of the partners for the WHO Southeast Asia Regional Office for the Antimicrobial Stewardship Guidance Programme for the session: "Role of Diagnostics in Antimicrobial Stewardship" in August 2022. The session highlighted the effectiveness of diagnostics to ensure right treatment delivery to the right patients at the right time frames in managing AMR.

#### Supply Chain Resilience and Industrial Policy

The region has seen a wave of pro-localisation policies that have impacted public and private procurement. GAMA Supply Chain Resilience and Industrial Policy Taskforce (SCRIPT) developed a policy communications toolkit through focus group discussions with country-based CoEs, to support members engaging policymakers on the agenda – advocating for a level playing field for local and global players alike and the need to maintain healthy competition for growth and innovation.



## —○ Government Affairs & Market Access Committee

### Country Activation

#### GAMA Secretariat Visit to Indonesia

During the 3-day visit, the APACMed Indonesia CoE delegation met with government officials to discuss healthcare transformation and innovation in Indonesia and gathered insights on closer collaboration with local Chambers and Associations towards a joint activation event, Innovation Day, in 1H 2023.



### Policy Watch

At the quarterly GAMA Committee meetings, experts were invited to share their views on salient geopolitical issues impacting the MedTech industry:

- Health System Resilience to COVID-19 in India (Presentation by Shweta Bhardwaj, Associate Director, Global Sustainable Health Systems Policy, Johnson & Johnson, March 2022).
- Enabling Growth and Innovation in the Indian Medtech Sector (Presentation by Nikhil Patil, Partner, Lifesciences and Healthcare, KPMG, June 2022).
- Market Access Challenges for MedTech in APAC (Presentation by Joe Caputo and Antony Morton-Small, Co- Managing Directors, Vista Health Consulting, December 2022).

### Events & Member Engagement

#### Public Policy & Market Access (PPMA) Expert Summit at MedTech Forum 2022

Held as part of MedTech Forum, the PPMA Expert Summit was attended by over 500 physical and virtual attendees. Industry leaders, clinical practitioners and academicians from across the region shared perspectives on disruptive and innovative models of service delivery, the value of diagnostics, and building resilient supply chains through partnerships.



#### GAMA Social Evening

GAMA members gathered for drinks in Singapore's historic Keong Saik Road in August 2022, to celebrate the completion of regional GAMA leadership elections.



#### GAMA Strategy Retreat

Between October and November 2022, the GAMA Secretariat collected feedback and insights into 2023 priorities from members through one-on-one interviews and a Strategy Survey, which facilitated the finalization of the 2023 Workplan. In December 2022, the GAMA Committee held its annual Strategy Retreat in a hybrid format; an opportunity for members across the region to come together to celebrate past achievements, gain insights from a keynote presentation on market access challenges by Vista Health Consulting, agree on key activities and countries of activation, and identify project leaders for each strategic initiative.



#### Regularly Leadership Team (LT), Working Group (WG) and Centre of Excellence (CoE) Meetings

Members gathered as a whole Committee every quarter. In addition, and where there was an interest, members initiated, led and/or served in advocacy and capability building initiatives in locally-based CoE teams and project-based Working Groups with GAMA Leadership Team convening every month to steer the committee's priorities and operations as a whole.

#### Advocacy

In 2022, the GAMA Committee undertook consultations and information sharing on medical technology policy and access challenges across the region, including:

1. Australia: Prostheses List
2. Indonesia: Local content requirement
3. Philippines: Pricing & Procurement
4. Singapore: MedTech Subsidy List
5. Thailand: UC Reimbursement Price Review
6. Vietnam: Price Declaration; Free Placement of Medical Equipment in Public Hospitals



# Digital Health Committee

Shares the voice of the industry with public and private digital health decision-makers and provides a neutral platform for public-private collaborations on regulatory, cybersecurity, reimbursement, health data and interoperability matters.



## Core Leadership



**Arif Fahim**  
Reimbursement Chairperson  
Regional Director, Health Economics & Reimbursement, Asia Pacific  
Abbott



**Jim Sarka**  
Cybersecurity Chairperson  
Vice President & CIO,  
Business Technology, Asia Pacific  
Johnson & Johnson



**Manan Hathi**  
Regulatory Chairperson  
Senior Manager,  
Regulatory Affairs, Software  
Stryker



**Alex Lee**  
Interoperability Chairperson  
APAC Strategic Planning & Partnerships Director  
Abbott Diabetes Care



**Varun Veigas**  
Reimbursement Vice-Chairperson  
Leader, Policy & Strategic Partnerships  
Roche Diagnostics Asia Pacific



**Paul Chua**  
Cybersecurity Vice-Chairperson  
Product Security Officer  
Becton Dickinson Greater Asia



**Yasha Huang**  
Regulatory Vice-Chairperson  
Regional Regulatory Affairs & Policy Head  
Roche Diagnostics

## Country Centres of Excellence

 CHINA



**Varun Veigas**  
Chairperson  
Policy & Strategic Partnerships  
Roche Diagnostics Asia Pacific




**Tony Liu**  
Vice-Chairperson  
General Manager  
ResMed China



**Manan Hathi**  
Vice-Chairperson  
Senior Manager, Regulatory  
Affairs, Software  
Stryker



**Qiang Shi**  
Vice-Chairperson  
Head, Health Economics & Market Access Team (HEMA)  
Johnson & Johnson  
MedTech China

 AUSTRALIA



**Michael Nobes**  
Chairperson  
Market Access Director,  
Asia Pacific  
Abbott Diabetes Care



**Michelle Costa**  
Vice-Chairperson  
Director, Health Economics  
Market Access  
Johnson & Johnson Australia

 INDIA




**Shweta Bhardwaj**  
Chairperson  
Director, Global Digital & R&D Policy  
Johnson & Johnson



**Seema Arora**  
Vice-Chairperson  
National Marketing Head,  
Asia & Latin America  
ResMed



**Sushant Jaiswal**  
Vice-Chairperson  
Manager, Regulatory Affairs  
Roche Diagnostics India


 JAPAN



**Jun Sekiguchi**  
Chairperson  
Director, Japan Government Affairs  
Baxter Ltd



**Danny Van Kerssaver**  
Vice-Chairperson  
Director, Business Development  
Dräger Japan

 KOREA




**Gordon Danton**  
Chairperson  
President, Japan & Korea  
ResMed



**Brian Suh**  
Vice-Chairperson  
Head of Government Affairs  
Varian Korea



**Christine Choi**  
Vice-Chairperson  
Sr. Reimbursement Manager  
Medtronic

 ASEAN



**Mary Kiang**  
Chairperson  
Manager, Peritoneal Dialysis Business  
Baxter



The Digital Health Committee was introduced in January 2020 to share knowledge and to advocate for policies that ease innovation across the whole digital health product journey, from regulatory approval to market access, reimbursement, and use.

The Committee has grown to more than 310 individual members from 85+ companies, with six country Centres of Excellence (CoEs) across the region that cover ASEAN, Australia, China, India, Japan, and South Korea. The CoEs bring the Committee's regional work into the countries and further enhance our engagement with local stakeholders.

### Strategic Initiatives

#### **Advancing Regulatory Capabilities and Advocacy Work in Australia, ASEAN, China and Korea**

Fit-for-purpose regulatory frameworks for digital health are strongly needed in Asia Pacific, as they can enable the delivery of life-saving solutions to patients in a safe, effective, and timely manner. Following the publication of the first industry paper on Software As a Medical Device (SaMD) in early 2021 and roundtables with Health Sciences Authority (HSA) in Singapore and Therapeutic Goods Administration (TGA) in Australia, in the Committee started a Working Group for country activation in Korea, and collaborated with the Korea Medical Devices Industry Association (KMDIA) to connect with the Ministry of Food and Drug Safety (MFDS). The Committee also engaged local trade association partners in ASEAN and conducted closed-door roundtables with ASEAN regulators and representatives from the TGA.

This year, the Committee's advocacy efforts has led to the incorporation of our recommendations into the updated HSA guidelines on SaMD in Singapore.

#### **Advancing Reimbursement Capabilities in Korea, Japan, China and Australia**

In 2022, the Committee launched a Digital Health Reimbursement Alliance. The Alliance includes additional stakeholders beyond the APACMed traditional network, both in terms of geography (beyond APAC) and industry (outside of MedTech). The objectives of the Reimbursement Alliance include (i) the creation of a platform for stakeholders

share knowledge and advocate for policies that increase access to digital health; (ii) provide learning opportunities to stakeholders in private and public sectors; and (iii) offer support to policymakers to develop value assessment, funding, and reimbursement frameworks for digital health.

This year, the Committee focused on launching the Alliance, onboarding members and organising several private-public dialogues, including:

- Three sharing sessions for private sectors in Korea, Japan, and China
- Three sessions with Australian, Chinese, and Korean policymakers as part of advocacy and policy-shaping efforts

Summaries of these dialogues are available on the APACMed website. The Committee also published a reimbursement paper in Chinese to further disseminate our work in the country.

#### **Cybersecurity Labelling Scheme for Medical Devices in Singapore**

The Committee collaborated with Singapore's Cybersecurity Agency (CSA), Health Sciences Authority (HSA), Ministry of Health (MOH) and Integrated Health Information Systems (IHIS), on developing a cybersecurity labelling scheme for connected medical devices. The pilot was launched this year.





## Publications

### Advancing Real World Evidence in APAC – Key Considerations for Policymakers

Within Asia Pacific, the utilization of Real World Evidence (RWE) is an emerging and crucial matter for the medical device industry, regulators, and policy makers. In March 2022, the Committee published a paper titled “[Advancing Real World Evidence in APAC – Key Considerations for Policymakers](#)” to explore the state of policy innovation regarding the use of RWE for regulatory and reimbursement decision-making. The paper examines the importance of RWE for the region, identifies challenges and global best practices, and outlines key considerations as policy makers look to advance RWE for evidence-driven healthcare outcomes.

### Strengthening Healthcare Systems Through the Critical Role of Diagnostics

Diagnostics technology is the starting point of the quest for solutions to major public health challenges. This resonates even more in the COVID-19 context. In line with the WHO Essential Diagnostics List (EDL) and Lancet Commission efforts, the Committee and its members have come together to publish an inaugural paper about the value delivered by diagnostic technologies in the region. Leveraging on the “[Strengthening Healthcare Systems Through the Critical Role of Diagnostics](#)” paper, APACMed provided a platform for public-private dialogue on improving the value recognition of diagnostic technologies by governments and payers through live case studies.



### Unlocking the Value of Quality Next-Generation Sequencing in APAC

Whilst the transformative powers and impact of Next-Generation Sequencing (NGS) is recognised, a multi-stakeholder perspective is needed on how we can standardize workflow optimisation, customisation, and data analysis to ensure quality and conformity. The Committee together with six member companies—Guardant Health, Illumina, Johnson & Johnson, Roche, Thermo Fisher Scientific and Vazyme—shared recommendations to ensure standardisations and quality NGS across the region through the paper “[Unlocking the Value of Quality Next-Generation Sequencing in APAC](#).”

### Remote Care Management in Asia Pacific

It is no secret that the COVID-19 pandemic, despite the many challenges faced, has accelerated the uptake of digitisation in the healthcare industry. The Digital Health committee published an op-ed on “[Remote Care Management in Asia Pacific](#)”, outlining three areas of focus for the region’s remote care management.

### Digital Health Webcast and Podcast Series: Doses of Healthcare

Since its creation in early 2020, the Committee has created extensive knowledge on crucial topics including regulatory approval and reimbursement of digital health technologies, cybersecurity and interoperability. Through the Digital Health webcast and podcast series, the Committee aims to provide theoretical and practical learning by sharing use cases and best practices. In 2022, the Committee has published two episodes of podcast: [Increasing Access of Digital Health Solution to Patients](#) and [Metaverse: The Healthcare of the Future?](#)

### Digital Health Policy Databases

The committee maintains a centralized database for digital health-related [regulatory](#), [cybersecurity](#) and [reimbursement](#) policies in APAC. Each database is updated in a quarterly basis, with the support of our working groups and centres of excellence.



## Events

### Digital Health Expert Summit at MedTech Forum 2022

More than 400 online and offline attendees joined the Digital Health Summit at the MedTech Forum 2022. In the span of three hours, 17 speakers shared their thoughts on five key topics:

- Health Data: Unlocking the Potential of Health Data
- Cybersecurity: Cyberstorm: MedTech's Response to Cyber Attack
- Regulatory/Reimbursement: The Korean Digital Health Reimbursement Strategy
- New Digital Health Publications
- Future-proofing Digital Health

### The Future of Patient Care Symposium 2022

The second instalment of Digital Health Symposium was held in June 2022 under the continued theme of Remote

Care Management (RCM). The [symposium](#) was attended by industry delegates from 17 countries, with a total of 210 online and offline attendees. The symposium sought to address a few key challenge statements:

- How can healthcare professionals and care providers work better, thanks to RCM?
- What is still not working for patients, despite the promises?
- What value does RCM deliver to the wider healthcare ecosystem and society?

[Highlights](#) of the event provided 3 key takeaways:

- Clinicians are a key enabler of RCM activation
- Patients (and caregivers) must have their RCM voices heard too
- RCM scalability is contingent on integration amongst wider society



### Advancing Real World Evidence in APAC – Paper Launch Webinar

Following the publication of the paper on [“Advancing Real World Evidence in APAC – Key Considerations for Policymakers,”](#) in March, the Committee hosted a webinar where our partner from Crowell & Moring International presented highlights of the paper, followed by a panel discussion between government and industry. The [webinar](#) resulted in some key discussion points related to the current and future state of RWE.

### Strengthening Healthcare Systems Through the Critical Role of Diagnostics – Paper Launch Webinar

Following the publication of the paper on [“Strengthening Healthcare Systems Through the Critical Role of Diagnostics,”](#) the Committee hosted a [webinar](#) in May. Representatives from the Lancet Commission and Committee members are invited to talk about the report as well as the next steps to strengthen the healthcare system through the critical role of diagnostics.

### Harnessing the Potential of Real-World Evidence for Policy Decision-Making

In collaboration with the Drug Information Association (DIA), the Committee held a conference with the theme of [“Harnessing the Potential of Real-World Evidence for Policy Decision-Making”](#). With a combined focus on both medical device and pharmaceuticals, the conference aimed to educate about RWE and how to advance the topic for evidence-driven healthcare outcomes, as well as regulatory and reimbursement decisions-making.

Key topics included:

- Overview of the RWE landscape in Asia Pacific
- Learnings from the EU and the US
- Roundtable with regulators and payers
- Presentations and panel with experts on the future of RWE

Regulators from the region were also invited to discuss on the use of RWE in regulatory decision-making in their respective countries: Japan, Australia and Taiwan.



# Regulatory Affairs Committee

Building capability to support implementation of globally harmonised regulatory frameworks.

## Core Leadership



**Miang Tanakasemsub**  
Chairperson  
Head of QA Commercial  
& Regulatory Affairs, APAC  
Cardinal Health



**Adelheid Schneider**  
Vice-Chairperson  
Regional Head for  
Regulatory & Quality  
Roche Diagnostics



**Jason Guo**  
Vice-Chairperson  
APAC Director, Regulatory Affairs,  
Quality & Compliance  
Abbott



**Marianne Yap**  
Vice-Chairperson  
Vice President, Quality, Regulatory &  
Government Affairs Asia Pacific, China & Japan  
Alcon



**Alex Budiman**  
Vice-Chairperson  
Vice President of  
Regulatory Affairs  
Becton Dickinson

## Country Centres of Excellence

### CHINA



**Echo Liu**  
Chairperson  
Regulatory Affairs  
Director, Baxter



**Crystal (Nie Jing)**  
Vice-Chairperson  
RA Director, APAC  
Johnson & Johnson



**Wang Ping**  
Vice-Chairperson  
Senior Regulatory Affairs  
Manager, Abbott



**Zhou Lipan**  
Secretary  
Roche

### ASEAN



**Sharad Shukla**  
Chairperson  
Head, Regulatory Affairs  
Johnson & Johnson MedTech



**Yenny Anggoro**  
Vice-Chairperson  
Director, RA & QA  
Stryker ASEAN



**Yu Hosokai**  
Vice-Chairperson  
Regulatory Affairs Manager - SEA  
Cook South East Asia



**Kenneth Cheong**  
Secretary  
RA & QA Manager  
Convatec

### INDIA



**Gaurav Verma**  
Chairperson  
Director, Regulatory &  
Government Affairs,  
Becton Dickinson



**Prashanth Prabhakar**  
Vice-Chairperson  
Head - Regulatory Affairs  
Boston Scientific India



**Jaya Sunil Lande**  
Vice-Chairperson  
Manager - Regulatory Affairs  
Abbott Healthcare



**Aaditya Vats**  
Vice-Chairperson  
Associate Director, Regulatory  
Affairs, Johnson & Johnson

### KOREA



**Leslie Kim**  
Chairperson  
RAQA Director  
Stryker East Asia



**Justin Yea**  
Vice-Chairperson  
Senior QRA Program Manager  
Medtronic



**Lena Kim**  
Secretary  
RA Director  
Cook Medical

## Working Groups

### IN-VITRO DIAGNOSTICS



**Yasha Huang**  
Chairperson  
Regional Regulatory  
Affairs & Policy Lead  
Roche Diagnostics  
Asia Pacific



**Jacqueline Monteiro**  
Vice-Chairperson  
Associate Director,  
Regulatory Affairs  
Abbott



**Qi Li**  
Vice-Chairperson  
Head of Quality &  
Regulatory Affairs,  
EAO  
Beckman Coulter



**Fadzlon Yunos**  
Secretary  
Senior Executive,  
Regulatory Affairs  
Beckton Dickinson

### REGULATORY INTELLIGENCE



**James Chan**  
Chairperson  
RA Director, APJI  
Varian Medical



**Shivkumar Hurdale**  
Vice-Chairperson  
Senior Director  
RA & QA, APAC  
Stryker Asia Pacific



**Jane Lin**  
Vice-Chairperson  
Head of ASPAC  
Regulatory Affairs  
Johnson & Johnson  
Medical



**Muhammad Sohail**  
Secretary  
Manager, RA &  
Pharmacovigilance QREM  
Fresenius Medical Care  
Pakistan

### CAPACITY BUILDING



**Yiting Cai**  
Chairperson  
Regional Regulatory Affairs  
Director  
Alcon Asia Pacific



**Kazuhiro Iwasaki**  
Vice-Chairperson  
Chief  
Terumo



**Chloe Tan**  
Secretary  
QA & RA Lead, Indochina &  
Frontier Market Plus  
Medtronic



The Regulatory Affairs (RA) Committee comprises of over 350 senior regulatory professionals from more than 50 corporate member companies, based across Asia Pacific. Much of the regulatory advocacy efforts coalesce around market-based Centres of Excellence (CoEs), covering: China, South Korea, ASEAN and India. Regional Working Groups (RWGs) are dedicated to: Regulatory Intelligence (RI), Capacity and Capability Building (CCB), and In-Vitro Diagnostics (IVD).

## Vision, Mission & Strategy

IMPROVE & EXPEDITE PATIENT ACCESS TO MEDICAL DEVICES



### REGULATORY INTELLIGENCE

#### REGULATORY AGILITY

Advocate for more effective alternative approval pathways for speed to market

#### REGULATORY CONVERGENCE

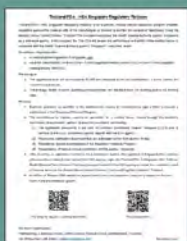
Promote regulatory convergence and harmonization across the region

#### REGULATORY CAPACITY BUILDING

Modernize and upskill RA capabilities for future ready leaders

## Strategic Initiatives

### Driving Regulatory Agility and Efficiency through Reliance



#### Expansion of Thai FDA & Singapore HSA Reliance Programme

In 2020 APACMed facilitated a regulatory reliance pilot between Thailand FDA and HSA Singapore which significantly shortens the duration of product registration. As an outcome of the pilot,

Singapore is now a reference country for pre-market regulations in Thailand for medical devices and IVDs. The programme was initially available for B, C, D classes of devices; however, through our continued advocacy and engagement with the concerned authorities, this year the programme was extended to all classes of devices effective June 2022.



#### Initiated MDA Malaysia & DRAP Pakistan Reliance Pilot

In August this year, we undertook a Mission to Malaysia with an aim to facilitate dialogue, seek consent, and drive alignment to formulate

a strategy for a proposed reliance pilot between MDA Malaysia and DRAP Pakistan for pre-market regulations. The outcome of the one-day workshop was positive, with both authorities agreeing to collaborate and to work on an action plan for the next six months in order to launch a pilot programme. The pilot programme includes formalising the partnership through an MoU between both authorities, followed by in-person training for DRAP officials in Malaysia.



#### White Paper on Regulatory Reliance

With an aim to provide an impartial view of the feasibility of adoption of regulatory reliance in ASEAN, we commissioned a white paper titled *'Evaluation of the Perception of Regional Regulatory Reliance and its Assessment for Medical Devices in ASEAN'* under the guidance of the WHO and GHWP. The paper studies some of the key ASEAN markets using advanced qualitative and quantitative research methods, and investigates the perception, inclination, and cooperative interests for regulatory reliance for medical devices across ASEAN. The analysis and recommendations in the report justify APACMed's vision to expedite the regulatory process across ASEAN, so that innovations in diagnosis and therapy, with robust collaborative protocols between manufacturers and regulators, can reach the market faster.

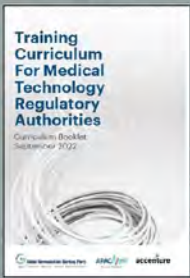




## Developing A Strong Regulatory Workforce Through Capacity & Capability Building

### E-Learning Hub

The RA Committee has developed significant content on competency frameworks, gap analysis and training curriculums over the years. As a progression, we wanted to see how we can also play the role of a training provider, thereby giving birth to the APACMed e-Learning Hub (ELH). The ELH was launched at the 2022 AGM and is our latest offering to corporate members. Currently the hub has 30 modules, covering different courses which are designed based on various stages of a product lifecycle from various regulatory functional domains such as Pre-Market, Regulatory Knowledge & Application, Regulatory Strategy, Quality & Compliance and Post Market.



### Regulators Curriculum White Paper

True to our mission of building and supporting a strong MedTech regulatory workforce, we collaborated with the Global Harmonization Working Party (GHWP) to develop the [‘Training Curriculum for MedTech Regulatory Authorities’](#). The objective was to come up with standardised and harmonised training curriculum cutting across different core competencies, with a primary focus of defining the future direction of regulatory trainings for all GHWP member jurisdictions in order to equip them to be able to stay ahead of the curve, especially during an evolving global regulatory landscape.

## Training Programmes For Regulators



### Singapore HSA - Thai FDA Workshop Series

We collaborated with the Health Sciences Authority (HSA) Singapore to jointly organise a five-day comprehensive training programme for Thai FDA officers, which took place in September 2022 in Singapore. The programme included topics such as understanding of Singapore’s medical device regulatory framework, overview of general as well as personalised medical devices, IVD & non IVD evaluations and Pandemic Special Access Route to name a few which helped advance the regulatory capabilities of Thai FDA.



### Training on EU MDR & IVDR for Indonesia MOH

In August 2022, we partnered with GAKESLAB (our partner local association in Indonesia) to jointly organised a full day workshop for Indonesian regulators on the new EU regulations. The purpose of the workshop was to manage changes and to ensure minimal market disruption with a smooth transition from the old directive. Senior leaders from APACMed delivered trainings on EU MDR and IVDR, which benefitted the regulators immensely.



### ASEAN Country Missions To Promote Convergence & Harmonisation

As part of our Regulators’ Outreach Programme to cement our relationship and advance our agenda with policy makers, the RA Committee mounted country missions to Malaysia, Vietnam and Philippines where a series of meetings were planned for the APACMed delegation with the respective country regulatory authority and other local stakeholders. The aim was to discuss and streamline on specific issues, explore opportunities for collaboration and position APACMed as their trusted industry partner.



**Vietnam Mission, Hanoi (Sept):** As part of our Regulators’ Outreach Programme to cement relationship with policy makers, APACMed along with Advamed paid a visit to Department of Medical Device & Construction (DMEC). The meeting was chaired by Director General, DMEC along with other senior DMEC officers. The purpose of this meeting was to formally introduce APACMed to the new leadership and to discuss some important tactical and strategic issues.



**Philippines Mission Manila (Dec):** Our mission to Philippines coincided with an invitation to participate and present at the 24th General Membership Meeting (GMM) of Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP). APACMed presented on emerging topics such as EU MDR/IVDR, Digital Health Regulations, and more. During our closed-door meeting with Engr. Cecille Matienzo, FDA-CDRRHR Director important issues such as such as EUMDR/IVDR, new IVD draft regulations, regulatory reliance, and capacity and capability building were discussed.



## Foster Platforms for Dialogue & Advocacy on Key Strategic Topics

### Regulatory Transformation Symposium

The Symposium in collaboration with the Global Harmonization Working Party (GHWP) was the Committee's flagship event for the year. Under the central theme 'Accelerating MedTech Innovations through Regulatory Agility & Harmonization', the Symposium witnessed eminent global organizations like IMDRF, GHWP, WHO, Academia and Industry who delved into topics around Regulatory Reliance and Capability Building. The delegates were also provided with latest updates from jurisdictions in and around the region including Singapore, Malaysia, Indonesia, Thailand, South Korea, Australia, Chinese Taipei, Saudi Arabia, Jordan, China, Pakistan, and the US.



### Regulatory Affairs Expert Summit at MedTech Forum 2022

This year the topics in focus were centered around post-pandemic regulatory frameworks for agile & expedited market pathways and how the regulatory system could better enable the adoption of innovative technologies for better patient outcomes. Regulatory authorities from the region including Australia, Singapore, South Korea, Thailand, Philippines, Malaysia and Indonesia along with leaders from industry and academia shared their perspectives and deliberated on the emerging opportunities for the post-pandemic healthcare world in Asia Pacific that is affordable as well as accessible to all.

## Advocacy

### Halal Policy, Indonesia

In 2014, the Indonesian government introduced a law that required medical devices to fall under the purview of halal labelling mandates. Since APACMed's inception in 2014, we garnered feedback from MedTech companies to confirm that halal certifications would gather strong momentum, considering Indonesia is home to world's largest Islamic population. We are thankful to those companies who attempted to execute this study on halal implications. Even though it was beyond their scope to publish conclusive insights publicly, member feedback allowed us to advocate through an enhanced research methodology. This, combined with cooperation from the Indonesian halal taskforce, has enabled APACMed to publish what may be considered as, the first industry-wide attempt to deliver a position on the implications of halal certifications in Indonesia through a strategic position paper. Our paper provides thorough insights on the challenges faced by the industry as well as comprehensive recommendations, based on contemporary analysis, by soliciting feedback with a holistic perspective.

## Regulatory Intelligence



### Regulatory Intelligence Bulletin

The new Regulatory Intelligence Bulletin now provides are members with up-to-date regulatory briefs and actionable insights which can contribute to key regulatory decision-making processes across Asia Pacific. The Bulletin now provides more advanced intelligence in the form of thought leadership editorials, regional regulatory trends and analysis, expert interviews with regulators, KOLs and other subject matter experts.

# Legal, Ethics & Compliance Committee

Supporting APACMed's objective to raise ethics and compliance standards in the MedTech industry.

## Core Leadership



**Ana Garcia Bello**  
Chairperson

Vice President, Law,  
MedTech Asia Pacific  
Johnson & Johnson



**Campbell Clark**  
Vice-Chairperson

Vice President  
Legal & Compliance, Asia Pacific  
Medtronic



**JyeMei Wong**  
Vice-Chairperson

Regional Senior Legal &  
Compliance Counsel, Asia Pacific  
Boston Scientific



**Christian Fitsch**  
Vice-Chairperson

VP, Chief Legal Counsel, Asia Pacific  
Stryker

Comprising of 100+ individual members from 30+ companies, the Legal, Ethics & Compliance (LEC) Committee works to raise standards of doing business across the Asia Pacific region, including the facilitation of ethical interactions between industry and healthcare professionals, as well as industry adherence to APACMed's Code of Ethical Conduct.

## Strategic Initiatives

### Support the modernization of the Kuala Lumpur Principles

In 2010 SME Ministers issued a joint statement which called for "facilitating open and transparent business environments free from the high costs of corruption by the development of APEC codes of business ethics in sectors of export interest to APEC economies, beginning with the medical device sector." Following this, an Expert Working Group convened in Kuala Lumpur to develop a set of APEC Principles for Codes of Business Ethics to Ensure Ethical Interactions Between Medical Technology Companies, drawing upon existing best practices and voluntary codes of business ethics in APEC economies.

The Business Ethics for APEC SMEs Initiative is the world's largest public-private partnership to strengthen ethical business conduct and drive a level playing field in our sector.

APACMed served as part of the expert group to review and modernize the [APAC Kuala Lumpur Principles](#).

## Knowledge Sharing Sessions

This year, the LEC Committee hosted a number of closed-door discussions and webinars with expert knowledge partners in order to provide members with relevant insights into critical compliance related matters.

### Opportunities and Challenges in the Procurement of Renewable Energy in South East Asia

"APAC is home to 60% of the world's population and accounts for half of the global carbon emissions. Growing demand for renewable energy, due to ESG targets and conscious consumerism, is forcing companies to change business models. However, on-site power generation is not feasible to provide sufficient electricity to achieve 100% renewable energy targets. [This webinar](#) showcased how to switch to renewable energy and comply with local regulations.



### Data Protection in Healthcare – Are you Ready?

It is no secret that digitisation in the healthcare space has caused the uploading, storage, and transfer of personal data to surge at unprecedented rates. Aside from the remote delivery of healthcare services via teleconsultations, e-pharmacies or healthcare wearables, companies are capitalising on new technological developments and formulating new ways to monetise personal data. Developers of online healthcare platforms may allow users to sell their anonymised data to earn virtual currencies or carry out transactions. Patient datasets may constitute helpful aids for machine learning.

These opportunities however, do not come without risk. The personal data held by healthcare organisations make them lucrative targets for cyber threat actors. During [the webinar](#), the Baker McKenzie team discussed some of the key data protection issues and complexities that healthcare companies may face.

### Sanctions & Trade Compliance

In today's globalized economy, companies must be able to ensure that their cross-border activities comply with government sanctions programmes as well as internal policies and procedures. During the session, Eric Carlson from Covington & Burling, presented some trade compliance issues, including new developments in economic sanctions and export controls, and helping to issue-spot on key risks areas to know when to consult specialists.

### Social Media Marketing - #Risks&Pitfalls

In today's digitally driven world, social media has radically changed how we communicate and consume information. It also offers medical device companies powerful ways to engage with customers, patients and the healthcare community. Focusing on Asia Pacific during [the event](#), our speakers Ren Jun Lim and Elisabeth White, Principals at Baker McKenzie, discussed thematic risks and pitfalls when marketing medical devices on social media. They also examined best practices, no-go areas and enforcement trends.

### The Lawyer & Compliance Professional of the Future: Are You Ready?

In-house legal and compliance departments have evolved over the years and there is no end in sight. From globalisation and supply chain complexity, the use of new technologies, the emergence of more flexible start-ups, economic turmoil, antitrust, ESG, and corporate governance compliance enforcement; Olivia Seet from MLA [presented some of the key LEC trends](#) in-house teams see globally. She also gave advice to compliance officers so they can keep adding value to their companies.



# Start-up & SME Committee

APACMed's shared goal continues to be the acceleration of innovation and success for the members, building on this ecosystem, expanding potential collaborations amongst large and small companies, as well as broader public sector agencies and like-minded organisations.

## Core Leadership



**Alan Goh**  
Chairperson  
Co-Founder & CEO  
NDR Medical Technology



**Arun Sethuraman**  
Vice-Chairperson  
Founder & CEO  
Crely Healthcare



**Simranjit Singh**  
Vice-Chairperson  
CEO  
Guardant Health AMEA

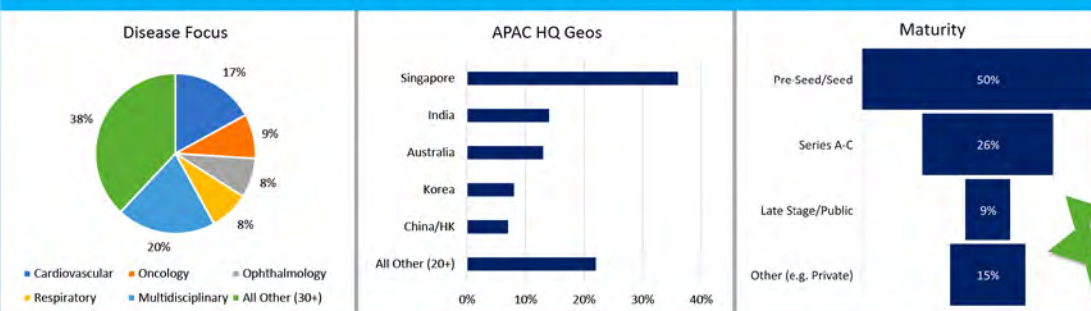


**Aileen Lai**  
Vice-Chairperson  
CEO  
Healthbeats

APACMed welcomed 53 new start-up members in 2022, taking the total to 163 companies spanning across a range of solution types, disease themes, and geographies. Below is a snapshot of the start-up companies, using proprietary analysis about APACMed members:

## APACMed Start-up member portfolio snapshot

APACMed start-up members cover the gamut of medical devices, digital health, and enabling services:



While clinical innovation is a common trend, there remain challenges in partnerships and financing for growth.

In 2022, we focused on providing start-ups with access to corporates, investors, accelerators, and health systems. A couple of highlights of which included:

- We continued our partnership with MedTech Innovator for the Asia Pacific Accelerator programme, which aligns with our mission to help shape the future of healthcare in the region. Selected from a pool of more than 250 applicants, APACMed member NousQ was the grand prize winner and awarded USD 175,000 non-dilutive funding to advance its business goals and mission. NousQ moreover won Enterprise Singapore's Start-up SG award of SGD 30,000 as well as the Cambridge Consultants Product Prize worth USD 25,000. Other

APACMed start-up members that emerged among the top finalists included Alimetry, SharpArrow, and Waycen.

- We supported the Singapore Centre for Healthcare Innovation (CHI) on its Healthcare InnoMatch challenge. The theme for 2022 was "Delivering Care Beyond Hospital Walls", with the aim to strengthen the focus on providing better care in the community and to raise awareness of preventive health and early intervention. Six innovations were selected as winners, including APACMed start-up member FathomX. The company will now go on to collaborate with National University Health System to test-bed their solutions for possible adoption in the wider ecosystem.



### Investor Day at MedTech Forum 2022

In addition to the above, we held our inaugural Investor Day at the MedTech Forum, with the ambition being to bring together start-up companies, corporates, and investors, to exchange on key content topics and collaboration opportunities. INSEAD Professor of Entrepreneurship Claudia Zeisberger and Bain & Company convened institutional and corporate investors to share more about their priorities, and also trained selected APACMed start-up members NousQ, HealthBeats, and Lifespans to demonstrate the “perfect pitch”. Start-up members rated Investor Day a 5/5 for its value, and we look forward to continuing more of these collaboration forums into the future.



In 2023, we are aiming to deliver several key activities. For start-up members, educational content on burning themes such as protecting IP, navigating regulatory pathways, attracting funding and investment, and improving commercialisation. For corporates, running corporate venturing bootcamps to boost the capacity and capability of business development teams in Asia Pacific. And lastly, to bring these activities together through event programming and regular updates about portfolio intelligence.

### Why a MedTech Startup Community?

- Enable innovation within the MedTech industry
- Accelerate the growth of start-ups transforming the healthcare system
- Champion founders and start-ups

### What's our Value Proposition?

- Unique focus on MedTech, bring together resources and expertise
- Ecosystem with leading corporates, investors, institutions, and agencies
- High touch support for partnerships, expansion, and pilot collaboration

# Country Insights:

## APACMed in ASEAN, Japan, Korea and ANZ

Partnering local trade associations to strengthen our voice in policy shaping to advance medical technologies in countries.

We continue to strengthen relationships built with local trade associations by collaborating with Japan, Korea and ANZ, and leading and supporting in ASEAN. We advocate for policy shaping with local governments by leveraging APACMed position papers and by building competencies in countries to advance MedTech solutions for patients and societies in the region.

### Our Partners

Our local and global partners are critical in our quest to advocate collectively in various strategic areas to local governments, shaping policies that will benefit patients, members and the overall healthcare industry. Besides coming together as a concerted voice, APACMed supports partners with knowledge creation through position papers and strive for capability building to upskill and reskill industry and regulators. Our partners in the region and globally include:

#### Japan

American Medical Devices and Diagnostics Manufacturers' Association (AMDD) and Japan Federation of Medical Devices Associations (JFMDA)

#### South Korea

Korea Medical Devices Industry Association (KMDIA)

#### Australia

Medical Technology Association of Australia (MTAA)

#### New Zealand

Medical Technology Association of New Zealand (MTANZ)

#### Singapore

Medical Technology Industry Group of Singapore Manufacturers' Federation (SMF) and Association of Medical Device Industry (AMDI)

#### Malaysia

Association of Malaysian Medical Industries (AMMI) and Malaysia Medical Device Association (MMDA)

#### Thailand

Thai Medical Device Technology Industry Association (ThaiMed)

#### Vietnam

European Chamber of Commerce in Vietnam (EuroCham VN)

#### Indonesia

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

#### Philippines

Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP)

#### Myanmar

Myanmar Pharmaceutical and Medical Equipment Entrepreneurs' Association (MPMEEA)

#### US-ASEAN Business Council

#### EU-ASEAN Business Council

#### American and European Chambers of Commerce

#### Europe MedTech Europe

#### United States AdvaMed

### Local Trade Association Partners



### Other Regional & Global Association Partners





## Key Collaborations with Partners

### Regulatory Affairs

#### Regulatory Reliance

Reliance as demonstrated by the successful pilot case between Singapore as a reference market for Thailand is a solid programme to expedite prompt access to safe, effective and quality medical technologies to those in need especially in developing countries. The programme also reduces time and cost to market for regulators particularly in a landscape of growing complexity of medical devices and technologies for regulatory authorities to assess.

In 2022, the successful reliance case between Singapore and Thailand was leveraged at events like the Regulatory Transformation Symposium and Regulatory Affairs Summit as a best practise and benchmark to seed interest to the rest of the ASEAN regulators. After these events, delegations followed up with visits to regulators in Malaysia, Vietnam and Philippines to kickstart discussions on the extension of the programme. These discussions will continue into 2023 to onboard more countries to the programme.

The team is also planning for Australia and Japan to be added as references for ASEAN countries.

#### Regulatory Capacity Building

Capability and capacity building is a strategic pillar of APACMed's work for the industry in this region. We continuously bring knowledge building to our partners and regulators for upskilling and reskilling in order to remain relevant in an ever-changing healthcare regulatory landscape.

The Regulatory Affairs Committee therefore launched APACMed's e-Learning Hub in 2022 as a 24/7 accessible portal for capability building for the industry, featuring 25 modules across the product life-cycle.

A skills matrix with Accenture was also developed to be used by the industry and governments for gaps and needs analysis. Customised regulator trainings were moreover conducted in the year for:

1. Ministry of Health Indonesia in collaboration with Gakeslab on topics such as Unique Device Identification, Regulations for Software and Artificial Intelligence, Robotics, Regulatory Agility in the Post Pandemic World and Digitization for Clinical Decision Support
2. Korean industry and MFDS in collaboration with KMDIA on the transition of EU MDR and EU IVDR

Similar workshops of such will be intensified in 2023 by APACMed based on the needs of the members and markets as economies reopen.



EU MDR & IVDR Transition Training

### Digital Health

#### Digital Health Regulation and Reimbursement

The COVID-19 pandemic has shown us the critical role of digital health and new healthcare models compared to traditional settings, as part of the new normal.

In 2022, we drove engagement of the "Digital Health Regulation Overview & Best Practices" and "Digital Health Technologies Policy Pathways for Value Assessment and Reimbursement" position papers. Engagement was achieved by hosting of sharing and discussion sessions (webinar and closed-door roundtables) conducted for each key market (ASEAN, Japan, Korea and Australia). Industry and regulators exchanged together, and the sessions were held in local languages so as to maximise participation.

Building on these sessions, in 2023 we will continue to advocate in Korea and Japan with roundtables to develop fit-for-purpose regulatory and reimbursement frameworks for Digital Health solutions.

Meanwhile, Singapore HSA is the first country to implement our recommendations into their regulations. Singapore and Australia will be leveraged as benchmarks and countries for learning in the region.

Proposed Value Assessment Framework for DHTs

- Safety and Clinical Effectiveness**: The number of cases and complications caused in real-world use.
- Economic Impact**: An index of cost-effectiveness comparing the DHTs with the traditional products to be replaced.
- Patient and Social Aspects**: The social aspects (patients) should be measured by quality of life, accessibility, and the quality of care.
- Organizational Aspects**: Health system readiness to support the adoption of DHTs by medical staff and training of staff.
- Usability**: Usability (patients) should be measured by patient satisfaction.
- Technical Aspects**: The technical aspects (patients) should be measured by patient satisfaction.
- Interoperability**: Compatibility of DHTs to other data sources to achieve an integrated health system through data exchange.
- Data Security**: The level of protection and privacy data security measures should be assessed.

Digital Health closed-door meeting with Australia

#### Advancing Real World Evidence in Asia Pacific

In Q2 2022, the APACMed position paper on Advancing Real World Evidence in APAC – Key Considerations for Policymakers was launched to advocate for policy reforms that leverage the use of Real-World Evidence (RWE) in regulatory and reimbursement decision-making.

Public and private stakeholders from across the region came together to present and discuss about where the utilisation of RWE is emerging while also highlighting the challenges and global best practices. The discussion concluded by outlining key considerations for evidence-driven healthcare outcomes.

That discussion was then followed by a conference on Harnessing the Potential of RWE for Policy Decision-Making, held in collaboration with Drug Information Association (DIA) involving regulators from Taiwan, US, Japan and Australia who presented on the following topics:

- Overview of the RWE Landscape in APAC
- Learnings from EU and the US
- Round Table with Regulators
- Panel Discussions with Experts on the Future of RWE

In 2023, roundtable discussions will be organized to engage and advocate to regulators on the use of RWE in policy decision-making.





## Country Insights: APACMed in ASEAN, Japan, Korea and ANZ

### Government Affairs & Market Access (GAMA)

#### Adoption of Self testing Regulation in COVID-19 Management

Leveraging on the Role of Diagnostics in COVID-19 Management position paper, when the Indonesia Ministry of Health was seeking inputs for rapid self-testing for COVID-19 management as their economy started to reopen in first half of 2022, APACMed was there to support with expert speakers bringing the best practices from across the region and globe. Recommendations from APACMed position paper were provided to the stakeholders at a focus group discussion held jointly with Gakeslab and IAKMI in March. This resulted with the issuance of an official set of technical guidelines for self-testing by the Indonesian Association of Clinical Pathology Specialists.

#### Value Based Healthcare

Thought leadership on Value-Based Healthcare (VBHC) in MedTech was a focus theme for the region in 2022, where in a June a symposium was held to discuss the meaning of real value, and how we can synergise VBHC to be achieved in a practical and efficient manner by bringing together experts to share their opinions and opportunities for industry collaborations. This was further boosted with capability building efforts through a series of peer-to-peer best practice sharing workshops in specific markets of China, Korea, Australia and Philippines. Efforts will continue in 2023 to repurpose the content for in-country advocacy and local engagement, as well as in emerging markets looking to adopt constructive value-based practices.



#### Indonesia

**Halal Presidential Decree Action:** Joint Letter with AdvaMed to Ministry of Religious Affairs

**Local Content Calculation Methodology Action:** On ground advocacy with Indo officials

**Review of Import Substitution in e-Katalog Action:** Policy briefing to members; seek clarifications with officials on timeline



#### Singapore

**MedTech Subsidy List (MTSL) Action:** Led inaugural Industry Townhall with ACE on policy announcement

#### Advocacy on Live Issues in the Region

The GAMA Committee collaborated with local, regional and global partners to support countries throughout the year on multiple live issues on the ground. Advocacy for reforms ranged from Halal regulations, local content calculation methodology, import substitution in e-katalog, pricing relief due to inflationary measures, medical devices subsidy listings, and reimbursement price cuts for medical devices to the prostheses list. Most live issues are continuously being monitored for further advocacy support to ensure sustainable and seamless access of innovations in the markets.



#### Korea

**Request for Pricing Relief / Pass-through of inflation costs** Sharing and alignment with other at-risk markets



#### Thailand

**UC Reimbursement Price Cuts for Cardio and Ortho devices** Letter to NHSO



#### Philippines

**Establishing Essential Medical Device List (PEMDL)** Working meeting with HITAP & PAMDRAP



#### Australia

**Prostheses List** Industry briefing from MTA

### Legal, Ethics and Compliance (LEC)

#### Strengthening Ethical Business Practices for the Medical Device Sector Across APAC By Modernising the Kuala Lumpur Principles

Adopted in 2011, the APEC Kuala Lumpur Principles serve as the world's only voluntary guidance, recognised by government and multi-stakeholders, for ethical business conduct in the medical device sector. Over the past decade, a significant majority of the region's medical device industry bodies have adopted these Principles into Codes of Ethics that extend to over 10,000 enterprises. The Principles also serve as a key reference for eight consensus framework agreements for ethical collaboration, that bring together more than 200 peak health organizations representing thousands of companies, hundreds of thousands of healthcare professionals, and millions of patients. For the first time, the Principles underwent a modernisation process to ensure they reflect the latest high standards while embracing the expanded role of industry and non-industry stakeholders alike.

The LEC Committee held a workshop for the regional industry and trade association members on the Kuala Lumpur Principles, followed thereafter with consultations with local partner associations on the changes required to harmonise Codes of Conduct.



# Country Insights: APACMed in India

Partner and work closely with local stakeholders in order to help strengthen systems, build capabilities, and drive access and affordability by leveraging a regional presence that fosters harmonisation, convergence, and best practices promotion from the region.



## Core Leadership



**Meenakshi Nevatia**  
Chairperson  
Managing Director, India  
Stryker India



**Narendra Varde**  
Vice-Chairperson  
Managing Director, India & Neighbouring Markets  
Roche Diagnostics India



**Madan Rohini Krishnan**  
ExCo Member  
Vice President  
India Subcontinent  
Medtronic



**Tushar Sharma**  
ExCo Member  
Managing Director & GM,  
India & South Asia  
Abbott



**Vivek Kanade**  
ExCo Member  
Managing Director  
Siemens Healthineers  
India



**Rishubh Gupta**  
ExCo Member  
Commercial Director  
Baxter



**Manoj Madhavan**  
ExCo Member  
Managing Director  
Boston Scientific India



**Sandeep Makkar**  
ExCo Member  
Managing Director  
Johnson & Johnson  
Medical India



**Shishir Agarwal**  
ExCo Member  
Managing Director  
Terumo India



**Mandeep Singh Kumar**  
ExCo Member  
Vice President & Country  
General Manager  
Intuitive India

True to our strategy of 'partnering' in India, in the last two years since setting up our office, we have been working closely with local trade associations (NATHEALTH, CII, FICCI, MTAI, ADVAMED), Government of India, Key Opinion Leaders (KOLs), and more to help strengthen systems, build capabilities, drive access and affordability, and leverage our regional presence to promote best practices of the region.

In this short journey so far, noteworthy progress has been made in creating visibility and awareness amongst key government departments through thought leadership initiatives. APACMed is now regularly invited to various industry consultations and government committee's such as the Steering Committee of the National Medical Devices Promotion Council (NMDPC), Standards Committee of Bureau of Indian Standards (BIS) as well as industry meetings organized by Department of Pharmaceuticals, Department of Health Research, National Health Systems Resource Centre (NHSRC) and Central Drugs Standard Control Organisation (CDSCO).

**In India our focus is on driving the 'Growth Agenda', and in 2022, our work revolved around five Strategic Pillars (ABCDE):**

**A - Accelerating Digital Health**

**D - Driving Market Access**

**B - Building the Regulatory Framework**

**E - Enhancing Value of the Industry**

**C - Capacity & Knowledge Expansion**



## Key Projects

### Government Affairs & Market Access (GAMA)

#### Transforming Healthcare Through Innovation - Our Impact in India



To showcase the journey of APACMed members and their contribution to the economy and overall healthcare system in India, the India GAMA team developed a publication highlighting our members journey, their impact and overall footprint in the country. The objective is to help create better appreciation and recognition of the role played by the MedTech industry. Some of the key indicators captured to demonstrate the desired impact include Public Health, Economic Development, Skill, and Infrastructure, Social and Environmental and Research & Development. The paper will be launched in Q2 2023.

#### White paper on Make in India



The India GAMA team in collaboration with Invest India and under the guidance of Department of Pharmaceuticals, Government of India developed a white paper titled 'Enabling Growth and Innovation in the Indian MedTech Sector'. The white paper was launched by the Hon'ble Minister for Health & Family Welfare & Chemicals & Fertilizers, Government of India at the inaugural session of 'India Pharma & Medical Devices 2022' – the Department of Pharmaceuticals' annual flagship event for the sectors. The white paper reviewed the current landscape and shared recommendations as well as a roadmap to support the government in realising the goals of Make in India for MedTech industry and to cultivate India as a global hub for innovation and manufacturing in the coming years.

#### Position Paper on Reimbursement Framework for Medical Devices in India



In 2022, the GAMA India CoE decided to broaden the scope of the HTA taskforce to work on suggesting a policy framework for reimbursement of medical devices. A study was launched with an objective to review the current framework, identify gaps and opportunities, highlight few regional reimbursement examples and propose pathways for reimbursement of medical devices in India.

#### White paper on Value Based Procurement (VBP) in India



To promote the principles and awareness of VBP, and to understand the current procurement models (their advantages and disadvantages), APACMed in partnership with NATHEALTH, pioneered the white paper "Value Based Procurement in MedTech - Building Blocks for Enabling Implementation in India." The white paper was launched at the NATHEALTH Annual Conference by the Secretary of the Department of Pharmaceuticals (GoI) which was followed by a presentation on the whitepaper and panel discussion with policy makers, providers and the MedTech industry on the way forward for India.



Digital Health (DH)

Digital Health India Knowledge Series

As part of the capacity building initiative under the DH India CoE, we launched the 'Digital Health India Knowledge Series', to increase members knowledge, understanding of the digital health landscape in India and to assess and leverage the implications of changing digital health reforms for the MedTech Industry, in terms of opportunities and mitigating potential risks. Quarterly sessions were organised on topics around Ayushman Bharat Digital Mission (ABDM) as well as on Draft Digital Personal Data Protection Bill, 2022

**Digital Health Knowledge Series**  
 Demystifying Ayushman Bharat Digital Mission (ABDM) for the MedTech Industry  
 Thursday, 23 June 2022  
 3pm (IST), Webinar

**Speakers**

- Nachiketa Dash**  
Sr Consultant, IQVIA
- Shweta Bhardwaj**  
Global Sustainable Health Systems Policy, IIS, Chair, Digital Health India CoE, APACMed

**APACMed India**  
 Digital Health Knowledge Series on Ayushman Bharat Digital Mission (ABDM)  
 Session 2: Identifying the Opportunities and Understanding the Role of the MedTech Industry within the ABDM  
 Thursday, 22 September 2022  
 3pm - 4pm (IST)

**Panelists:**

- Dr. Anshul Chaudhary**  
Senior Consultant, IQVIA  
Health Informatics Expert and Product Manager, ABDM
- Shweta Bhardwaj**  
Director, Global Digital and R&D Policy, Johnson & Johnson  
Chairperson, DH India CoE, APACMed
- Seema Arora**  
Business Head of Consumer & Digital, South Asia, Medtronic Pvt Ltd  
Vice-Chair, DH India CoE, APACMed
- Manoj Grover**  
Lead of Health Economics, Policy & Reimbursement, Medtronic India

**APACMED INDIA**  
 DIGITAL HEALTH KNOWLEDGE SERIES  
 Digital Personal Data Protection Bill 2022  
 Wednesday, 14 December 2022  
 3pm IST

**SUPRATIM CHAKRABORTY**  
 Partner, Khaitan & Co.

Position Paper on Policy Pathways for Value Assessment & Reimbursement of Digital Health Technologies in India



The India CoE developed an India specific position paper on DH Reimbursement. The paper assesses existing frameworks for DH Reimbursement in the country, highlights key challenges and makes recommendations to help provide greater access to and adoption of Digital Health solutions in India. The paper also highlights few key learnings from the region with regards to DH reimbursement.



## Regulatory Affairs (RA)

### Position Paper on Development of Product Standards for Medical Devices by Bureau of Indian Standards (BIS) – An Industry Perspective



The role of standards for regulatory purpose has always been a matter of debate and discussion, given the rapid innovation and uniqueness of the medical device industry. The India RA CoE in collaboration with ADVAMED developed a position paper on 'Development of Product Standards for Medical Devices by BIS – An Industry Perspective' with an objective to take the dialogue away from standards and towards conformity with essential principles. The position paper was followed by a physical roundtable with the senior officials from BIS, along with industry, to present the key findings and recommendations from the paper and to debate on the issues.

### FAQs: Medical Equipment Regulations in India



The RA India CoE worked on the development of an FAQs document for 'Medical Equipment Regulations' to help encapsulate some of the common queries along with suggested responses, with regards to the issues revolving around Medical Equipment Regulations.

### Position Paper on Pathway for Harmonising the Medical Devices Registration Process in Sri Lanka



The RA India CoE published a position paper with the objective to highlight the key issue of lengthy approval timelines for medical devices and IVDs in Sri Lanka and to suggest suitable recommendations to streamline the process. The paper was submitted to senior officials within the Ministry of Health, Sri Lanka and the National Medicines Regulatory Authority (NMRA) through an in-person meeting in August 2022 in Colombo.

### Advocacy on Live Issues in India

While maintaining its focus on the "Growth Agenda", APACMed India has continuously been involved in discussions with policymakers regarding live issues that are affecting the industry. Some of the key topics that were taken up during the year included:

- Issues around Medical Equipment Registrations
- Request for Exemption - "Residual Shelf-Life Requirements" at the Time of Import
- Industry concerns related to BIS/MeitY Registration Requirement for Service/Spare Parts/Consumables and Accessories
- Approval of Product with Shelf Life More Than 60 Months
- NHA's Consultation Paper "Provider Payments and Price Setting Under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana Scheme (PM-JAY) in India"
- NHA's Consultation Paper "From Volume Based to Value Based Care"
- BIS Draft Standards National Action Plan (SNAP) 2022



# Country Insights: APACMed in China

Envisions to continue to present the unique values of the MedTech industry in one of Asia's most important markets, and to share the voice from the industry to improve patient access to medical technologies and solutions.



## Core Leadership

### Regulatory Affairs



**Echo Liu**  
Chairperson  
Regulatory Affairs  
Director  
Baxter



**Crystal Jing Nie**  
Vice-Chairperson  
Director, Regulatory Affairs  
and Regulatory Compliance  
Microvention China



**Wang Ping**  
Vice-Chairperson  
Senior Regulatory Affairs  
Manager  
Resmed China

### Digital Health



**Varun Veigas**  
Chairperson  
Leader, Policy &  
Strategic Partnerships  
Roche Diagnostics



**Tony Liu**  
Vice-Chairperson  
GM  
Resmed China



**Manan Hathi**  
Vice-Chairperson  
Sr. Manager, Regulatory  
Affairs, Software  
Stryker Corporation



**Qiang Shi**  
Vice-Chairperson  
Head, Health Economics &  
Market Access Team (HEMA)  
Johnson & Johnson  
MedTech China

### Government Affairs & Market Access



**Anita Song**  
Chairperson  
Director, Health Economics, Policy and Reimbursement  
Medtronic Greater China



**Ning Yue**  
Vice-Chairperson  
Strategic Access Director  
BD China



**Jenny Jin**  
Vice-Chairperson  
Senior Director, GA & QREM  
Fresenius Medical Care China

In 2022, APACMed continued its exciting journey in China. After less than two years of operation, APACMed in China has built a vibrant member community, engaged key government bodies and influential Key Opinion Leaders (KOLs), and established the vision to bring MedTech innovation to China via sharing best regional practices. A milestone achieved in 2022 was that APACMed was officially registered as a foreign Non-Governmental Organisation in China under the Beijing Science and Technology Commission, laying the foundation for an even more fruitful year in 2023.

## Key Projects

### Government Affairs & Market Access (GAMA)

#### Value Assessment of Innovative Medical Technologies in the Context of DRG

The GAMA China CoE developed a landmark report on the value assessment framework of innovative medical technologies in the context of DRG reform. The objective of the report is to help identify key challenges facing innovative medical technologies in the ongoing DRG reform of China and to advocate for increased access to innovative medical technologies. The report analyses the current challenges based on multiple methodologies, including through an expert dialogue held in June 2022 to provide a multi-stakeholder perspective, a survey among healthcare providers and KOLs, and use cases from industry. The China GAMA CoE will continue to engage with key policymakers, KOLs, and healthcare providers in China in order to work towards ensuring patient benefits.

#### DRG Expert Policy Dialogue



#### DRG Position Paper





### Out-of-hospital Care Services in China

Noticing the urgent need to develop out-of-hospital care in China, the GAMA China CoE worked with our influential partner Tsinghua University on the out-of-hospital project in 2022. In August, we organised an expert dialogue with 150 attendees from esteemed academia, healthcare providers, and industry leaders to share global and regional learnings, recommend solutions, and strategic approaches for China. We also developed a position paper on Medtech-delivered services beyond hospitals.

We released our first China report on out-of-hospital care in both Mandarin version and English summary, aiming to provide solutions for China's health services sector and health reform:



China expert dialogue on out-of-hospital care in August 2022

### Regulatory Affairs (RA)

In 2022, APACMed activated the RA community by setting up four Working Groups, namely Regulatory Harmonisation, IVD, Digital Health and Mandatory Standards. Our highlights are listed as follows:

#### Digital Health (DH) Regulatory



The China DH Regulatory Working Group focused on shaping Software as a Medical Device classification policies. In February, we organised a sharing session on DH Regulatory with the Hainan Health Bureau.

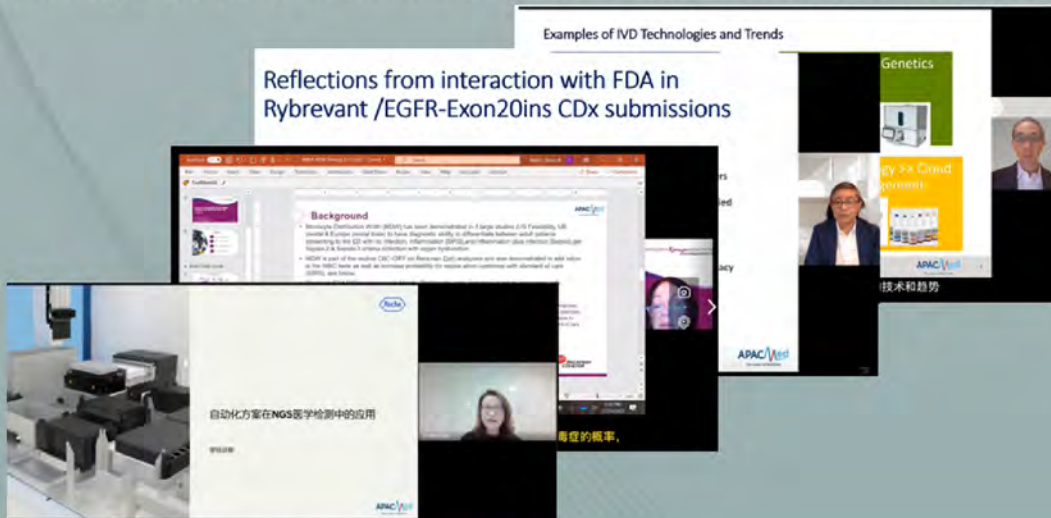


We also organised a closed-door meeting with CCCMHPIE for NMPA to share regional practices on SaMD classification. The initiative resulted in a position paper on Policy Recommendations on SaMD based on IMDRF Guidelines (China). The paper was submitted to the NMPA to recommend DH Regulatory guidelines for NMPA.



### Tailor-made IVD Capacity Building course for CMDE with Tsinghua University

As part of the capacity building initiative under the DH China CoE, APACMed launched an IVD training course for Center for Medical Device Evaluation, with the objective of leveraging regional APACMed position papers for knowledge sharing and to shape the IVD regulatory pathway. The project was developed in partnership with Tsinghua University, the appointed partner of CMED for regulatory capacity over the next three years. The APACMed CoE will continue to engage with Tsinghua University to demonstrate APACMed's strengths from regional and country level best practices.



### Digital Health (DH)

#### Digital Health Reimbursement

The position paper 'Policy Paper for Digital Health Value Assessment and Reimbursement' was published with the objective to highlight the value assessment and reimbursement policy pathways of digital health solutions in the Asia Pacific, its use in the social-economic reform context, to provide an evidence-based value assessment and to offer best practices from region to country. By engaging Chinese local stakeholders, the DH China CoE aimed to discuss the framework of DH Reimbursement policies in China. [The paper in Mandarin was released on CIFTIS in September.](#)







# MEDTECH FORUM ASIA PACIFIC 2022

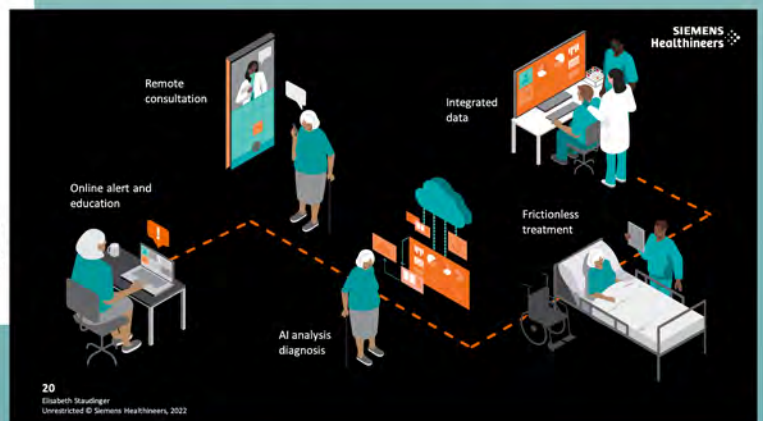
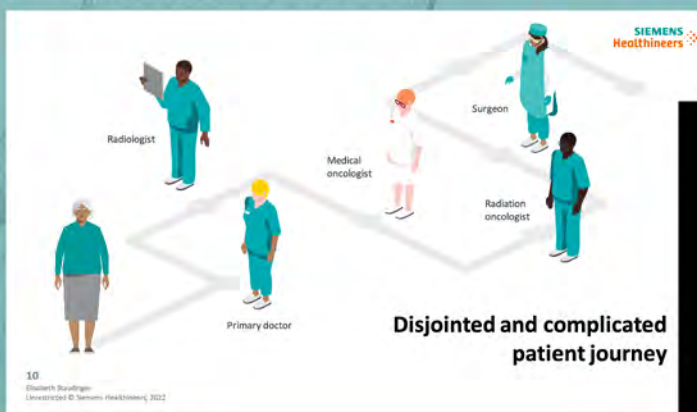
## PATIENT FUTURES 2025

The notion of “Health Futures 2025” was introduced at the APACMed MedTech Forum 2021 (during the height of the pandemic), and we continued with this vision in 2022 to check our progress, albeit with a more explicit focus on the role of the patient. While Asia Pacific represents some 60% of the world’s population, there are more than 1.6 billion people in the region who lack access to even the most basic healthcare, many of whom have fallen further into poverty as a result of the pandemic.



Moreover, patient activation is seen as a critical enabler, having been shown to improve outcomes and to lower the cost of healthcare by as much as 30%. The often-mentioned “patient-centred care” must recognise the reality that disease management is a job for the patients too, in terms of following up on referrals, complying with treatment regimens and collecting reimbursement. It is estimated that patients with chronic illness, for example, spend as much as two hours per day managing their condition! Studies show that for patients to feel motivated to be active, critical ingredients include trust, open communication and an operationally effective environment. Yet, in Asia Pacific, healthcare literacy in some countries is as low as 20%.

There is opportunity for the MedTech industry to do more, including by collaborating together and with other stakeholders to help manage and measure patients throughout the continuum across care settings (including virtually and at home), while also recognising that the promises of technology (hardware and software alike) must increasingly be tailored toward the unique needs of different patient personas. The MedTech industry is therefore critical for broader smart nation objectives that drive economic and population productivity. Such as in Singapore, where MedTech contributes to 9,000 jobs with an output valued at SGD 15 billion.



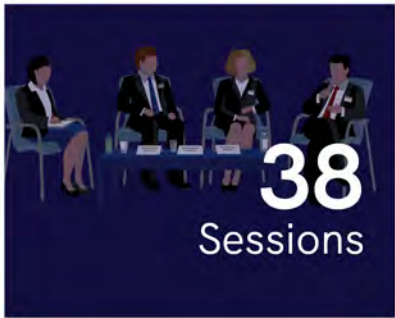
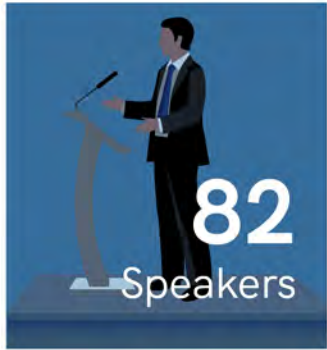


### Forum at a Glance

The [Asia Pacific MedTech Forum 2022](#), along the theme of “Patient Futures 2025” was strategically designed around two major segments - a plenary morning of use case sharing, followed by an afternoon dialogue on integration of use case concepts for transformative patient care.

The use case sharing covered a few dimensions important to the Forum theme - patient-centric care models, trust, financial security and empowerment. Speakers represented global and regional experts, ranging from industry executives to tech evangelists, care providers, payers and patient group representatives. These multistakeholder perspectives moreover discussed what works, and what doesn't, in integrated care becoming a reality. Even the WHO leadership team dropped in to provide a patient-centric vision to march toward.

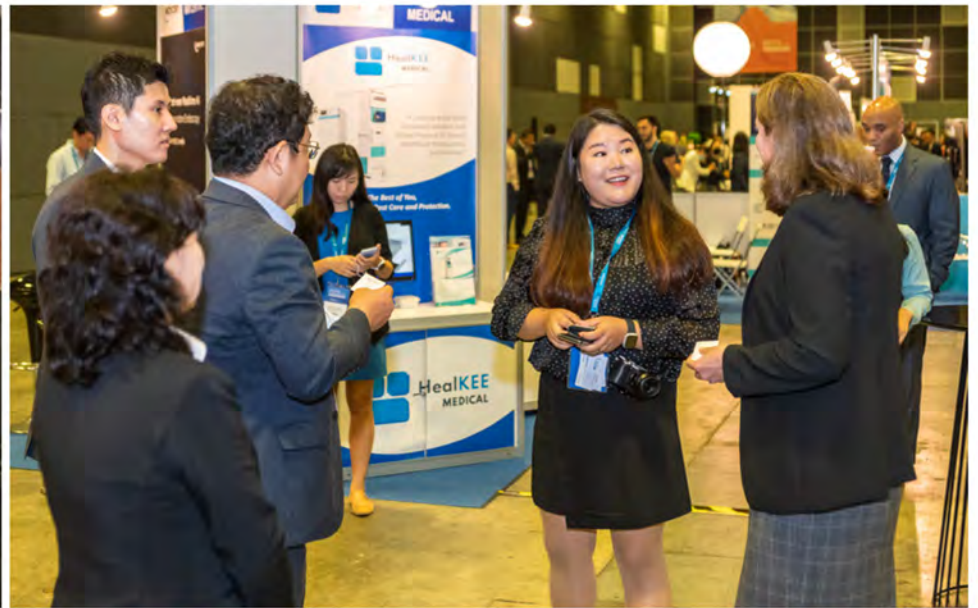
Aside from the plenary programme, the Forum featured an event hall with technology booths (for corporates and start-ups), a stage to connect investors to innovation companies, and expert summit tracks in areas such as Digital Health, Regulatory Affairs, Public Policy and Market Access. There were as well ample networking space and time, which proved to be a big hit after the COVID hiatus.





## Return to Live Networking

Space and time for networking was a key planning feature of the Asia Pacific MedTech Forum 2022, especially after a mostly virtual event format over the prior years. Networking was achieved through a multifaceted approach of Forum breaks, technology booths (for corporates as well as start-ups), the Investor Day stage, and a social reception.



# APACMed Membership

APACMed grew our membership from 263 in the year 2021 to 310 in 2022, representing an 18% increase in total membership number. In the year 2022, we added 86 new members, including 11 new Corporate Members. We also recorded membership growth across all five membership categories – Corporate, Digital Health, Associate, Start-up & SME and Industry Association.

## New Corporate Members

APACMed welcomed 11 new Corporate Members in 2022:





## Membership Category

### Corporate

Corporations manufacturing and conducting R&D in medical equipment, devices, in vitro diagnostics or digital health solutions with global annual sales above USD50 million.

### Digital Health

Tech and Digital Technology Companies that do not have device sales, including mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine.

### Start-up & SME

Start-ups or SMEs manufacturing and/or conducting R&D in medical technology with annual sales less than USD50 million.

### Associate

Service Providers including consultants, contract manufacturers, CROs, investors, distributors, recruiters, lawyers and etc.

### Industry Association

National Associations representing the interests of the medical technology industry in any country in Asia-Pacific.

Membership Category	2021	2022	Growth
Corporate Members	53	60	11%
Digital Health Members	3	5	67%
Associate Members	53	68	28%
Start-up & SME Members	141	163	16%
Industry Association Members	13	14	8%
<b>Total</b>	<b>263</b>	<b>310</b>	<b>18%</b>

## Membership Benefits



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



- Join regular webinars, workshops, seminars and roundtables.
- Participate in the annual MedTech Forum, the industry's most impactful gathering of people and ideas in the region.
- Join networking events.



- Benefit from exclusive market insights and analysis from APACMed Knowledge Partners.
- Receive timely information providing early warnings about regulatory and policy developments in the region and guidance on how to deal with them.
- Access extensive resources on our Members-only section on the website.

# Annual Report 2022

# APACMed

The voice of MedTech

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚洲太医技术协会) is the 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.



To access a digital copy of this report, visit [www.apacmed.org/annualreport2022](http://www.apacmed.org/annualreport2022)

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

2 Science Park Drive,  
Ascent Tower A, #02-07,  
Science Park 1,  
Singapore 118222  
Tel: (65) 6816 3180



@APACMed