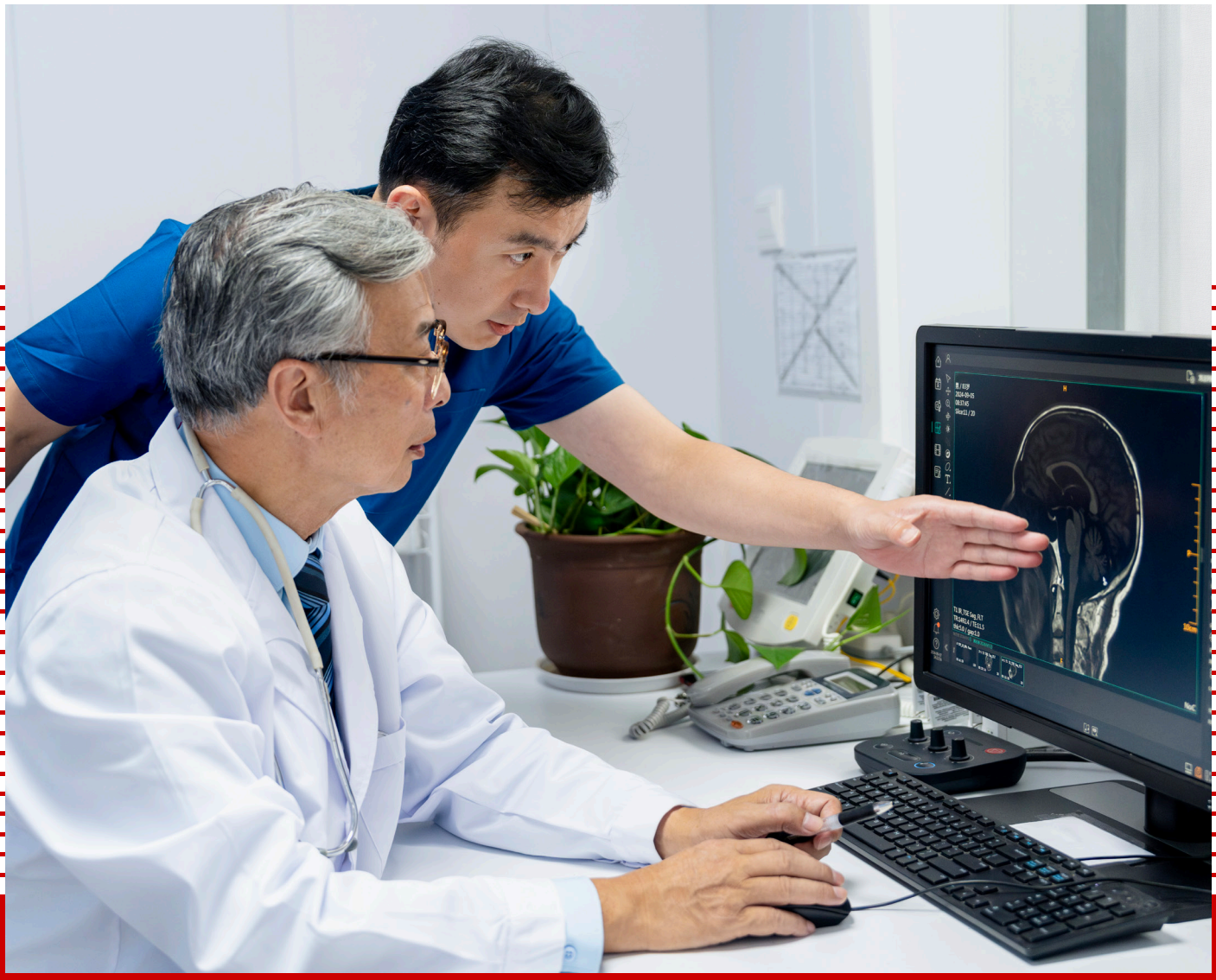
BAIN & COMPANY



Building Global Champions: The Asia-Pacific Region's Next Medtech Wave

With the right strategic commitments, the Asia-Pacific region could become a central exporter of medical innovation.

Authors and acknowledgments

This report was jointly produced in partnership between Bain & Company, Agency for Science, Technology and Research (A*STAR), Enterprise Singapore (EnterpriseSG), J.P. Morgan, SG Growth Capital (SGGC) and the Singapore Economic Development Board (EDB).

Fabio La Mola, Partner, Singapore
Bain & Company

Vikram Kapur, Partner, Singapore
Bain & Company

Kevin Chang, Partner, Hong Kong
Bain & Company

Dhruv Sukhrani, Partner, Mumbai
Bain & Company

Mei Young, Associate Partner, Singapore
Bain & Company

Mark Foo, Healthcare Sector Lead, Asia Pacific
Global Corporate Banking, J.P. Morgan

Contents

At a Glance

- Many medtech companies in the Asia-Pacific region are building novel, globally competitive products.
- For innovations to expand internationally, companies must move beyond manufacturing efficiency and toward clinical and regulatory mastery.
- Five structural gaps—underfunding, scarce talent, late-stage intellectual property strategies, infrastructure deficits, and reimbursement delays—block regional medtechs from achieving global scale.
- These gaps reveal clear priorities for the next 12–24 months. With the right strategic commitments across the ecosystem, the Asia-Pacific region could become a leading medtech exporter.

Executive summary

Traditionally, the Asia-Pacific medtech industry has absorbed global innovations. Now, it's creating, validating, and exporting them. A structural change is afoot, broadening the region's capacity and geography for meaningful innovation. This paper covers the full spectrum of medical devices, from capital equipment and implantable devices to software as a medical device (SaMD) and digital health platforms. It excludes in vitro diagnostics (IVD), which follow a distinct development and commercialization path.

Over the past 20 years, Japan and Australia have led the region in product development, supported by regulatory maturity and deep clinical infrastructure. Without those advantages, the rest of the region was forced to compete on cost and execution alone. Recently, however, that equation has changed.

China and India have moved beyond volume manufacturing and incremental adaptation, and South Korea has emerged as a credible engine for software-only medtech innovation. Meanwhile, Singapore has established a strong medtech ecosystem, combining its advanced regulatory standing and clinical translation infrastructure with precision engineering and end-to-end productization platforms. From this foundation, Singapore is turning promising prototypes into globally validated devices.

Across the region, medtechs are running global trials, securing regulatory approvals in the US and the EU, and attracting significant institutional capital. Rather than replicating or incrementally improving existing innovations, Asia-Pacific medtechs are creating novel, globally competitive products of their own.

The region has also become one of the most important demand centers. Its share of global medtech demand is expected to reach USD $132 billion by 2030, growing at a 6.9% CAGR—well ahead of the global

rate (5.5%). Today, the region represents approximately 16% (USD $94 billion) of the USD $583 billion global medical device market (as defined in the BMI Asia Medical Devices report, excluding IVD and laboratory equipment). Demand is being driven by aging populations and an expanding chronic disease burden across the Asia-Pacific region. A severe shortage of healthcare workers is also increasing demand as providers look for ways to do more with less.

The region's elevated role in medtech innovation affects every player in the medtech value chain.

Multinational corporations: Asia-Pacific-originated medtechs are no longer low-cost competitors focused solely on emerging markets. These companies are earning international market share (Mindray), securing global clearances (United Imaging), publishing trial data in esteemed publications (Meril), and increasingly competing head to head with incumbent Western multinational corporations (MNCs) in the global premium segments.

Asia-Pacific-originated emerging medtechs: The path to global relevance has never been clearer. However, it requires deliberate investment in specific talent areas, such as regulatory affairs, clinical trial management, health economics and outcomes research (HEOR), and quality systems. Rising firms need clear global commercialization strategies and the foresight to make hard choices early.

Ecosystem builders: This includes governments, development agencies, investors, academic institutions, and incubators. For those with solid ideas and early-stage companies, the next challenge is translation: turning talent and clinical evidence into validated innovations that can reach global markets at scale.

Rising firms need clear global commercialization strategies and the foresight to make hard choices early.

Meanwhile, several forces are pushing the medtech market in a new direction:

- **An intensive shift toward clinical value:** Providers and payers now reward measurable clinical results and total cost of care, not just the lowest price. With this shift, the Asia-Pacific region is becoming the world's proving ground for value-based innovation.
- **Supply-side evolution:** The region's manufacturing and engineering base has matured, elevating its role from assembly partner to co-developer of complex devices. Asia-Pacific-based challengers are now competing directly with incumbent multinationals in innovative segments.
- **Regulatory modernization:** Regulatory frameworks in China, Korea, India, and Singapore have all been redesigned since 2021 to accelerate clinical breakthroughs.

- **The rise (and rewards) of globalization:** The region's share of global medtech research jumped from 29% in 2012 to 36% in 2022, and regional medtechs received more than two-thirds of global patent filings in 2023.

Despite holding meaningful advantages, many Asia-Pacific-originated medtechs have not launched globally competitive, commercially viable products. This report explores how to overcome constraints and reach global scale. It also includes clear takeaways on how Western MNCs, Asia-Pacific-originated emerging medtechs, and ecosystem builders in the region can shape the conditions for scale.

Moving up the innovation ladder

In biopharmaceuticals, the development path is typically direct: Companies evolve from generic manufacturing to R&D acceleration to outbound monetization. However, for Asia-Pacific-originated medtechs, moving up the innovation ladder is not strictly sequential. Some companies may operate across multiple phases simultaneously, depending on the market or therapeutic area. Moving up the ladder requires more than technical novelty; an innovative device must also improve the clinical workflow, generate payer-relevant evidence, integrate into hospital procurement, and win physicians' trust.

Medtechs in the Asia-Pacific region typically evolve through three phases:

- **Phase 1: Import substitutes (me-too)**
  In the most nascent stage, medtechs compete on affordability and distribution strength, serving as a substitute for imported solutions ("me-too"). They often localize manufacturing and simplify product specifications to fit provider workflows. Success is driven by procurement access, channel reach, and manufacturing efficiency.

- **Phase 2: Fast followers (me-better)**
  In the next phase, companies accelerate R&D to match incumbent performance. They iterate to improve specific attributes, such as workflow fit, usability, durability, or digital features. Medtechs start to differentiate themselves by offering "me-better" versions at a lower total cost.

- **Phase 3: Globally recognized innovators (me-first)**
  In the third phase, medtech companies develop novel platforms for themselves and generate credible, global validation ("me-first"). Regional medtechs need strong clinical and economic evidence to gain approval and adoption outside the home market.

When regulatory bodies, capital, talent, and infrastructure mature, pathways to international expansion open up quickly.

Where innovation sits today

While most Asia-Pacific-originated medtech players have won through incremental innovation, the region is beginning to move toward breakthrough innovation.

According to US Food and Drug Administration (FDA) approval datasets, the region's share of De Novo authorizations was less than 5% between 2021 and 2025. However, the region's share of total approvals is growing. The region claimed around 30% of global FDA 510(k) clearances from 2021 to 2025. About half of those were driven by China, with South Korea claiming a far second.

The quality of submissions is also rising. Shanghai-based United Imaging accumulated 49 FDA 510(k) clearances by year-end 2024 and more than 20 for AI-enabled devices.

While most Asia-Pacific-originated medtech players have won through incremental innovation, the region is beginning to move toward breakthrough innovation.

This shift is supported by a growing research base. The region's share of global medical device clinical research jumped from 29% in 2012 to 36% in 2022, led by China, Japan, and India. According to the World Intellectual Property Organization, the Asia-Pacific region received more than two-thirds of global patent filings in 2023, up from less than 60% a decade earlier.

The evolution is a result of governments across the region deliberately redesigning their regulatory environments to shorten the innovation pathway. For example:

- The National Medical Products Administration in China approved 76 innovative medical devices in 2025—a 2.2 times increase over four years. An additional 104 products were admitted to its "Green Channel" fast-track pipeline, according to regulatory updates.
- Singapore's Health Sciences Authority (HSA) runs a pre-market consultation scheme that allows developers to engage HSA directly during development—before formal submission—to clarify requirements and stress-test their evidence package early, avoiding costly rework and compressing registration timelines. For breakthrough innovations that address unmet clinical needs in priority healthcare areas, HSA has a priority review scheme that grants companies 35% shorter turnaround times.
- In South Korea, the Ministry of Food and Drug Safety designated 29 innovative devices in 2024, nearly 80% of which were software-based. Applications increased 137% year over year, signaling an accelerated SaMD pipeline, and that was before full implementation of the Digital Medical Products Act in January 2025.

Four archetypes are shaping Asia-Pacific medtech innovation

Each medtech's competitive posture is shaped by the market conditions in which it was built, including the maturity of local clinical infrastructure, the depth of regulatory frameworks, domestic demand, and available capital and talent. Based on these foundations, we identified four archetypes that describe how Asia-Pacific medtechs compete and where they sit on the path to global scale:

1. **Seasoned innovators: built on deep clinical infrastructure** (prominent in Japan and Australia)
   These companies benefit from decades-long clinical credibility and established global commercialization success, advantages supported by mature clinical trial and research infrastructure and established regulatory systems. In Japan, companies like Terumo and Sysmex are global leaders and lead international M&A. In Australia, firms have carved out leadership positions in high-tech niches such as neuromodulation and cochlear implants. Companies in this archetype face a common constraint: Technologies are outpacing reimbursement frameworks in their home markets.

2. **Scale challengers: competing on breadth, speed, and value** (prominent in China)
   These companies have been forged in one of the world's most demanding domestic markets, defined by high volume, intense price competition, rapid iteration cycles, and deep vertical integration. Historically, scale challengers innovated primarily for home market conditions (e.g., China for China). However, value-based procurement pressure at home is compressing margins and making global expansion a strategic necessity. For example, Mindray announced globalization as its key pillar of growth and has invested in building its international footprint to over 40 countries with the goal of increasing its international business proportion from around 50% of its revenue today to more than 60%. In addition, Chinese companies have proven their ability to innovate and build at speed; their next challenge is building the clinical credibility and regulatory trust required by global buyers.

3. **Digital-first innovators: software as the value driver** (prominent in South Korea)
   These companies have placed software at the core of their value proposition, a posture enabled by strong domestic engineering talent, progressive regulatory support, and concentrated investment in AI-driven diagnostics. From 2019 through 2023, software-only medtech exports from South Korea grew at a 312% average annual rate. In 2024, software accounted for 79% of the country's "innovative medical devices." In January 2025, South Korea's Digital Medical Products Act became the world's first standalone law on digital medical products, establishing a regulatory pathway for AI diagnostics and SaMD.

   Seoul-based Lunit is a clear indicator of commercial success from digital-first innovation: Its AI diagnostics system is now deployed in 10,000 institutions across more than 65 countries. The company's prospective randomized clinical trial findings were published in *The Lancet Digital Health*, demonstrating that its AI could replace a human radiologist in routing mammography screening protocols.

4. **Access-led innovators: purpose-built for constrained environments** (prominent in India)
   These companies design products for clinical environments where infrastructure is limited, workforces are stretched, and cost is a binding constraint—conditions that fit a growing share of

global markets. India's Production Linked Incentive Scheme has commissioned 24 greenfield manufacturing plants and generated INR ₹6,425 crore (about USD $670 million) in exports from beneficiaries. Poly Medicure exports to more than 125 countries and Wipro GE to about 70, demonstrating that access-led design can meet global pricing and quality standards. India's medical device exports reached USD $4 billion in FY 2025. However, the country's USD $5.5 billion import bill for high-end electromedical and surgical equipment indicates there's significant runway for growth in complex, higher-value manufacturing categories.

The access-led posture has a natural extension into digital health. Major technology players like Tata, Wipro, Infosys, and L&T run deep medtech practices for global original equipment manufacturers. Meanwhile, AI-native platforms such as Qure.ai already generate the majority of their revenue outside India. Companies that combine their emerging component ecosystems—seeded in part by the automotive sector—and software capabilities will be positioned to develop integrated, software-defined solutions for the global market.

Partnership and investment opportunities in the region must be considered holistically. The Asia-Pacific medtech industry is an integrated system in which the whole is far greater than the sum of its parts. Companies can extract far more value by leveraging market-wide strengths and partnering across the region than they can by focusing on any single company or market.

Two routes to global scale

Global commercialization and leadership are possible for every archetype, though each company's path may look different. Asia-Pacific-originated medtechs typically pursue two distinct routes to global expansion: the global, evidence-led pathway and the local-first, access-led pathway.

The global, evidence-led pathway

In this model, companies design products to meet the gold-standard requirements of mature markets to reduce the risk of adoption. For example, China's Venus Medtech and India's Meril Life Sciences used multinational trials to launch their heart valve programs. Meril's Myval device was commercialized in India, followed by rapid international expansion to Europe, and backed by investments in benchmark-comparator evidence.

Early US regulatory validation is often viewed as the highest bar of confidence for breakthrough platforms. Synchron, an Australian-founded neurotech firm, received FDA approval for an investigational device exemption feasibility study for its permanently implanted brain-computer interface. Similarly, Australian-based Saluda Medical secured a pre-market approval (PMA)—passing the FDA's most rigorous review process—for its Evoke spinal cord stimulation system, backed by data from the EVOKE clinical trial.

The local-first, access-led pathway

In this approach, companies first build products for local market conditions such as cost and infrastructure constraints, disease burden, and clinical workflows. Design choices that make these products competitive locally often translate into genuine differentiation when they are exported to global markets as simpler, more accessible, or lower-cost alternatives.

GE Healthcare India followed this strategy by developing products to handle high patient volumes in health centers with limited infrastructure, a challenge commonly found in emerging markets. For example, the MAC400 and MAC800 portable electrocardiograph systems, developed for rural Indian clinics, and the Vscan portable ultrasound, for rural clinics in China, were originally designed to expand access to imaging in resource-constrained settings. These products were eventually introduced globally, demonstrating that regional fit-for-purpose design can successfully scale upstream into more mature healthcare markets.

Design choices that make these products competitive locally often translate into genuine differentiation when they are exported to global markets as simpler, more accessible, or lower-cost alternatives.

Similarly, Sonova recently announced its plans to establish a new Innovation Centre for Affordable Hearing Solutions in Singapore, which will focus on developing high-quality, cost-efficient products and care models tailored to the diverse needs of Asian markets.

Pulnovo Medical, a Nanjing-founded cardiovascular device company, built its pulmonary artery denervation system to address unmet medical needs in pulmonary arterial hypertension (PAH) treatment. Asia accounts for approximately 60% of global PAH cases. Pulnovo developed a onetime interventional procedure and validated it entirely through Chinese hospital trials over a decade. Evidence was published in *JACC: Cardiovascular Interventions* before the company pursued approval from the National Medical Products Administration (NMPA) in China, a CE Mark in the EU, and an FDA Breakthrough Device designation. In April 2026, Medtronic led a USD $100 million financing round alongside EQT, OrbiMed, and Lilly Asia Ventures, demonstrating that a product designed to solve an Asian disease burden and validated in Asian hospitals can earn the confidence of the world's largest medtech companies and scale globally.

Five gaps holding medtechs back

Despite holding meaningful advantages, many Asia-Pacific-originated medtechs have not launched globally competitive, commercially viable products. Five gaps impede their progress.

1. **Underfunding and a "mid-market" gap**

Capital is heavily concentrated in later stages, leaving early-stage and translational rounds under-resourced. According to venture data from 2025, global medtech venture capital (VC) rounds exceeding USD $50 million accounted for the large majority of capital deployed while sub-USD $50 million rounds fell to their lowest count since 2021. In contrast, seed and Series A rounds combined were only USD $2.2 billion across 124 rounds—a significant shortfall for early innovation.

Private equity (PE) capital is abundant: Asia-Pacific-based buyout value hit a record USD $23 billion in 2025 with medtech deal value estimated to be around USD $2.3 billion. However, this funding was rarely directed toward growth-stage medtechs. Instead, it went to large, already-scaled platforms through corporate carveouts and take-private transactions.

Implications:

- VC-backed companies need to map their full funding arc early, including intellectual property (IP) strategy and milestone sequencing. They should also diversify inflows through grants, MNC partnerships, and corporate ventures to reduce dependency on a single funding channel.
- For those with PE ambitions, the entry bar is high. Investors are looking for licensing deals, MNC partnerships, or international commercial traction before they commit.
- This gap represents a structural opportunity for investors who can evaluate early- and clinical-stage assets and navigate regulatory complexity. VCs, PEs, and strategics can access innovation that is underpriced relative to its global potential.

2. **Regulatory and clinical talent gaps**

To launch "me-first" devices, emerging medtechs need professionals who have already navigated FDA De Novo and PMA submissions, managed trials to ISO 14155 standards, and built ISO 13485-compliant quality systems. This level of global experience is scarce across the Asia-Pacific region.

Companies that reach their first regulatory milestone without this expertise often face setbacks measured in years, not months. The model for closing the talent gap varies by scale: Smaller firms typically engage specialist consultants to shape their clinical and regulatory strategy while larger ones build dedicated in-house teams. Both approaches require early clarity on priority markets and clinical evidence specific to each regulator. Companies that resolved these questions before entering pivotal development have moved significantly faster and attracted stronger partners (e.g., Meril with its 31-site clinical trial or Venus Medtech with its US-based study).

Implications:

- Early movers who secure global regulatory and clinical talent before they "need" it can build a durable competitive moat.
- Companies need clarity around priority markets and the clinical evidence they require before entering development phases.

3. **IP protection gaps**

IP strategies often start too late for emerging medtechs, severely limiting the firms' strategic options.

Delaying global IP filings may work for "me-better" devices competing solely on cost or execution, but it's risky when products are genuinely novel. When conversations shift toward licensing, partnership, or acquisition, IP becomes the most valuable asset.

Global buyers conduct rigorous due diligence during negotiations. Gaps in patent coverage in the US, the EU, or Japan could compress valuations or narrow exit opportunities at the moment companies need them most.

Implications:

- Execution excellence cannot save a transaction; medtechs need clean, enforceable patents to close deals.
- Freedom-to-operate analysis and international filing strategies must begin years before any commercial conversations.

4. **Infrastructure gaps**

Most Asia-Pacific-originated emerging medtechs have yet to build the commercial foundations—such as market prioritization, entry models, channel infrastructure, and key opinion leader (KOL) networks—required to compete beyond their home markets.

In complex, regulated markets, acquiring these capabilities through partnerships, co-promotion, or licensing is often more capital-efficient than building from scratch. Companies like Mindray and Venus Medtech acquired Western commercial infrastructure to support their global expansion. In doing so, they also gained access to sales teams and important hospital relationships.

For novel "me-first" devices, the challenge is even greater because it requires active market development. Global adoption requires physician training, reimbursement, workflow integration, and clinical leaders' willingness to champion something new. These factors vary significantly by market, and building a credible KOL network can take years to develop globally.

Implications:

- For novel products, KOL engagements offer more than endorsements; they have the power to influence established care pathways and help build category-level evidence required for procurement and payers.
- Market development is a multiyear investment that must be embedded in product strategy from the start.

5. **Reimbursement and evidence gaps**

Regulatory approval is the beginning of the commercial challenge, not the end. According to a study by Stanford University and the *Journal of the American Medical Association* Health Forum, only 44% of novel devices granted FDA authorization between 2016 and 2019 achieved even nominal Medicare coverage from the Centers for Medicare & Medicaid Services (CMS). The median wait was 5.7 years, longer than the FDA authorization process itself.

Regulatory approval is the beginning of the commercial challenge, not the end.

The new CMS-FDA RAPID pathway, announced in April 2026, may eventually compress the timeline for breakthrough-designated devices; however, implementation is pending. In the meantime, barriers remain around clinical evidence, channel entry, and KOL advocacy.

In the EU and Japan, evolving Health Technology Assessment (HTA) frameworks are raising the evidence bar even higher. These systems include formal "comparative effectiveness" data—proof that a new device is superior to existing treatments—that most Asia-Pacific-based clinical programs aren't equipped to provide.

Evidence design is a key part of the problem. Trials that lack demographic diversity or fail to meet endpoints prioritized by the FDA or required under the EU Medical Device Regulation (MDR) often must be duplicated—at great cost—regardless of the underlying data quality.

There are early signs that some markets are working to close this gap. In Singapore, HSA and the Agency for Care Effectiveness can already share company and product information with companies' consent, reducing the need to resubmit similar documentation across regulatory approval and HTA processes. Both agencies have also signaled their intent to develop more coordinated pathways that would allow clinical development, regulatory review, and HTA to progress in closer alignment for selected technologies that address priority disease areas or unmet clinical needs.

Implications:

- Clinical approval opens the door, but it does not guarantee commercial success.
- To generate revenue, companies must develop their reimbursement and evidence strategies in parallel with their clinical programs.

Stakeholder playbooks

Closing these gaps is a strategic mandate. The following playbooks outline specific actions each stakeholder can take to bridge the divide between local innovation and global scale.

Implications for multinational medtechs

Many Western MNCs have localized production to counter market or competitive pressures, but these efforts often underdeliver, especially when importing expensive global operating models into cost-sensitive segments.

To win in the next decade, Western MNCs must transition from "selling in" to "buying from" or co-creating with Asia-Pacific medtechs.

To win in the next decade, Western MNCs must transition from "selling in" to "buying from" or co-creating with Asia-Pacific medtechs. With this shift, the region can become both an innovation engine and a proving ground.

Immediate priorities

- **Partner early and co-create:** Proactively identify early-stage innovations while maintaining a high bar for acquisitions. Prioritize licensing and partnership models to capture upside while minimizing integration risk.
- **Establish learn-and-transfer loops:** Use minority stakes or structured collaborations to study local speed and cost disciplines, then import those best practices into global R&D and operations. Co-investing alongside Asia-Pacific venture funds can lower friction compared to only building a standalone corporate VC arm.
- **Make Asia-Pacific-first innovation repeatable:** Identify categories where Asia-Pacific-born products can win globally (e.g., value segments, ambulatory care, productivity tools) and build dedicated pathways for export.

Priorities for the next 12–24 months

- **Empower regional hubs:** Establish one or two co-creation hubs with genuine decision-making authority over product roadmaps, evidence plans, and cost engineering.
- **Formalize partnerships:** Build a dedicated partnership capability with standard deal templates, governance, and shared evidence infrastructure.
- **Exchange talent:** Launch structured secondment and talent exchange programs with regional innovation partners.

Case study: Boston Scientific and Acotec

In 2022, Boston Scientific acquired a majority stake in Acotec, a Chinese leader in interventional products and techniques. The deal offers a blueprint for moving up the innovation ladder. Boston Scientific accessed Asia-Pacific-based innovation in stages: distribution first, minority/majority equity second, and then full integration for assets that have proven to be globally portable.

Boston Scientific also demonstrated a willingness to source innovation in "me-better" categories rather than in entirely new "white space" categories. Instead of treating Acotec as a standalone local player, Boston Scientific partnered with them on commercialization, manufacturing, and R&D, turning it into a global operating asset.

Case study: Philips and Respiree

Singapore-founded Respiree, a spin-off from the Agency for Science, Technology and Research (A*STAR), Singapore's lead public sector R&D agency, develops AI-enabled wearable sensors and predictive algorithms for continuous cardiorespiratory monitoring used in hospital, transitional, and home care settings. Philips integrated Respiree's wearable sensors and 1Bio™AI platform directly into its enterprise monitoring infrastructure, creating a combined solution for inpatient monitoring optimization and hospital-at-home programs. The partnership has since extended to North America, where Respiree technology is available through Philips' enterprise systems.

Implications for Asia-Pacific-originated emerging medtechs

To graduate from "me-too" substitutes (Phase 1) to "me-first" innovators (Phase 3), Asia-Pacific-originated emerging medtechs must pair engineering speed with clinical credibility. Winners will treat clinical and economic proof as core products and seek partners to complement and extend their expertise instead of attempting to do it all in house.

Immediate priorities

- **Provide evidence of value:** Roadmaps must specify endpoints that matter to payers from the start (e.g., outcomes, productivity, complications, length of stay). HEOR should be built in parallel with clinical trials, not post-launch.
- **Establish a global-ready quality management system (QMS):** Invest in an exportable QMS and documentation before scaling production to avoid the high cost and delay of retrofitting systems later.
- **Define the path to payment:** Diagnose the reimbursement landscape before pivotal trial design, not after approval. Where a coding and coverage pathway exists, design trials to satisfy payer evidence requirements alongside regulatory endpoints. Where a pathway does not exist, if a procedure is not yet recognized as the standard of care, the strategic response is to sequence market entry. Prioritize markets where reimbursement and standard-of-care readiness already support the technology. Build your evidence base in those environments, and re-enter more difficult markets when commercial conditions are favorable.
- **Create switching certainty:** Winning approval does not guarantee adoption. Companies can reduce the risk of the transition for clinicians with training, proctoring, and service models.

Priorities for the next 12–24 months

- Standardize a market-entry dossier, covering clinical outcome data, a health-economic value narrative, cybersecurity posture, and interoperability roadmaps.
- Pursue approval and coverage simultaneously. Identify whether existing reimbursement codes cover your intended use, and engage payers and coding bodies before designing trial endpoints.
- Identify one or two global reference sites with KOL standing and publish outcomes in peer-reviewed channels.

Case study: Advanced Medtech

Advanced MedTech is an integrated urology platform headquartered in Singapore. Over the past decade, it has built a platform for integrating engineering innovation, high-quality manufacturing, and scalable product development capabilities across the Asia-Pacific region.

Its thesis was grounded in a structural opportunity: The Asia-Pacific region has become an increasingly important source of competitive medical technology. China-originated innovations and products serve as one example of the region's strong engineering depth, cost-efficient manufacturing, and fast product iteration cycles. However, China-developed medical devices often face challenges when expanding into Europe and the US.

Several factors influence the path to widespread adoption.

Market access and adoption infrastructure: Successful adoption in Europe and the US requires more than a competitive product. It requires credibility among physicians, a clear reimbursement path, and long-term support. Earning trust takes sustained local engagement with physicians, hospitals, distributors, and regulatory stakeholders. Companies must build on-the-ground infrastructure to support clinical education, post-market feedback, and long-term customer confidence.

Clinical credibility: Even strong products with cleared regulatory pathways need Western clinical champions to endorse them. For Advanced MedTech, building KOL relationships is not a downstream activity; it is central to commercialization and adoption. The company also uses in-market knowledge to help partners refine products for Western clinical workflows, physician preferences, reimbursement expectations, and broader market requirements.

Advanced MedTech's Singapore base gives it a differentiated position to use established European engineering discipline. It boasts a US and global commercialization presence, plus access to the broader Asia-Pacific innovation ecosystem. These factors enable the company to source and scale technologies with strong technical foundations and adapt them for international clinical practice.

Takeaways for Asia-Pacific-originated emerging medtechs:

- Use a strategically positioned regional headquarters to bridge the gap between Asia-Pacific innovations and global clinical needs.
- Protect the engineering and R&D culture that created value in the domestic market while adapting products and evidence generation for customers abroad.
- Build Western KOL relationships early. Regulatory clearance opens the door, but clinical adoption requires champions who can shift established care pathways.
- Invest early in market access and adoption infrastructure, including local clinical engagement, physician education, and post-market support.

Case study: Biobot Surgical

Biobot Surgical was formed out of a clinical need identified at SingHealth: Prostate biopsies were generating dangerously high infection rates, and cancer detection rates were low. A team of urologists developed the Mona Lisa transperineal robot to improve needle positioning accuracy for prostate biopsy and treatment. The technology was licensed from SingHealth and incubated by ZIG Ventures, initially the corporate investment unit of Zicom, a diversified engineering group founded by Mr. Sim Giok Lak, an EY Entrepreneur of the Year award winner for Industrial Products in 2008.

Biobot's go-to-market strategy was clear from the start, focusing initially on Europe, Asia (excluding China), and Australia. The first-generation device was launched commercially in 2017 for prostate biopsies; a second-generation model that expanded the device's indication to include prostate ablation was released in 2021. Although early revenue was in the low millions annually, it has since increased, and the company is aiming to exceed double-digit millions in 2026, supported by a growth-financing round led by ClavystBio. Today, roughly 80 systems are deployed across more than 35 countries, with more than 30,000 procedures performed.

Biobot did not pursue the US market initially, as what appeared to be a delay was actually strategic discipline. Proactive engagement by the Biobot team with US clinicians identified that transperineal access was not yet the standard of care and lacked differentiated reimbursements, even though transperineal access for prostate biopsies was widely regarded as safer, with outcomes similar to transrectal access. Biobot instead focused on European and Asia-Pacific markets (excluding China) that prioritized transperineal access over transrectal access and had public and private health insurance that provided differentiated reimbursements with some out-of-pocket pricing. When the US standards changed—thanks to advocacy efforts, post–Covid-19 infection awareness, and the issuance of dedicated transperineal *Current Procedural Terminology* (CPT) codes in 2026—Biobot had growth financing and a second-generation device ready to go.

Talent was a second drag on ROI. Biobot prioritized its clinical and regulatory engine first to build a defensible evidence base. But approval is the start of the commercial challenge, not the end. And there is no shortcut for building a direct sales organization in a foreign market. Outside the US, Biobot runs a channel model, leveraging a small in-house team that owns key accounts and supports training—working alongside distributors rather than behind them. In the US, the company is collaborating with top American academic medical centers to champion the platform. More US peer-reviewed publications are expected, supplying influential local evidence.

Takeaways for emerging medtechs:

- Treat reimbursement and standard-of-care readiness as inputs for market sequencing, not post-approval problems. Resist entering markets that are not ready, even with regulatory clearance in hand.

- Lock in clinical and regulatory hires early to build evidence, then treat commercial talent as the primary constraint for scaling. Reset decisively when a build isn't working.
- Build IP continuously. Biobot grew from a single, local-hospital-originated patent family to 16 patent families and 28 patents granted. A robust and growing patent estate can shape valuation during an exit.
- Lead channel partnerships actively rather than relying on distributors to drive commercial success.
- Build strong investor syndicates that can open doors into US clinical and commercial ecosystems.

Implications for ecosystem builders

Governments, development agencies, investors, academic institutions, and incubators all share a common function: removing structural barriers so promising innovations can reach global markets. The Asia-Pacific region is full of promising ideas, but they frequently stall before reaching the global market. The actions below are designed to address the three foundational layers where stalling occurs most often: talent infrastructure, evidence systems, and commercial pathways.

Immediate priorities

- **Prioritize talent infrastructure:** Fund talent as a primary investment, not an afterthought. The region needs deeper expertise in prototyping, validation, and specialized manufacturing. Talent bridges between academia, hospitals, and industry can help close immediate gaps in product management, quality, and clinical affairs.
- **Establish translation hubs:** Early-stage companies require shared clinical engineering and regulatory support hubs to navigate the steps between prototype, product, and scale.
- **Industrialize evidence generation:** Build and fund shared clinical infrastructure—including multi-site trial networks, patient registries, and master protocol frameworks—that comply with international standards so data are acceptable for submission to the FDA, the EU authorities under MDR, or Japan's Pharmaceuticals and Medical Devices Agency (PMDA) without costly duplication.
- **Drive regulatory alignment:** Adopt international standards and harmonize documentation expectations across the region. Dossiers built for the home market need to travel more easily to the FDA, EU regulators, and PMDA.
- **Provide global export support:** Create market-entry playbooks and connect overseas distributors to local providers and post-market compliance experts.
- **Redesign capital inflows:** Blend catalytic public funding with private investment, using funding milestones to reward evidence quality and global ambition.

Priorities for the next 12–24 months

- Launch or expand regional contract research organizations (CROs) and shared HEOR services platforms to provide start-ups with professional-level clinical support. Ensure trial and registry infrastructure meets international governance standards.
- Make data quality standards and publication commitments non-negotiable conditions for public funding. Tie milestone-based disbursements to evidence outputs such as protocol registration, interim data reviews, or journal submission not just regulatory filings.
- Develop on-the-ground sales and marketing support, KOL networks, and distributor relationships in priority markets. Structure the support as a pooled service or a co-investment vehicle to spread commercial costs across a portfolio of validated companies.

Case study: Singapore medtech ecosystem

Singapore has built an integrated innovation and productization hub to translate medical concepts into globally launchable products. The ecosystem gives companies access to multinational R&D infrastructure, multi-site trial networks, precision engineering manufacturing partners, and an advanced regulatory framework.

The ecosystem is underpinned by a deliberate approach to talent development and productization. Platforms such as Singapore Biodesign and Duke-NUS train clinicians to identify unmet needs and turn ideas into investable, development-ready products. Through A*STAR's Singapore Biodesign platform, more than 2,600 individuals have been trained since 2010, leading to more than 76 funded projects and 20 spin-offs. The talent pipeline is reinforced by S$1 billion in government commitments on its National AI Strategy (NAIS) 2.0 to build local AI capabilities between 2025 and 2030.

The ecosystem offers shared infrastructure and specialized venture-creation support to help companies move from concept to commercial readiness. A*STAR's MedTech Catapult provides seed capital, engineering resources, and product development support to bridge design, validation, and manufacturing gaps. Its Diagnostics Development Hub supports innovation and productization in digital health solutions and integrated point-of-care diagnostics. Through a partnership with Santé Ventures and its planned Santé Accel program, SG Growth Capital surrounds medtech founders with venture, clinical, regulatory, engineering, and commercial expertise and supports them through the earliest stages of company formation. Promising early-stage companies gain access to specialized capabilities that help them progress toward venture financing, market readiness, and manufacturing.

Institutions such as the Singapore Clinical Research Institute and the National Health Innovation Centre connect clinical innovators to trial design and commercialization support. By using a KOL

network, they help Singapore-born medtechs build trusted, quality evidence for global adoption. For example, LimFlow's percutaneous deep vein arterialization system completed its first-in-human pilot study at Changi General Hospital in 2013 and 2014, generating clinical evidence to underpin its CE Mark in October 2016 and its FDA PMA in September 2023.

Singapore's HSA has achieved WHO Maturity Level 4 for medical device regulatory systems. Other regulators, like Malaysia, Australia, Hong Kong, the Philippines, Thailand, and Sri Lanka reference HSA's approval, significantly compressing the time it takes companies to enter those markets. Recently, HSA refreshed memorandums of understanding with Japan's PMDA and China's NMPA to reaffirm its commitment to regulatory collaboration.

HSA has also introduced a regulatory sandbox that supports the scaling of AI solutions. The AI-SaMD Exemption Sandbox allows public healthcare institutions to deploy low to moderately low risk AI-driven medical devices for in-house use with some exceptions to typical registration requirements. Singapore's IP regime ranks among the top five globally for innovation and IP rights, giving companies confidence that novel platforms will be protected.

Singapore's manufacturing base is also significant: Roughly one in seven hearing aids and one in five cardiac-related implants used globally are produced there. Decades of MNC investment have yielded a high-compliance, Class C- and Class D-capable production ecosystem. Leading medtech MNCs (e.g., Biotronik and Resmed) and electronics manufacturing services (e.g., Jabil and Flex) have both manufacturing and R&D operations in Singapore. This concentration of industry leaders, backed by financial support from the Economic Development Board and Enterprise Singapore, reduces some of the capital and execution risks for scaling.

This manufacturing infrastructure is increasingly relevant to advanced global medtech start-ups looking for reliable partners for regulated systems, components, and consumables. DeepSight Technology, a US-based company that combines advanced sensing, real-time imaging, and procedure guidance into a single system, illustrates this shift. With support from SG Growth Capital, DeepSight partnered with Singapore-based contract manufacturers for its medical device systems and consumables. This signals that Singapore's appeal extends beyond regional headquarters, distribution, or business development. It encompasses the hardest, highest-value parts of scaling: precision engineering, regulated manufacturing, supplier reliability, quality systems, and global logistics.

Enterprise Singapore helps Singapore-based medtechs grow into globally competitive businesses. Through the Startup SG initiative, founders access funding, mentorship, industry networks, and investor communities, gaining the commercial foundations to secure follow-on funding and forge strategic partnerships. This is bolstered by a network of international hospital partners in the US, Europe, and Asia. Accelerator partners such as MedTech Actuator, MedTech Innovator, and Angelini Ventures offer specialized support across the long and capital-intensive path from prototype to regulatory clearance.

Ultimately, close coordination across the broader ecosystem ties these support systems together, ensuring companies can access all the resources they need to transition from concept to global commercialization.

The 2030 vision

Companies that close strategic gaps by 2030 will transform the region's medtech landscape. By the end of the decade, a successful ecosystem could be defined by:

Global evidence validation: De Novo applications and PMA-track programs from the region will no longer be considered exceptional; they will be a standard part of the FDA's annual docket. The number of Asia-Pacific–based pivotal trials meeting FDA and international standards will have grown substantially.

Higher shares of global revenue: Regional leaders will generate a majority of their revenue outside home markets. Once the Asia-Pacific region is validated as an innovation source, hospital systems in the US and Europe will actively source Asia-Pacific-born devices for their superior clinical outcomes and purpose-built designs rather than just for their lower costs.

A self-reinforcing talent cycle: The region will produce a generation of regulatory and HEOR professionals capable of launching global programs from the Asia-Pacific region. This will be supported by national talent initiatives, specialized CRO platforms, and MNC secondment programs.

Companies that close strategic gaps by 2030 will transform the region's medtech landscape.

Routine partnerships and acquisitions: Global players will view the Asia-Pacific region as a primary source for innovation, and outbound licensing, co-development, and acquisition will become standard practice.

Compounding investments: High-quality clinical evidence will trigger a self-reinforcing cycle: Proven results attract global partners, partners generate revenue and credibility, and that credibility attracts institutional capital to fund the next generation of innovation. As an example, consider Cochlear (137 times return from its 1995 IPO to its 2024 peak), Mindray (10 times per-share return for A-share investors from its 2018 ChiNext IPO price to its 2021 peak), and Resmed (425 times return from its 1995 IPO to its 2021 peak).

Conclusion

Asia-Pacific-originated medtechs have the potential to move beyond local leadership and produce global champions. Reaching that milestone requires moving beyond manufacturing excellence to clinical and regulatory mastery.

How far Asia-Pacific-based innovations go depends on how well stakeholders address structural gaps between innovation and commercialization:

- MNCs must redefine their relationships with Asia-Pacific medtechs, moving from a "sell to" model to a "co-create" model that identifies and builds exportable winners.
- Asia-Pacific-originated emerging medtechs must think globally from day one. This means prioritizing go-to-market strategies and investing in talent, quality, and evidence infrastructure long before they are "needed" in the home market.
- Ecosystem builders must fund infrastructure to support this process, including shared talent bridges, trial networks, and regulatory advisory services. Individual start-ups cannot afford to build these structures alone, and they can't scale without them.

Enablers are already compounding. Investments made over the next 24 months will determine the role the Asia-Pacific region plays in the global medtech landscape. With the right strategic commitments, it will be a leading role.

The Bank of the Innovation Economy

J.P. Morgan is a global leader in financial services, providing comprehensive, scalable solutions in investment banking, commercial banking, financial transaction processing and asset management. Committed to being the leading bank for the innovation economy, J.P. Morgan and its bankers across the globe provide venture-backed and high-growth companies with specialized services, access to a robust professional and venture capital network, and money-management solutions.

www.jpmorgan.com

For where you're growing

Enterprise Singapore is the Singapore government agency championing enterprise development. With a global network in over 35 locations around the world, it drives Singapore companies' global expansion while connecting international businesses to trusted partners in Singapore. Singapore is a powerhouse of growth. As a global hub for trade and innovation, it offers access to a thriving ecosystem of global enterprises, start-ups, and investors. Known for their commitment to quality and innovation, Singapore companies are also ideal partners for growth.

www.enterprisesg.gov.sg

We think big and start small

The Singapore Economic Development Board (EDB), a government agency under the Ministry of Trade and Industry, is responsible for strategies that enhance Singapore's position as a global centre for business, innovation, and talent. We undertake investment promotion and industry development, and work with international businesses, both foreign and local, by providing information, connection to partners and access to government incentives for their investments. Our mission is to create sustainable economic growth, with vibrant business and good job opportunities for Singapore and Singaporeans.

www.edb.gov.sg

Bridging Innovation and Capital to Scale Global Leaders

SG Growth Capital is the strategic investment platform of the Singapore Economic Development Board (EDB) and Enterprise Singapore, advancing Singapore's economic priorities through targeted investments in key industries. By bridging capital, networks, and market expertise, SG Growth Capital accelerates the growth of its portfolio companies, helping them scale faster in the region and globally. Its investment arms, EDBI and SEEDS, back global leaders and co-invest in early-stage local startups, respectively. Together, we drive the development of innovative solutions and create high-value jobs, strengthening Singapore's long-term economic resilience.

www.sggc.sg

Creating Growth, Enhancing Lives

The Agency for Science, Technology and Research (A*STAR) is Singapore's lead public sector R&D agency. Through open innovation, we collaborate with our partners in both the public and private sectors to benefit the economy and society. As a Science and Technology Organisation, A*STAR bridges the gap between academia and industry. Our research creates economic growth and jobs for Singapore, and enhances lives by improving societal outcomes in healthcare, urban living, and sustainability. A*STAR plays a key role in nurturing scientific talent and leaders for the wider research community and industry. A*STAR's R&D activities span biomedical sciences to physical sciences and engineering, with research entities primarily located in Biopolis and Fusionopolis.

www.a-star.edu.sg

BAIN & COMPANY

Bold ideas. Bold teams. Extraordinary results.

Bain & Company is a global consultancy that helps the world's most ambitious change makers define the future.

Bain & Company works with leaders worldwide to solve their toughest challenges and deliver enduring results. Since 1973, we've partnered with clients, including private equity and portfolio companies, to build the capabilities they need to stay ahead of change and help them redefine their industries. We measure our success by our clients' success, and we proudly hold the highest levels of client advocacy in our field.

Bain is consistently recognized globally as one of the best places to work. We operate as one global team, uniting strategists, industry and functional experts, technologists, and advisors with a vibrant ecosystem of technology partners.

For more information, visit **www.bain.com**