



# Medical devices & diagnostics in Asia-Pacific

## *Balancing risk and reward*

Medical device companies are turning to outsourcing to manage complexity and cost while seizing opportunity in the world's fastest-growing device market.

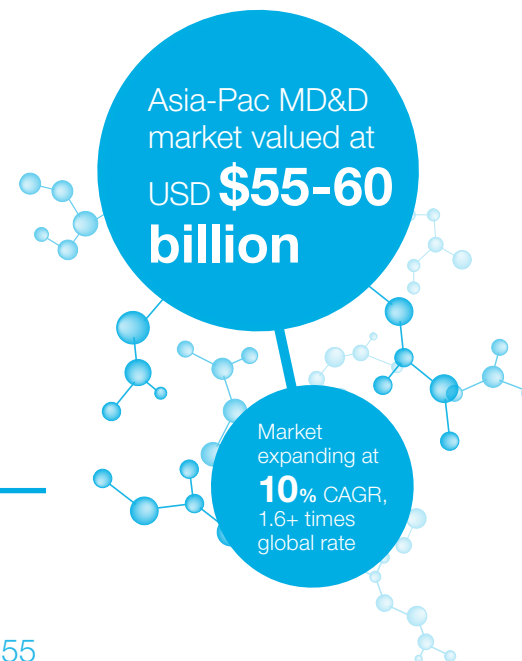
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### Executive summary

Medical device makers are bullish about the future in general and about Asia-Pacific in particular. With a current commercial market size of USD \$55 billion to \$60 billion<sup>1,2</sup>, the region is a hot spot for medical device companies worldwide for sales, investment and expansion.

This paper looks at the factors behind the attractiveness of Asia-Pacific for medical device development and commercialization and what companies should consider to take advantage of opportunities in the region.



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## Focusing on Asia-Pacific

### By the numbers

The Asia-Pacific medical device and diagnostics commercial market is valued at USD \$55 billion to \$60 billion<sup>1</sup>, and comprises nearly a quarter of the worldwide medical device market. The region's medical device market currently has a compound annual growth rate (CAGR) of 10%, which is 67% higher than the global CAGR of 6%.<sup>1,2,9</sup>

For wearable devices, the region is growing even faster, at 18%+ CAGR for 2013-2019 – exceeding global growth of 16.4% CAGR. This is attributable to increased medical investments; improving healthcare infrastructure; and an increasing awareness and participation in sports and fitness.<sup>3</sup>

**Figure 1 Driving high expectations for the Asia-Pacific medical device market: Demographics, economics**

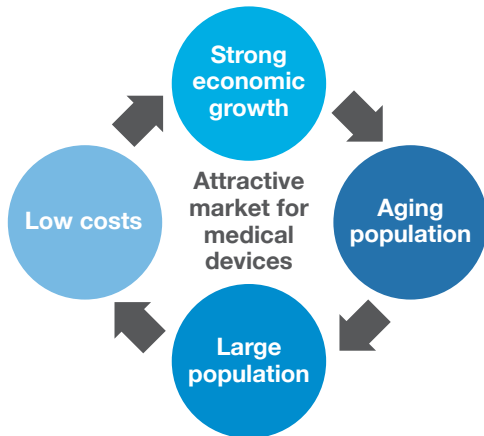
	Population Change 2015 – 2050 <sup>4</sup>	% of Population 65+ 2015 – 2050 <sup>4</sup>	Current Healthcare Spend <sup>5</sup> (USD)	GDP Per Capita (Current USD) <sup>6</sup> 2014	Estimated MD&D Market Size
Global	2050 9.73 B 2015 7.35 B	16.0% 8.3%	>9 trillion	10,595	USD \$240 B in 2014 growing to USD \$320 B by 2019, 6% CAGR <sup>1,2</sup>
Asia	2050 5.27 B 2015 4.39 B	18.2% 7.5%	>2 trillion	9,002	USD \$55-60 B in 2014, growing to USD \$100 B by 2019, 10% CAGR <sup>1&amp;2</sup> (2013-2019)
China	2050 1.35 B 2015 1.38 B	27.6% 9.6%	580.5 billion	7,594	USD \$16.1 B in 2013 growing to USD \$32.8 billion by 2018, 15.3% CAGR in US dollar terms
Japan	2050 107.4 M 2015 126.6 M	36.3% 26.3%	479 billion	36,194	USD \$30.2 B in 2013 increasing to \$34.9 billion in 2018, 2.9% CAGR in US dollar terms <sup>6</sup>
S. Korea	2050 50.6 M 2015 50.3 M	35.1% 13.1%	116.2 billion	27,971	Medical device market growing at annual average rate of 13.3% <sup>6</sup>
Australia	2050 33.5 M 2015 24.0 M	22.5% 15.0%	152 billion	61,887	USD \$5.1 B in 2013 increasing to USD \$7.4 B by 2018, 7.7% CAGR <sup>14</sup>
ASEAN*	2050 792.1 M 2015 633.5 M	15.6% 5.9%	~93 billion	3,911	USD \$4.9 B increasing to USD \$5.2 B by 2018, 1.2% CAGR <sup>14</sup>

\*ASEAN: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Vietnam

■ 2050 ■ 2015

## Reasons for growth

Western device companies are looking to Asia for sales, investment and expansion; the same goes for local companies, many of whom have global growth aspirations. Both groups want to seize the region's potential for rapid development of devices for global and local Asian markets. Fueling Asia-Pacific's high potential are:



**Population size:** Asia is home to about 4.5 billion of the world's 7 billion people. China and India, the world's two most populous countries, have a combined population of 2.8 billion. While smaller, Southeast Asian countries also are highly populated: Indonesia has about 250 million people and Vietnam 100 million.<sup>2</sup> These countries are also becoming more developed with rapid economic growth, thus, they have a significant need for more advanced medical devices.

**Economics:** Despite the global economic downturn, Asia is the fastest growing region, enjoying a 5-8% GDP growth rate. Comparatively, the United States and Europe have been growing at 0-2.5%.<sup>2</sup> This strong

economic growth means that Asian countries have the resources to invest more in their healthcare markets.

Additionally, Asia's middle class is expanding rapidly and is expected to have 50% of the world's middle class population by 2030<sup>2</sup>. This will also lead to an increase in consumer spending. The majority of the Asian middle class also lives in urban cities that are easily accessible to international medical device companies.

**Healthcare:** Asian countries such as China, India and Vietnam have already invested heavily in healthcare, making it amongst the priority sectors in these markets. As the spending power increases, Asian consumers have also become increasingly brand conscious. This will lead to a rise in demand for high-end Western medical devices.

**Aging population:** By 2050, senior citizens over 60 are estimated to constitute 25% of the Asian population, a significant increase from 10% in 2012<sup>2</sup>. These demographic trends also provide growth opportunities for device companies specializing in geriatric products.

**Low costs:** Manufacturing in the region is an effective cost-reduction strategy, and device manufacturing is increasingly moving to Asia and away from the U.S. and European Union.<sup>11</sup>



*Both Western and local companies want to seize Asia-Pacific's potential for rapid development of medical devices.*

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## Device development in Asia-Pacific

With increasing pressure to reduce manufacturing costs and accelerate time-to-market, many device and diagnostics companies are looking to conduct clinical trial operations in Asia-Pacific. Countries such as China, Japan, Singapore and South Korea are seeing an increased interest in clinical trials.

One study found that nearly two-thirds of clinical leaders expect to see clinical trials conducted in Asia-Pacific increasing<sup>10</sup>. This is not surprising given that there is a significant saving on clinical trial costs when conducting drug studies in Asia apart from the following drivers.

Access & retention	<ul style="list-style-type: none"> <li>• Access to patients from different ethnicities as well as socio-economic strata</li> <li>• Retention of patients</li> </ul>
Acceptance & regulatory	<ul style="list-style-type: none"> <li>• Acceptance of APAC data by U.S. and European regulatory bodies</li> <li>• Regulatory standards conforming to global standards</li> </ul>

### Considerations for medical device and diagnostic companies expanding in Asia-Pacific

Asia-Pacific is a widely diverse “market of markets” with a complex and rapidly changing regulatory landscape. Gaining market access in this fertile but fragmented region – home to 4.4 billion people and the world’s two most populous countries – requires a deep understanding of the regulations, culture and payer expectations of each market, and collaborative relationships with payers, providers and vendors to ensure development and commercialization strategies align with regulations and market demands.

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## Regulations

One of the greatest difficulties for foreign device firms in Asia-Pacific is navigating its diverse and fast-changing regulatory environment. Each country often has different regulations for post-market surveillance, quality control and product registration. Regulation of devices ranges from comprehensive to sparse, depending on the market, the device and the national regulatory body in question.

As such, a wise device maker, looking to reach multiple Asia-Pacific markets, should evaluate strategies and processes for clinical trials that enable speedier commercialization. This would require a thorough planning of their clinical and regulatory strategy for Asia.



*Navigating the complex and changing Asia-Pacific regulatory landscape is a key issue for medical device companies seeking to conduct trials in the region.*

## Regulatory environment for medical devices in China <sup>17</sup>

### Chinese medical device classification and pre-market requirements

	Class 2	Class 3
	STED* for technical review	STED* for technical review
	Type testing	Type testing
<b>Class 1</b>	Type testing	Clinical trial data (unless exempted)
Filing with CFDA	Clinical trial data (unless exempted)	Clinical trial approval (selected high-risk device)

\* STED Summary Technical Document: A Summary Technical Document (STED) is a harmonized format for submitting information for regulatory approval of new devices.

### Clinical trial requirements

#### **Previously**

Most imported devices did not require in-China clinical trials – overseas clinical data was sufficient for product registration.

#### **Now**

October 2014 onwards, Class II & III device applications will require in-China clinical trials.

#### **Exemptions**

- Device listed in list of Class II/III Medical Device Exempted from Clinical trials, or;
- Well-designed pre-market clinical trial for product approval in origin country or license holder country with providing the evidence of no racial difference, or;
- Demonstrated safety and efficacy via clinical data of an equivalent China approved device (China Clinical Evaluation Report)

#### **Key features of in-China clinical trials**

- Established Chinese GCP guidelines for Devices and IVD
- Mandatory CFDA notification for clinical trials, regulatory authority may audit the sites
- Trial data generation for Class II & III devices & IVD Class II reagents: 2 or above qualified clinical institutes
- Trial data generation for IVD Class III devices: 3 or above qualified clinical institutes
- Selected Class III high risk devices: clinical trial application pre-approved by the CFDA

## Harmonization on the horizon

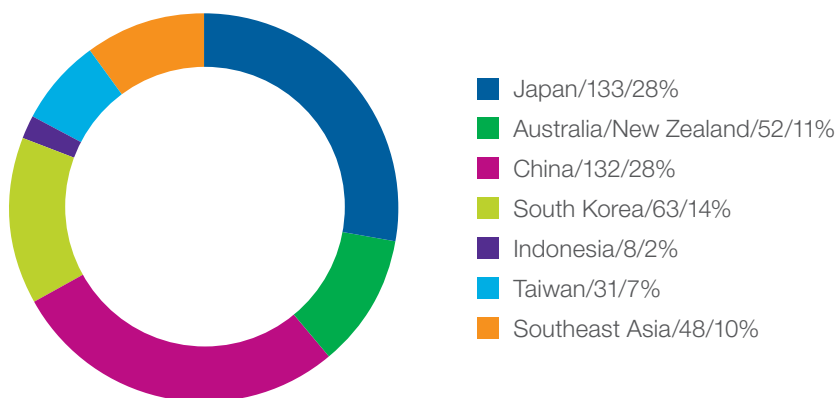
Efforts are under way to harmonize medical device regulations to foster innovation and speed development while protecting patients. The ASEAN Medical Device Directive (AMDD) is designed to allow easier access for medical device companies to serve the 10-nation ASEAN regional market of more than 600 million people.<sup>4, 12</sup>

## Seizing opportunity with confidence: Effective expansion of medical devices and diagnostics in Asia-Pacific

Asia-Pacific's importance to the medical device industry was highlighted in early 2015 when more than a dozen of the world's largest device companies created the Asia Pacific Medical Technology Association. APACMed, based in Singapore, is the first medical device industry association focused solely on Asia.

The association, of which Quintiles is an associate member, aims to work with stakeholders affect positive changes and create a more harmonized device regulatory environment in the region, with the ultimate goal of bringing needed devices to patients faster.

Figure 2 Asia-Pacific device trials by country / region in 2014 (467 total)



Source: BioPharm Clinical and Clearstate CROscape data 2014<sup>14</sup>

Navigating the complex and changing Asia-Pacific regulatory landscape is a key issue for medical device companies seeking to conduct trials in the region – which increased from 238 in 2009 to 467 in 2014 (a 20% increase). Local knowledge and relationships with regulatory bodies in each market are keys to success in managing this complex regulatory environment.<sup>14</sup>

We believe that device makers looking to enter or expand in Asia-Pacific must carefully examine four key areas:

- **Trial essentials**

Designing a successful trial begins with understanding the unique needs and limitations of the local population. Data alone is not enough; expertise and experience are also needed to yield insights with low risks and higher probability of success. Insights into the local trial environment are vital to help choose the best principal investigators and sites, ensuring that the right patients participate in a study that has the optimal design for treatment protocols and endpoints.

- **Reimbursement strategies**

Sponsors should include health-economic and cost-effectiveness data as part of their reimbursement arguments and in trial protocols, particularly in countries where escalating healthcare costs are driving public and private scrutiny from hospitals as well as payers. Such data can help demonstrate the benefits of the device compared to existing therapies or the standard of care, making a strong case for the market value of new devices.



*Designing a successful trial begins with understanding the unique needs and limitations of the local population. Data alone is not enough.*

- **Regulatory requirements**

Regulatory requirements in the region are complex, varying and in a state of evolution. Device makers should assume the need to demonstrate a conformity assessment procedure, often dependent upon the classification of the device. Low-risk products may only require a supplier's declaration of conformity, in which the manufacturer is responsible for ensuring that the product complies with the relevant requirement and produces a written self-declaration statement. Higher-risk products require a conformity assessment of the manufacturer's documentation by the regulatory authority.

Companies must also provide documentation for each agency specific to the device type and its intended use. These assessments can include, but are not limited to:

- Rationale for product classification
- Rationale for risk significance
- Summary pathway to clearance
- Applicable guidance documents
- Comparison to predicate devices (if any)
- Design verification (bench) testing requirements
- Animal study requirements
- Clinical study requirements
- Post-market requirements
- Submission type / content / format requirements / ancillary document list

- **Vendor selection**

One of the most effective way to overcome many of the obstacles that device manufacturers face in the region is to build partnerships with experts who have specific knowledge of the region, its regulatory environment and key therapeutic areas. This targeted knowledge can help identify the best resources, including vendors for conducting trials, training clinical-research associates, data analysis and marketing approval submissions.

When device manufacturers take the time to understand these markets and build strong partnerships with local experts, they make better decisions about their trial design and implementation. In this way, they improve the quality of the trial, and meet time and budget goals, while amassing the best data to support regulatory and commercialization efforts.

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## Conclusion

This high potential of Asia-Pacific – given the favorable economic, demographic and healthcare trends – is attracting lots of attention from medical device manufacturers looking for investment and expansion.

However, the region is not without challenges in terms of regulations and market access, and navigating this complex landscape requires a thorough understanding of the regulations, culture and payer expectations of each market. A company would need to build collaborative relationships with key stakeholders to ensure development and commercialization strategies align with regulations and market demands.

This very complexity and diversity of the Asia-Pacific market makes outsourcing an attractive option to manage costs and risk. A recent survey of major medical device makers reinforces this, showing an increase in outsourcing as local regulators require more in-market trials.<sup>16</sup>

Outsourcing provides companies with expertise in unfamiliar markets and complex environments, making it possible to expand in regions more rapidly and efficiently, and better manage development and market-access issues.



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## About the authors



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Mr. Singh leads the Medical Devices & Diagnostics business in Asia-Pacific for Quintiles. He is responsible for providing solutions to help medical device companies enhance their R&D activities in the region, and has been instrumental in putting together Quintiles' strategic partnerships with several medical device companies in Asia.

Prior to joining Quintiles, he spent six years as the Director of Healthcare Consulting at Frost & Sullivan, where he managed its Asia-Pacific healthcare practice and implemented several strategic consulting projects for multinational and local medical device companies to develop their R&D and manufacturing operations in Asia; support their merger and acquisition strategies; and increase their market penetration. Mr. Singh also serves as chairman for BioSingapore, an industry association that plays an integral role in developing the biomedical sector in Singapore.

Mr. Singh holds a bachelor's degree in biomedical sciences from the National University of Singapore and earned his MBA from the Graduate School of Business, University of Chicago. He also has a graduate diploma in bio-entrepreneurship from the University of Pennsylvania.



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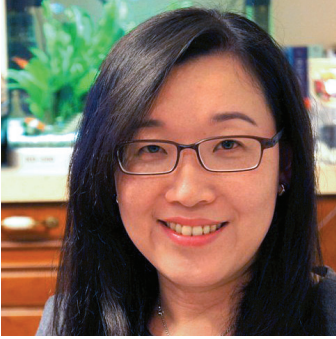
Mr. Shrivastava is responsible for advancing Quintiles' Medical Devices & Diagnostics business in Asia-Pacific. He has more than 18 years' experience in leading business operations and clinical research projects involving medical devices, including pivotal first-in-human studies and post-marketing studies in Asia and the European Union.

Prior to joining Quintiles, Mr. Shrivastava held key positions in the areas of clinical research, portfolio management and marketing and business development with Guidant Corporation and Abbott Vascular. He has extensive experience in coordinating with local regulatory bodies regarding approvals for clinical studies and to commercialize products in Asia.

He earned his bachelor's degree in statistics from the University of Bhopal and his MBA from the International Management Institute, New Delhi.

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Ms. Yuan is responsible for advancing Quintiles' Medical Devices & Diagnostics business in Greater China (China, Hong Kong and Taiwan). She also leads operational teams to support effective high-quality execution of medical devices and diagnostics project delivery in Greater China.

Ms. Yuan has more than 10 years of clinical development experience, including roles as senior clinical monitoring manager; clinical operations manager; clinical resource and project performance manager; and roles in quality, process and training. She is an expert in device regulations and clinical practice, and has strong connections to investigator sites and key opinion leaders. Ms. Yuan also helps medical device and diagnostics customers formulate development and therapeutic strategies to maximize the value of their portfolios.

She earned her bachelor's degree in health science from the University of Western Sydney, Australia, and her master's degree in nursing from the University of Wollongong, Australia.



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