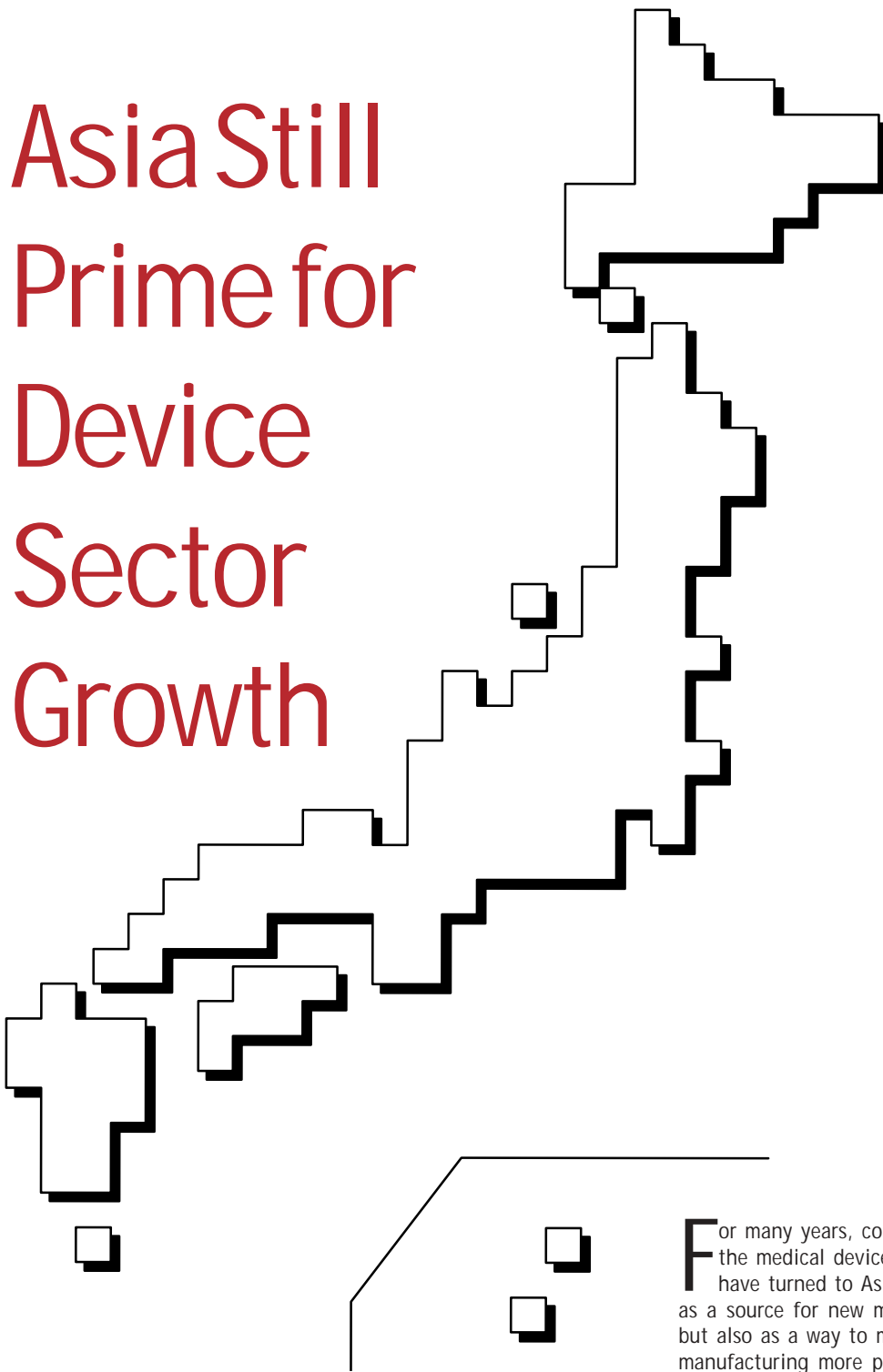


# Asia Still Prime for Device Sector Growth



## Countries Remain Hotbeds for Product Sales and Outsourcing Opportunities

By Christopher Delporte  
Group Editor

For many years, companies in the medical device sector have turned to Asia not only as a source for new markets, but also as a way to make manufacturing more profitable.

As the device market increasingly has become more competitive, companies in the US med-tech sector (as has been the case with many industries before it) have turned to Pacific partners for lower labor costs, reduced research and development costs and even

more economical clinical trials. Historically, Asia has produced lower-tech products and components, but that trend is changing.

While it can be a formidable undertaking for most companies, exporting to or outsourcing in Asia isn't exactly uncharted territory. So it begs the question, is Asia still an "emerging market"?

For Ames Gross, president of Pacific Bridge Medical, the answer is a resounding "absolutely." Founded in 1988, Bethesda, MD-based Pacific Bridge Medical is a medical consulting firm assisting companies with business development and regulatory affairs in Asia.

"More and more companies are selling their devices [in Asia], and more are outsourcing," Gross said, adding that along with the lower labor cost, the skilled labor force and fast-growing economies make for a powerful draw for US companies. For example, an engineer in China or India earns roughly one tenth the salary of a worker employing similar skills in the United States.

Add a quickly aging population (much like the United States), and this only sweetens the pot. Japan's population of people older than 65 years is close to 20%, while it's a little more than 12% in the United States, according to Pacific Bridge Medical.

Nancy Travis, associate vice president, global strategy (Asia) for the Advanced Medical Technology Association (AdvaMed) based in Washington, DC, agrees with Gross' optimism.

"Overall, our membership is very excited about Asia; they see a number of emerging markets there that they think are very promising," she said, referring to US-based companies finding export markets in Asia.

Travis categorized the quickly growing Asian market as “dynamic” and said it remains attractive for American companies.

“Most of the governments [in Asia] are very open to engaging with industry, even in China,” she explained. “Not only are the opportunities growing from a market sense, but many of the countries are just now rolling out medical device policy, so there’s an opportunity to influence how these policies are shaped.”

According to both Travis and Gross, gross domestic product is increasing in many Asian countries and wealth and living conditions continue to improve, which has a snowball effect on the healthcare sector. Standard-of-living increases fuel demand for improved healthcare.

#### By the Numbers

Asia holds 60% of the world’s population, with more than four billion people. Annual economic growth rates in Asian countries have been as high as 10% during the past decade, in comparison to some developed countries where growth has been 4% or lower.

At \$25 billion, Japan is the largest market in Asia and the second largest device market in the world (behind the \$86 billion US market in 2005). It also is the largest export market for US medical devices (ahead of Germany, the Netherlands, Canada, the United Kingdom and Mexico) at a little more than \$3.5 billion in 2005, a 12.5% increase from the year before.

China is the second-largest market and export target for US medical device products in Asia, with far more growth potential, according to analysts. Depending on the source of the information, the size of China’s device market for 2006 is anywhere from \$4 billion to nearly \$8 billion.

South Korea, India and Taiwan

markets trail just behind China, valued in the neighborhood of \$1.5 billion to \$2 billion. However, at \$600 million, US exports to Korea are almost double those of goods sent to India or Taiwan.

#### Asia’s Pros and Cons

Japan, as shown by the market size values, clearly is the 400-pound Gorilla in Asia’s device market. It has an established, sophisticated market with well-educated medical professionals. But Japan’s regulatory system, according to both Gross and Travis, is particularly burdensome and has become even more so recently, making it more difficult, costly and time consuming for US companies to have products approved.

“In Japan, there’s been a big change for small, innovative companies, in particular,” Gross explained. “Japanese regulations favor big companies. The new PAL [Pharmaceutical Affairs Law] has made it much harder for smaller companies.”

In Japan, the PAL, which was changed in April 2005, applies to pharmaceutical and medical device manufacturers.

Travis said the impact has been felt by larger companies as well, and new product applications in Japan have fallen off sharply in recent years due to the increasingly onerous regulatory and reimbursement environment. Some companies, according to Travis, have held off sending the latest technology to Japan, sending previously approved products because of lower reimbursement rates for newer, cutting-edge products.

For reimbursement, Japan will lump newer, more expensive technology into similar predetermined product categories until a correct value can be assessed for new technology. Thus, even if the latest implantable cardioverter defibrillator, for example, offers

innumerable benefits over previous models, Japan’s reimbursement methodology would place the device in the same category as older, less expensive devices. Korea follows a similar model.

As such, some AdvaMed members “aren’t as

companies compared to its Japanese neighbors. The country has experienced increased US device exports and growth in outsourcing. According to Fredrik Nyberg, managing partner at Biomedical Strategy Consultants Pte Ltd. in Singapore, there is a “continued focus on China by US OEMs above all other Asian



enthusiastic” about selling new technology in Japan or Korea, Travis said.

China, on the other hand, while still not operating with an ideal regulatory model, offers more growth opportunities for

markets.”

Pacific Bridge Medical’s Gross said China’s State Food and Drug Administration (SFDA), which regulates drugs and medical devices, has attempted to create a more transparent

regulatory environment by simplifying medical device application and review processes and releasing new product registration requirements.

Many challenges in navigating China's regulatory waters still remain, however, Travis cautioned. Although the SFDA

China also employs a strict product re-registration process. In most countries around the world, unless there's been a significant adverse event or a major product change, re-registration is relatively routine. Regardless of product changes or adverse events, China requires every product to be re-

syringes), of which about 3,000 produce single-use devices and supplies.

Along with China and Japan, significant growth markets in Asia also include India, Malaysia, Singapore, Taiwan and Thailand. "Malaysia and Thailand, in particular, have industry-friendly polices," Travis said. US exports to Singapore more than doubled between 2004 and 2005. Gross also singled out Vietnam as another growth market to watch, particularly for outsourcing.

Nyberg cited some geographical specialization in outsourcing markets. For example, he said Taiwan's core expertise is in general electronics, diagnostics (including point-of-care devices), respiratory care devices and rehabilitation equipment. Malaysia's strengths are in latex products, printed circuit board assembly (PCBA) and box-build assembly. Singapore-based manufacturing service providers tend to focus on electronics, box build and injection molding. Thailand is known for surgical drapes and textiles.

India's strengths remain in active pharmaceutical ingredients and generic drugs, Nyberg said. But the device sector continues to grow, experiencing 10% to 12% growth during the past several years.

"India's indigenous medical device industry is still far behind that of China's, although quality levels are improving in some sectors such as injection-molded IV devices and orthopedic implants," he said. "One major advantage of working with Indian contract manufacturers is language, as most businesses are English-speaking."

Following in China's footsteps, India's government also has been active in setting up special economic zones that offer tax breaks for foreign companies setting up facilities there. According to Gross, Indian pharmaceutical companies are

becoming more FDA compliant, which inevitably will pave the way for device companies there to follow suit.

India also is becoming a leading location for clinical trials. Companies can save up to 50% by conducting trials in India, and patient recruitment usually is easier and faster.

Another growing trend in Asia (particularly in India) that Travis mentioned was an increase in "medical tourism"—the term used for patients who travel overseas for less expensive, quality medical procedures. The surge of patients to these countries has resulted as the rising costs of healthcare have forced an increasing number of US patients to look overseas for medical services.

According to Pacific Bridge Medical, India's medical industry offers more than 15,000 hospitals,

300 medical colleges and more than a million physicians. With the medical tourism in India growing at a rate of around 25% annually, Pacific Bridge Medical predicted that the industry will generate at least \$2 billion within the next decade. In 2004, according to the Confederation of Indian Industry, about 150,000 medical tourists were treated in India.

"It used to be just cosmetic surgeries," Travis said. "But increasingly, there are more serious, big-ticket procedures being performed."

Patients from the United States pay a fraction of the cost in India for a procedure. For example, a \$200,000 heart surgery in the United States would cost \$10,000 in India—often, the discounted price will include travel expenses and recovery time.

#### Other Trends

According to Nyberg, there are a number of other trends to watch during the next few years.



does conduct factory inspections examining safety and efficacy (much like the FDA), the agency also tests individual samples of products. Most developed countries, according to Travis, took a step back from that approach at least 10 years ago.

"If you're relying on product testing, you could have one good batch that's initially tested and then have problems later," she explained. "We've been working with China to reconsider [its] product testing approach, because for our companies it really wastes a lot of time and money."

registered every four years, which takes the form of a full registration with new product testing and factory inspections.

As far as products go, Nyberg said China has developed considerable strengths in several areas including electronics and injection molding. "It has become the world's production house for medical supplies ranging from dressings and surgical textiles to syringes and IV devices," he noted. According to Nyberg, China has about 7,500 medical industry manufacturers (including more than 200 local manufacturers of

Beyond China, he said an increasing number of international procurement offices is being established in Asia by multinational OEMs. In addition, OEMs of more complex medical equipment increasingly are outsourcing complete sub-assemblies to Asia rather than sourcing for just the PCBAs.

"More OEMs are also open to consider complete box-build assembly in Asia, as they are discovering the benefits of sourcing mechanical parts from Asia," Nyberg said.

Another trend worth noting is the localization of

markets, including China.

"As regulatory requirements increase for the marketing of medical devices in the local Asian markets, we can expect quality standards across the local industries to go up," he said.

**IP Concerns**

While increased market growth and expansion of the types and sophistication of products being produced in Asia reflects confidence and comfort on the part of US manufacturers, one important

weighing the risks against the return. He said Singapore is widely regarded as the safest country in the region in terms of respecting IP.

China, however, can be a problem for device manufacturers, he said, adding, "Our general advice to clients is not to manufacture anything in China that, if copied, could jeopardize your entire business. This is particularly important to smaller companies that hold relatively few patents."

make it more difficult for an Asian manufacturer to keep up the pace of copying."

For small, emerging growth companies with a limited number of patents/technologies or a single product, Nyberg recommends against outsourcing an entire product to certain countries, including China.

"In countries with a dubious IP track record, stick to outsourcing subassemblies or non-critical components," he cautioned.

The bottom line, according to Gross, is relationship building. "You need to know who you're



medical device sterilization and testing. Asian contract service providers of medical supplies and disposables increasingly are ensuring that their products are sterilized and tested before shipping them to OEM customers overseas. Today, the bulk of Asian-made supplies is still transported back to the United States for sterilization and testing. Nyberg said he's seeing more opportunities for independent sterilization facilities and testing laboratories.

Nyberg also urged companies doing business (or considering the market) in Asia to familiarize themselves with new medical device regulations coming up in India this year; Singapore, expected at the end of 2006; and Malaysia, expected in 2008. He also predicted major regulatory reviews in other

concern that hasn't lessened is intellectual property (IP) protection. India recently passed new IP laws specifically for the pharmaceutical sector, but the new regulations should have an impact on the device side as well.

One reason many companies haven't moved into higher-tech goods in Asia is concern about IP protection, Travis said.

"Device companies have watched as other industries have had problems in that area. Trade secrets are not well protected at all," she said. "Especially with the speed of innovation in our sector, it is very important to maintain that technical edge and anything that would cause that to be undermined would cause people to really hesitate."

Nyberg said it is a matter of

Intellectual property risks, however, can be mitigated, Nyberg said.

An OEM from the United States, for example, can use Asian manufacturing to manage product life-cycle extensions. Companies can lower costs by producing older models overseas, while new products (for which IP infringements may be a concern) can be produced in the United States.

He also said that large multinational OEMs seeking to manufacture complex devices in Asia with relatively short product life cycles could do so relatively comfortably.

"They are able to spread risk across many product lines," Nyberg said. "In addition, a shorter product life cycle would

doing business with," he said. "Relationships are the key to doing business in Asia."

**Future's Still Bright**

For the foreseeable future, countries such as China and India will have greatest growth potential due to their large populations and developing healthcare system. Also, countries in Southeast Asia represent high-growth opportunities as their economies and healthcare systems continue to improve. As long as companies—whether they're outsourcing, manufacturing or marketing—do their homework first, Asia promises to be a source of significant returns for the medical device industry.