

SOURCING AND MANUFACTURING MEDICAL DEVICES IN ASIA 2014

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I. Introduction

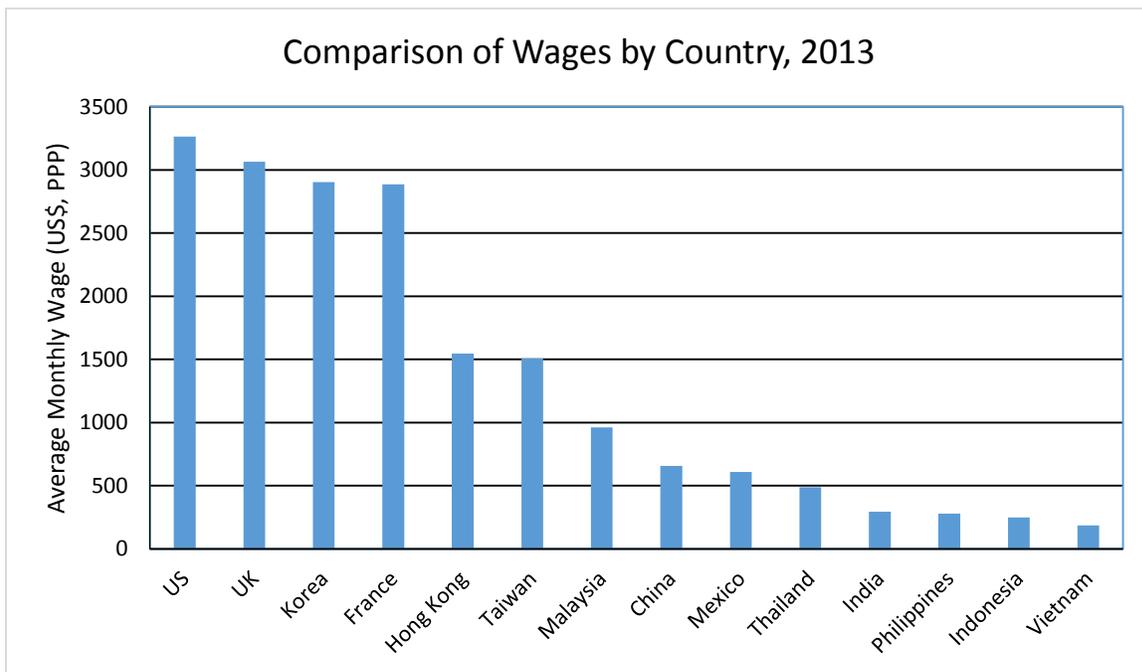
Sourcing and manufacturing goods in Asia has become very common as more and more companies take advantage of the lower overheads, lower labor costs, and increasing technical capabilities available in Asia. Foreign medical companies can procure a wide array of medical device products, components, and raw materials from Asian suppliers at significantly lower cost and relatively high quality. Foreign device makers manufacturing in Asia can also reduce costs and get closer to their Asian customers. However, different business practices, different languages, and different cultures can make business relationships between Western and Asian companies challenging. When outsourcing medical devices in Asia, it may take considerably more energy and effort to achieve a successful, productive, and efficient working relationship. However, the benefits of doing so can be significant. This report helps medical device manufacturers, importers, and distributors better understand how to source and manufacture in Asia.

Topics covered in this report include: how to identify suppliers/manufacturers, how to perform due diligence, what to look for during factory visits, contract negotiations, regulatory requirements, logistics, quality control, and other issues related to the sourcing and manufacturing equation. This report will also offer advice on how to avoid and troubleshoot problems and pitfalls that may arise in the course of the sourcing and manufacturing processes, as well as information about insurance, sterilization, payment arrangements, freight forwarding, and customs.

Furthermore, we have included Microsoft Excel spreadsheet templates on CD-ROM with this report to help facilitate your transportation and shipping decisions when dealing with multiple SKUs being shipped in one container.

II. Why Outsource to Asia?

In general, the most common motives for sourcing or manufacturing medical device products from Asia relate to lower costs. In most Asian countries, labor costs are significantly lower than in the US. China and India in particular offer a surplus of labor; these two countries alone make up 37% of the world's population (2.6 billion of a total 7.1 billion people). Table 1 below shows a cross-country comparison of manufacturing wages for selected countries. In addition, there is also a large and growing pool of talented and educated Asian "returnees" who are capable of handling jobs that may have been reserved for expatriate American or European employees in the past. These workers often do not require salaries or benefit packages as high as expatriate Westerners do, have the cultural advantage of being an Asian citizen, and in some cases have been educated or previously worked in the US or Europe. There are large numbers of highly skilled scientists and engineers (in India and China in particular). And in some countries such as India, the Philippines, and Singapore, many workers speak fluent English. Thus, in terms of personnel and manpower, Asia can provide greater value.



Source: Compiled by PBM

Lower overhead costs, such as rent, utilities, equipment, and raw materials, also contribute to Asian suppliers' ability to manufacture at lower costs. Due to the Internet, the cost and time involved in overseas communication and information transfer has dropped significantly. In addition, shipping goods from Asia to the US and Europe has become easier and less expensive, making it even less cumbersome to source from Asia. Sourcing medical products in Asia also allows companies to take advantage of the cost savings and economies of scale gained from specialized large-scale production. It is clear that there are significant cost savings as well as increased operational efficiency to be gained from sourcing in Asia. If your competitors are sourcing or manufacturing their medical devices in Asia, you may need to do so as well in order to remain competitive.

Another cost advantage of sourcing in Asia is the presence of free trade or special economic zones, which are special areas, generally located along ports or border cities, created to attract foreign investment and development. An example of this is Shanghai's Waigaoqiao Free Trade Zone. Foreign companies who set up shop and invest in these free trade or special economic zones can benefit from incentives such as tax breaks and lowered tariffs or duties. In addition, many Asian countries offer investment incentives to foreign investors that establish factories in their countries. Science and technology research or industrial parks (both public and private) are also becoming common for companies engaging in high-tech research or innovation. Companies also benefit because they can warehouse their goods there.

In many cases, companies may choose not only to purchase goods from Asian manufacturers, but may also want to collaborate with an Asian manufacturer as a sub-contractor or via a joint venture.

In the past, Asia has been known more for manufacturing simpler, low-tech goods, such as shoes, toys, etc. However, there is now a significant degree of variance in the level of capability among the Asian countries. While it is true that there are still plenty of Asian factories churning out low-tech medical products, there are also many companies that are now capable of manufacturing complicated and technologically advanced products. For example, more developed Asian countries like Taiwan and Singapore have the ability to manufacture very high quality products and components, including some sophisticated medical devices and equipment. These countries' technical capabilities have increased tremendously and have made Asia a preferable alternative for sourcing some medical devices. There are numerous factories and manufacturing plants in Asia that specialize in a wide range of medical products.

Asian manufacturers have also become more aware of and familiar with international standards such as ISO or Good Manufacturing Practice (GMP), as well as US FDA and European regulations, and have developed systems and infrastructure to conform to these standards.

All of these arrangements are helpful for the sales end of the business, as Asia itself has become a major end market as well. As Asian countries become even wealthier, their demand for medical devices and other products also increases. In fact, many companies have decided to source or manufacture in Asia because of the easier market access and proximity to their Asian customer base. In addition, by making their products in the region, medical companies will be able to tailor their medical products to the local buyers' needs more easily.

In summary, there are many benefits to sourcing and manufacturing in Asia; however, it is also important to highlight some of the potential pitfalls and problems that may arise. Protection of intellectual property is one of the primary concerns. First of all, there is the issue of intellectual property laws—are they restrictive enough and do they properly penalize those that infringe upon the laws? Second, there is the problem of how strictly or laxly intellectual property laws are enforced in practice. Intellectual property protection has been a clearly recognized problem in Asia, and countries are taking various steps to address it. For example, since China's accession to the WTO, the Chinese government has been working to create more transparency and openness in the Chinese market. However, many problems still exist.

III. Asian Medical Market Statistics

DEMOGRAPHIC DATA

Country	Population (millions) (2013)	Population Growth (2013)	GDP (PPP) (2012)	Per capita GDP (PPP) (2012)	Life Expectancy (Years) (2013)
China	1,351	0.46%	\$12.2 trillion	\$9,100	75
Hong Kong	7	0.39%	\$366 billion	\$50,900	82
India	1,221	1.28%	\$4.7 trillion	\$3,800	67
Indonesia	251	0.99%	\$1.2 trillion	\$4,900	72
Japan	127	-0.1%	\$4.6 trillion	\$35,900	84
Korea	49	0.18%	\$1.6 trillion	\$31,900	80
Malaysia	30	1.51%	\$495 billion	\$16,800	74
Philippines	106	1.84%	\$420 billion	\$4,400	72
Singapore	5	1.96%	\$323 billion	\$60,800	84
Taiwan	23	0.27%	\$894 billion	\$38,400	80
Thailand	67	0.52%	\$645 billion	\$9,500	74
Vietnam	92	1.03%	\$336 billion	\$3,800	73

Source: CIA World Factbook.

HEALTH CARE STATISTICS (2013)

Country	Health expenditure as % of GDP	Total Per Capita Spending on Healthcare (USD)	Hospital Beds per 1,000 People	Physicians per 1,000 People
China	5.5%	\$394	4.0	1.9
Hong Kong	5.3%	\$1,899	5.1	1.9
India	3.9%	\$82	0.9	0.6
Indonesia	2.8%	\$136	0.6	0.2
Japan	9.4%	\$4,833	13.8	2.1
Korea	7.1%	\$2,239	10.4	2.0
Malaysia	4.4%	\$486	1.8	1.2
Philippines	4.1%	\$122	1.0	1.2
Singapore	6.0%	\$2,645	2.7	1.9
Taiwan	6.5%	\$1,358	4.3	1.8
Thailand	4.1%	\$242	2.1	0.3
Vietnam	6.8%	\$114	2.3	1.2

Sources: Various, PBM estimates

ASIAN DEVICE MARKET SIZE (2013)

Country	Device Market Size (US\$)
China	\$13 billion
Hong Kong	\$860 million
India	\$4.2 billion
Indonesia	\$790 million
Japan	\$29 billion
Korea	\$5 billion
Malaysia	\$1.2 billion
Philippines	\$315 million
Singapore	\$540 million
Taiwan	\$2.6 billion
Thailand	\$1.1 million
Vietnam	\$640 million

All data collected by Pacific Bridge Medical

ASIAN PHARMACEUTICAL MARKET SIZE (2013)

Country	Pharmaceutical Market Size (US\$)
China	\$65 billion
Hong Kong	\$7 billion
India	\$20 billion
Indonesia	\$5.9 billion
Japan	\$104 billion
Korea	\$15 billion
Malaysia	\$3.1 billion
Philippines	\$3.4 billion
Singapore	\$840 million
Taiwan	\$5.4 billion
Thailand	\$4.8 billion
Vietnam	\$3.2 billion

All data collected by Pacific Bridge Medical

IV. Growing Asian Markets for Sourcing or Manufacturing Medical Devices

China

When discussing the sourcing of medical products in Asia, we generally think about China as being the “world’s factory.” Although China has in the past been associated with low-tech goods, medical device manufacturers in China have made significant improvements in medical technology and product quality. Chinese factories are more sophisticated than they were before. Some have even received certification from the US FDA as well as other international standards organizations. China’s accession to the World Trade Organization (WTO) in 2002 has been a key catalyst to China’s development efforts. The country now faces the constraints of being a member of an organization run by Western-style “rule of law,” and must take on the responsibility of enforcing the laws. Laws regulating environmental standards are beginning to be enforced more strictly than they were previously. The WTO rules on intellectual property (TRIPS) also compel China to deal with the notorious problem of lax intellectual property right enforcement. In addition, WTO membership has prompted China to ease restrictions on foreign companies that want to market and sell medical products directly in China.

The existing presence of many multinational medical device companies has already attracted support service companies like law firms, accounting firms, and other business services providers. Furthermore, China’s health care system is undergoing reforms and modernization, paving the way for further medical device market development.

The Chinese medical device industry is quickly moving up the ladder of technical sophistication and improving in quality. In particular, GMP standards are currently being implemented officially for sterile and implantable medical devices. On December 16, 2009, the State Food and Drug Administration of China published medical device GMP regulations that became effective on January 1, 2011. China released a draft version of revised GMP inspection assessment standards in December 2013. If adopted, this regulation will make the manufacturing certificate approval system more standardized and strengthen government supervision of medical device manufacturing.

In December, 2010, China’s Food and Drug Administration announced 96 new industry standards that will affect medical devices manufacturing in China, beginning June 1, 2012. Of these new industry standards, 34 are mandatory while the remaining 62 are recommended. The CFDA released 107 more medical device industry standards in 2013 -- 31 mandatory and 73 recommended -- as well as two revised medical device standards. These will come into effect October 1, 2014.

In March 2011, China announced the main objectives for its 12th Five-Year Plan for National Economic and Social Development. One of China’s main objectives is to advance in scientific and technological developments. This includes healthcare. To achieve this, China will be committing 2.2% of the country’s GDP for scientific research and development. This is in tandem with reforms of the pharmaceutical and healthcare systems. In its 12th Five-Year Plan, China targets to have basic medical and health services available to all citizens.

In addition to developing the manufacturing capacity and equipment to make almost any product, China has taken specific policies to attract foreign investment and development. This has been done successfully through the creation of six special economic zones (SEZs), located in Guangdong Province (Shenzhen, Zhuhai, and Shantou), Fujian Province (Xiamen), Xinjiang Province (Kashgar), and all of Hainan Province. Foreign companies that invest in these SEZs can benefit from incentives offered by the Chinese government, such as low income tax rates or tax breaks. For instance, a firm may be exempt from paying income taxes during the first few years of a newly invested project; however, the exemption is granted once the company achieves a certain percentage of its production capacity. These zones are technically not under the jurisdiction of China's Customs authority, so they are not subject to the same customs laws that would apply in China.

SEZs have traditionally been located along the coastal and southern parts of China, but in recent years, the Chinese government has also opened up a number of cities to investment and has designated other zones in more inland regions. In addition to the SEZs, there are also economic and technological development zones (54), high-tech industrial development zones (54), free trade zones (15), and provincial-level development zones (245). For example, the Pudong New Area in Shanghai is the location of the Waigaoqiao Free Trade Zone, the Jinqiao Export Processing Zone, the Zhangjiang Hi-Tech Park, and the Lujiazui Finance and Trade Zone.

In the Waigaoqiao free trade zone, for example, companies may be exempt from paying tariffs, customs duties, and value added taxes. They may also benefit from lower income tax rates, as well as tax exemptions or deferrals, simplified customs procedures, and waived export quotas. The technological development zones have their own industry focus as well; i.e., attracting foreign investment in high-tech industries. Medical device companies can benefit greatly from China's SEZs and free trade zones, as medical devices and equipment are one of the targeted high-tech industries.

There have also been development zones designated for healthcare and medical development. These development zones focus on scientific research and product innovation in life sciences, including medical equipment and pharmaceuticals. An example is the Shanghai International Medical Zone (SIMZ). SIMZ focuses on medical treatment, medical R&D, training and medical equipment manufacturing. The zone was established by the Shanghai municipal government and approved by the Ministry of Health. It is expected to be fully completed by 2015. SIMZ has two main sectors -- advanced medical device manufacturing and modern medical service industry. SIMZ has six functional areas. These are the International Hospital Center, the Industrial Area for Medical Devices and Biomedicine, the International Medical Campus, the Clinical/Medical Research Park, the International Rehabilitation Center, as well as the International Business Center.

A list of China's other medical development zones are highlighted in Appendix G on page 82.

Generally, each economic zone has its own advantages and disadvantages since it targets different companies or types of investment. The incentives may also be different depending on the specific region, so it is important to do appropriate research. Companies should be aware

that there are often conditions attached to the incentives offered in SEZs, such as export quotas, price caps, or other restrictions placed on incentives. More information can be found on China's Ministry of Commerce website (www.mofcom.gov.cn).

According to the China Association of Development Zones (CADZ), 90 state-level economic development zones achieved significant growth from January to September 2011. Financial income of these zones grew over 30% to \$373 billion from the same period in 2010. Total exports and import from the zones also grew by 15% during the same period.

Finally, China's provinces and cities aggressively offer a wide variety of investment incentives of their own. This is particularly true in the parts of China further inland, compared to the coastal areas which have been industrializing for a long time. A company in a "third-tier" area may enjoy great incentives thanks to local governments eager for their business. Wages are also lower the farther one goes from the coast and the major cities. On the other hand, infrastructure and talent are at lower levels there.

China is a key location for establishing a manufacturing base, as well as a huge market for Western companies. Large multinational medical companies such as General Electric, Siemens, Johnson & Johnson, Philips, and Toshiba have all invested in China through joint ventures or wholly foreign-owned enterprises (WFOEs). These large companies dominate the Chinese high-end medical device market.

While there are local device manufacturers all over China, two areas in particular have a high density of manufacturers. These are the Shenzhen area (Guangdong province) and the Shanghai-Nanjing corridor (Shanghai and Jiangsu provinces). Each area has companies making a wide range of devices, but the Shenzhen area is more oriented around electrical devices, whereas the Shanghai-Nanjing corridor makes a greater proportion of disposable products.

On May 6, 2009, the Chinese State Council endorsed a proposal to extend more economic privileges to the Shenzhen SEZ as it seeks to transform the zone into an international metropolis. The State Council approved the proposal on July 2010, and the SEZ has expanded fivefold from 400 sq km to 1,950 sq km, nearly twice the size of Hong Kong. The area includes suburb districts, such as Baoan, Longgang and Guangming, to lessen the inequality between the area inside and outside the SEZ. The cheap land has attracted hi-tech industries and helped to relieve the shortage of land the SEZ currently faces.

While China is generally thought of as the leading location in Asia for sourcing low to medium-tech medical products, other countries have also become attractive (i.e., Vietnam). In fact, as China's capabilities and competencies have improved and developed, the cost of doing business in China has also increased. These changes in the business environment are particularly harmful to low-cost, labor-intensive industries. In late 2008, with the global economic slowdown, many local Chinese manufacturers of toys, plastics, etc. have been forced to shut their doors. However, by contrast, Chinese medical device manufacturers are well positioned in this environment, since China's response will be to develop its expertise and move up the value chain to more sophisticated, high-tech products.

From the perspective of foreign-invested companies in China, some incentives are being lowered. Starting from January 1, 2008, the corporate income tax rate was unified. Previously, most foreign-invested companies paid 15% tax, whereas domestic companies paid 33% (not counting various exemptions). These rates are to be unified gradually to 25% for all companies. However, this is partly symbolic, as most domestic companies do not pay the official tax rate in practice.

In 2010, China expanded and improved its trade relations with multiple Asian countries. The much-anticipated China-ASEAN Free Trade Area (CAFTA) is the largest free trade zone in the world by population and third largest by nominal GDP. By grouping China with the ten ASEAN nations, the area integrates a market with a trade volume of over \$7 trillion and a combined GDP of \$11.4 trillion.

Tariffs were eliminated for 90% of goods traded between China and the more developed ASEAN-6 (Singapore, Brunei, Indonesia, Malaysia, Philippines and Thailand). Tariff reductions for the remaining four ASEAN countries (Cambodia, Laos, Myanmar and Vietnam) will be implemented by 2015. The Pan-Beibu economic zone and the Nanning-Singapore economic corridor, both South China-ASEAN areas, are two examples of emerging economic zones since CAFTA entered formal operation.

China is now ASEAN's largest trading partner. From 2010 to 2012, bilateral trade increased 90% to \$400 billion. This is over 7 times as large as the 2002 trade volume, when the initial agreement was signed, equivalent to annual growth of almost 24%. In the first 9 months of 2013, bilateral trade rose a further 11.6%. Since 2010, China has invested almost \$13 billion in ASEAN countries and set up a \$10 billion China-ASEAN Fund for investment cooperation. China has also lent \$12 billion to ASEAN countries for infrastructure projects. Mutual cumulative investment totals over \$110 billion.

In 2013, China and ASEAN announced new negotiations to upgrade CAFTA by expanding the coverage and scope of the agreement as well as further facilitating trade and investment. The two sides also announced a goal of reaching \$500 billion in trade by 2015, \$1 trillion by 2020 and intra-CAFTA investment of \$150 billion by 2022.

In May 2009, the Chinese State Council approved plans to construct a Haixi Economic Zone (HEZ) on the western side of the Taiwan Strait. The idea was first proposed by Fujian authorities in 2004. The Haixi region encompasses 23 cities from four provinces (Fujian, Zhejiang, Guangdong and Jiangxi), with the largest city being Quanzhou. Its location is not only crucial to improving cross-strait relations, but it also links two major economic areas – the Yangtze and Pearl River deltas.

The investment area between Fujian and Taiwan has shifted somewhat from manufacturing to scientific research and technical services recently. In the first ten months of 2011, the trade volume between the two regions reached \$9.72 billion, up 15% from the previous year. The city of Xiamen provides nearly half of Fujian's total trade volume. Xiamen is currently

constructing new advanced industrial facilities and upgrading others. In September 2009, Fujian authorities also announced that Pingtan Island will become a SEZ.

Fujian and Taiwan have longstanding cultural and business ties. More than 100,000 Taiwan businesspeople live as permanent residents in the province and over 75% of Taiwanese can trace their roots to Fujian.

In April 2010, to further encourage foreign investment, China's State Council released new guidelines for foreign investment in China. These guidelines include tax incentives and easier business procedures, particularly for investments into the lesser developed 'West Delta' region. These are the central and western regions of China. The 'West Delta' comprises Chongqing Municipality as well as the provinces of Sichuan and Shanxi. Existing tax incentives for qualifying foreign companies will continue for new investments into this region. In addition, existing foreign investment in China's coastal regions intending to expand or relocate to the western region will be given government support.

The targeted sectors for foreign investment are high-end manufacturing, high-technology and eco-friendly sectors. With this development, multinationals are encouraged to set up regional headquarters, R&D centers, purchase centers, financial management centers as well as other supporting business units in China.

New tax incentives are now available for qualified foreign invested R&D centers, effective January 1, 2011 through December 31, 2015. These incentives include an import tax exemption (import customs duty, value-added tax and consumption tax on imported equipment specified in the equipment list) and a value-added tax refund on purchases of certain domestically-manufactured equipment. The eligible equipment is specified in the "Equipment List for Scientific Development, Scientific Research and Training."

Taiwan

Since Taiwan is one of the most advanced medical device markets in Asia, manufacturing here will naturally be more expensive than in China or Southeast Asia. The domestic Taiwanese industry is growing, but it is primarily export-oriented and is still somewhat fragmented. Almost 80% of the Taiwanese medical market is made up of imports, and the US contributes more than 30%. It is more common to find high-tech or sophisticated medical equipment being produced here. Taiwan-made devices with high penetration on the global market include contact lenses, glucose test strips and blood glucose meters.

The Taiwanese government also has tax incentive programs to encourage foreign companies to manufacture in Taiwan. For example, companies in strategic or emerging industries (including healthcare) that meet government criteria can be exempted from corporate income tax for five years starting from their first year of operation; alternatively, they can choose to receive a 20% tax credit for capital investment. Tax credits are also given for 30% of R&D expenditures. There are also a variety of R&D grant programs available in Taiwan.

Since President Ma Ying-Jeou took office in May 2008, Taiwan has relaxed more than 520 economic regulations in such areas as taxes, capital market development and employment of foreign workers. Significant initiatives include the reduction of the business income tax from 20% to 17%. This is the second lowest business income tax in Asia, after Hong Kong. The government also implemented the Industrial Innovation Act, which promotes research and development activities by offering technical support and financial incentives.

Generally, Taiwan has more than 70 special industrial zones in operation. There are three main types of special industrial zones: science-based industrial parks (13), export processing zones (4), and industrial parks (61). In 2011, the science parks had combined revenues of NT\$2 trillion (\$66 billion), equivalent to more than 10% of Taiwan's GDP. The same year, the 61 industrial parks had an output value of NT\$6 trillion (\$198 billion).

Export processing zones are under control of the Export Processing Zone Administration Office and the Ministry of Economic Affairs (MOEA) (www.moea.gov.tw). Industrial parks are started by the Industrial Development Bureau (IDB) (www.moeaidb.gov.tw), local governments, or private firms. These parks do not offer special investment incentives, but are meant to develop clusters of talent, logistics, support services, etc., to make them favorable sites to locate. Also, they offer preferential rent rates.

There are three core biomedical parks in Taiwan. They are the Hsinchu Science Park, Central Taiwan Science Park and Southern Taiwan Science Park, each having its own satellite industrial clusters. There are a growing number of companies operating in these parks that focus on information and communications technology, biotechnology, precision machinery and optoelectronics.

The Taiwanese government is focusing on driving the country's medical device industry to advanced, high-value products. For several years, the IDB has collaborated with the Industrial Technology Research Institute (ITRI) to help medical device companies develop and market new products. Their assistance extends to areas like small-scale test production, clinical trials, frontier research, providing market information, drafting mass production plans, and resolving issues with certification of devices.

The Taiwanese government has identified biotech as a key industry for promotion. The IDB is encouraging biotech in a number of ways, including inviting international investment, identifying new products in which Taiwan has a competitive advantage, and coordinating export alliances.

The biotech industry production value in 2011 was NT\$80 billion (about \$3 billion). It had a relatively large percentage of the global market share for pre-filled syringes, electronic thermometers, and micro-cellulose (MCC) products. By 2015, the IDB hopes to increase production value to NT\$650 billion (about \$22 billion) and to develop niche products, such as clinical biochemical analysis instruments and generic biomedicines.

In November 2009, the Ministry of Transportation and Communications (MOTC) (www.motc.gov.tw) filed an application to make Suao Port in northeastern Taiwan a free trade zone. The approval was granted in April 2010 and Suao Port free-trade zone began operations in May 2010. Taiwan officials expect the port to evolve into a green energy industry zone, creating about NT\$6.8 billion (\$223 million) in trade through 2015. So far, Suao Port has received about \$25 million in investment. The Suao Port is Taiwan's sixth free trade port zone, after Taipei, Keelung, Kaohsiung, Taichung and Taoyuan.

Philippines

The Philippines claims to have some of the most liberal foreign investment policies and regulations in Southeast Asia. Restrictions on foreign investments are generally not based on the foreign investor's nationality, but on the percentage of foreign ownership for a particular project. Although foreigners are not discriminated against in general, they can only own a certain percentage of projects. For example, 100% foreign ownership is permitted for export enterprises (where at least 70% of the production is exported). However, foreign ownership is limited to 60% for industries such as financing companies and investment houses, 40% for many other sectors such as utilities, and not permitted at all for mass media and smaller retail trade (less than \$2.5 million capitalization).

The incentives granted to companies can be obtained from the Board of Investments (BOI) (www.boi.gov.ph). The BOI grants incentives to projects in those industries or activities targeted in its annual Investment Priorities Plan. Examples of these priority areas are: export activities, health products and services, science and technology related research and development, and engineering. So-called "pioneer" activities are projects that involve the production of goods and services that are not yet available in the Philippines, or use any methods of production, process, or design that is not yet in use in the Philippines. "Non-pioneer" activities are products and services that are already available in the Philippines and considered to be important to the national economy.

Foreign companies registered with the BOI can benefit from incentives such as: 6 years of income tax exemption (for pioneer companies; 4 years for others); simplified customs procedures; duty-free importation of capital equipment as well as parts or components used for export production; tax credits for purchasing raw materials; and exemptions from wharfage duties and export taxes. In addition to the advantages available to new firms, *expanding or modernizing* firms can also register to receive 3 years of income tax exemption, but only on the amount of their new sales or new investments.

The Philippine Economic Zone Authority (PEZA) (www.peza.gov.ph) also offers incentives to foreign investors who locate their manufacturing facilities in the Philippines' economic zones. Firms in these areas, besides usually receiving the above incentives from the BOI, have the option of paying a simple, unified tax of 5% of gross income instead of the many complicated taxes and fees assessed at the national and local levels. This perk is provided by the Special Economic Zone Act of 1995 (Republic Act 8748). The Omnibus Investment Code of 1987 provides at least a four-year income tax holiday to investors, with a maximum of two

additional years if the investment increases for the same activity. To be granted these incentives, companies must follow an application procedure (about 1-2 months) that is described in more detail here (<http://www.peza.gov.ph/images/stories/export1.jpg>).

Nevertheless, in March 2011, the government proposed a Fiscal Investments Reform Bill to harmonize the country's tax incentive schemes. Under the proposed scheme, income tax incentives to investors would be reduced regardless of location. The unified tax of 5% on gross income would also be capped to a maximum of 25 years at reduced rate. The aim is to remove any location bias in favor of economic zones or free ports.

Economic zones in the Philippines can be established by the government or registered by private groups. The vast majority are privately held. As of December 2012, there were 277 economic zones in the Philippines, including 178 information technology parks, 65 manufacturing economic zones, and two medical tourism parks. New economic zones are also being developed. There are more than 260 American companies operating at in Philippines' special economic zones.

In September 2009, the Filipino House of Representatives adopted Senate bill 2118 to convert the Bataan Economic Zone into an autonomous free port (FAB). This will be the sixth free port in the Philippines and the third in Central Luzon.

The Bataan Economic Zone will be modeled after the Subic Bay Freeport Zone. The Authority of the Freeport Area of Bataan (AFAB), a state-run firm, will manage the zone instead of PEZA. In addition to the incentives offered by the two acts described earlier, all goods that enter the zone's jurisdiction will be exempt from tariffs as long as they remain there. In other economic zones, only goods used in production are exempt from tariffs. The Bataan Freeport announced in early 2014 that it was planning a \$35 million containerized cargo port. Year-on-year investments in the Bataan port rose five-fold to \$47 million in 2013.

Thailand

Thailand's Board of Investment (BOI) (www.boi.go.th) oversees the granting of special guarantees, tax exemptions, and other investment incentives for foreign investors. Companies interested in receiving investment incentives must submit certain applications and paperwork to the BOI. Certain factors can increase the chance of receiving promotion. Such factors include whether the project will strengthen Thailand's industrial and technological capacity, utilize domestic resources, create employment opportunities or earn foreign exchange. In 2013, foreign investments increased 42% year-on-year, with the US accounting for 40%.

Incentives are granted on a project-by-project basis contingent on certain conditions being met. For smaller companies (initial capital under 500 million baht, or about \$16 million), these conditions are: at least 20% value-added; liability-to-assets ratio of no more than 3 to 1; using modern processes and machinery; and adequate environmental protection systems. For larger companies, the above conditions are also examined, but decisions are more ad hoc.

Incentives vary depending on what region of Thailand a firm is in, as well as whether it is located in an industrial estate. The period of corporate income tax exemption, for example, varies from 3 years in the greater Bangkok area to 8 years in more remote provinces. Import duties on machinery and raw materials can also be reduced or eliminated. There are currently more than 50 industrial estates in Thailand with over 4100 factories. The majority of these industrial estates are privately run. In early 2014 the Thai government announced that five new industrial estates would be built by the private sector at a cost of \$10 billion.

In September 2009, the BOI granted additional privileges to high potential business activities, including technological development and healthcare. Healthcare promotion products, such as hygienic paper, will be eligible for incentives similar to those offered to medical and pharmaceutical manufacturers. Privileges include corporate income tax exemption according to zones and import duty exemption for machinery. Eligible projects must meet Good Manufacturing Practices (GMP) standards within two years from inception.

In June 2010, the Thai government revised the incentives offered for investment in *Regional Operating Headquarters*. This was to attract foreign businesses to set up regional headquarters in Thailand. In July 2010, the government also signed a co-operation agreement with the Office of Public Sector Anti-Corruption Commission to enhance the protection of foreign investors and entrepreneurs from corruption. This entails greater information sharing and opening of new channels for investor complaints on corrupt government officials.

Thailand is looking to strengthen its medical services industry by enhancing quality control on medical equipment and devices. Thailand has about 1,700 medical device companies. 80% of the medical device manufacturers are locals. However, Japanese manufacturers have started to penetrate the Thai medical device market. Most of the devices manufactured in Thailand are exported to neighboring ASEAN countries. To improve the quality of design, research and development of medical devices, the government is considering establishing a medical device institute. Currently, Thailand has a Science Park managed by the Ministry of Science Technology. This park focuses on research and innovation in technology, with four full-time national research centers and more than 60 corporate investors. There are also tax exemptions and incentives associated with investments in the Science Park.

India

India is another Asian country that stands to benefit from the increasing trend to source and manufacture medical devices in Asia. With a long history in pharmaceutical development, India already commands a large portion of the drug manufacturing market, and is one of the largest world exporters of active pharmaceutical ingredients. It has taken many steps to impose standards that compare to the regulatory standards of the US and Europe. In the past, most medical devices were not regulated, but the Ministry of Health recently reclassified several implantable medical devices to be regulated as drugs.

The medical device market in India has been growing at a rate of more than 10%. The market has a projected growth rate of 15%, reaching \$10 billion by 2022. There is already a significant

manufacturing base in India for simple products such as disposable medical supplies. India offers low costs in many respects, especially labor, since wages are even lower than Chinese wages for manufacturing workers. On the other hand, the country has significant infrastructure defects compared to China, such as poor transportation and spotty electricity provision. Still, technical sophistication is growing, with large companies like GE Healthcare surmounting obstacles to make X-ray and other imaging equipment there.

Although SEZs have existed in India since 2000, there were no official rules until the Indian government passed the Special Economic Zones Act in 2005 (with SEZ rules approved in 2006). The act delegated powers to the Board of Approval, consisting of 19 members and headed by the Secretary of the Department of Commerce (sezindia.nic.in). The Board reviews all proposals from SEZ developers and companies interested in investing in existing zones.

Foreign companies that invest in the SEZs are entitled to 100% income tax exemption for the first 5 years, 50% tax exemption for the next 5 years, and up to 50% of any reinvested profits for the following 5 years. They are also exempt from customs duties on imports of capital goods, raw materials, or consumables, as well as central and state sales taxes and other state taxes. However, the policy has been heavily criticized domestically and the government has diluted these incentives. In 2011, SEZs were also made accountable for India's dividend distribution tax and minimum alternative tax. Current legislation in Parliament would further reduce tax benefit incentives for SEZs.

A series of reports in 2013 hinted that the government might repeal its 2005 SEZ legislation. Instead, a 2013 amendment to the SEZ rules has tried to increase incentives for setting up SEZs, including reduced area requirements for SEZs, flexibility in setting up additional units in an existing sector specific SEZ, extended duty exemptions, and introduced an exit policy that would allow sale of SEZ units and ownership transfer.

Presently, India has a total of 589 approved SEZs, of which 389 are notified and 170 are functional. Of the functional SEZs, seven were set up by the central government: Kandla (Gujarat), SEEPZ (Mumbai), Noida (Uttar Pradesh), MEPZ (Tamil Nadu), Cochin (Kerala), Falta (West Bengal), Visakhapatnam (Andhra Pradesh). The remaining functional SEZs were developed by private companies or by the state government. Five SEZs currently specialize in pharmaceuticals and/or biotechnology; many approved but not yet functional SEZs will also specialize in those industries, including one at Kolthur (Andhra Pradesh) and one in Gurgaon (Haryana).

In January 2014, more than 20 SEZ developers asked the government for more time to begin production in their SEZs. This includes several pharmaceutical companies such as Cadila Healthcare and Dr. Reddy's Lab, which have argued that they have not had enough time to receive the mandatory regulatory approvals.

In 2012-2013, exports from Indian SEZs increased 29% to almost \$90 billion, after an increase of 17% in 2011-2012. SEZ exports accounted for almost 30% of the country's total exports in 2012-2013 -- India's total exports actually dropped 1.8% over the same period. Total

investment in SEZs increased to \$4 billion in 2012-2013, while the zones have generated over 1 million jobs.

The Indian medical device industry has pressed for an SEZ specifically for medical device production in the past. In 2009, the Indian government announced plans to set up a dedicated zone for medical devices manufacturing near Sanand in Gujarat. The Greenfield Medical Devices and Equipment Park is estimated to cost more than \$65 million. A feasibility study was conducted in 2010, but it is still waiting for final approval from India's Planning Commission.

The government also proposed to have a National Center for Medical Devices (NCMD) located in Ahmadabad. This center will help develop good manufacturing practices and other quality control standards. It will also deal with standard issues such as sterilization and process validation. The NCMD is aimed to complement the Greenfield Park and will focus on product development and assessment.

In January 2010, the Chennai-based medical device manufacturer Trivitron set up a 25-acre medical technology park in Irungattukottai, near Chennai. The park is designed to house 10 international medical technology manufacturers. A range of medical devices, including ultrasound systems, x-ray equipment, implantable devices, in-vitro diagnostic reagents and cardiology diagnostic instruments, are expected to be manufactured in the park.

Singapore

Singapore's biomedical industry is one of the country's fastest growing segments. With a population of just 5 million people, more than 10,000 people are employed in the manufacture of drugs and medical devices. Singapore is a very good location for sourcing medical devices. The country has a talented pool of scientists, researchers, and engineers. This is supported by highly developed electronics and precision engineering infrastructure, as well as the strong presence of support services such as sterilization and logistics companies. Official data show that Singapore's biomedical industry contributes more than \$21 billion to the country's total manufacturing output. In 2011, the industry contributed 5% of GDP growth.

Many large medical device companies have chosen to manufacture their products in Singapore, including Applied Biosystems, Baxter, Becton Dickinson, CIBA Vision, Fisher Scientific, Medtronic, and Siemens Medical Instruments. In addition, Singapore provides strong protection of IP rights, which is not typical in many Asian countries. On the negative side, wages in Singapore have skyrocketed over the last five years and many commodity medical devices can no longer be made here.

The Economic Development Board (EDB) (www.edb.gov.sg) of Singapore is an agency that formulates strategies to promote and sustain Singapore as a global hub for business and investment, and it offers a number of incentives for companies locating their manufacturing operations in Singapore. For example, the Pioneer Incentive grants full exemption of corporate taxes for up to 15 years on qualifying profits for strategic projects that lead to the creation of

“desirable industries” in Singapore. Higher value-added business activities that generate significant economic spin-offs to Singapore are encouraged through the Development and Expansion Initiative (DEI), which offers 5% - 10% reduced corporate tax rates on qualifying profits that exceed a certain predetermined level during a set period of time. The Investment Allowance (IA) is a 30% - 50% cost allowance for new equipment to improve productivity or technology. Funding aid is also given to R&D expenditures for Singapore-registered businesses.

The Singapore Government (business.gov.sg) has also established a number of incentives for foreign companies. Foreign companies that establish Regional Headquarters (RHQ) or International Headquarters (IHQ) in Singapore enjoy lower corporate tax rates. RHQ status lowers the rate to 15% from 18%; IHQ status lowers the rate to less than 10% from 17%.

Starting 2005, new companies that meet certain qualifications have been exempt from income tax for the first SGD\$100,000 (about \$80,000) for each of the first three years of assessment (YA). Beginning in YA 2008, 50% income tax exemption have been given for the next SGD\$200,000 (about \$160,000) for each of the first three consecutive YAs. In order to receive the incentive, the company must be incorporated and a tax resident of Singapore, and there must be no more than 20 shareholders.

The Biomedical Sciences Group of the EDB focuses particularly on developing the biomedical sciences sector in Singapore (medical devices, biotech, pharmaceuticals, and healthcare). In conjunction with other public/private entities, its goal is to make the biomedical sciences sector a “key pillar” of Singapore’s economy.

Biopolis, Singapore’s premier biomedical research hub, is located near Buona Vista. The research hub focuses on biomedical sciences and houses both public and corporate research laboratories. Apart from key government agencies and publicly-funded research institutes, other organizations that have established new facilities at Biopolis include the Johns Hopkins University arm in Singapore, Novartis, GlaxoSmithKline and Isis Pharmaceuticals. Biopolis completed construction on its third phase in 2010, adding another 40,000 square meters to the area. Now in its fifth phase, Biopolis has space of over 3.5 million square feet.

Other biomedical hubs include Singapore’s Tuas Biomedical Park, which was designed for bulk active pharmaceutical, bio-pharmaceutical manufacturers and all biomedical-related companies. The Tuas Biomedical Park is already home to a number of the world’s top pharmaceutical companies, including GlaxoSmithKline, Merck, Novartis, Pfizer, Roche, and Wyeth. But it is becoming a growing base for medical device companies as well: CIBA Vision also has a manufacturing and logistics center there.

In April 2008, SPRING Singapore (www.spring.gov.sg) (another governmental investment promotion bureau) announced a new program to fund small to medium-sized companies in commercializing their concepts. The Technology Enterprise Commercialization Scheme (TECS) is available for start-up companies or research scientists and engineers. Start-up companies must be incorporated in Singapore, have at least 30% Singaporean ownership, and a maximum of 200 employees, among other requirements. It offers up to SGD\$250,000 (about \$200,000) to help companies demonstrate proof of concept, or up to SGD\$500,000 (about

\$290,000) to demonstrate proof of value. The medical device industry is one of the industries targeted for this assistance.

In June 2010, the development of a new medical park, MedTech Hub was announced in Singapore. The Hub is being developed at Tukang Innovation Park in the Jurong Lake District. MedTech Hub aims to bring major industry players together, where companies are able to collaborate and reduce costs through mutual co-operation. The Hub will provide common facilities such as shared utilities, testing laboratories, sterilization and a centralized warehouse. Initial estimates for the cost of the Hub are between SGD\$60 million and SGD\$80 million. The first phase yielded a size of almost 80,000 square meters and was completed in late 2013.

Malaysia

Malaysia's advantages in medical device manufacturing are comparable to Singapore's. With English as a common business language, it has a technically advanced manufacturing base and a number of English speakers with technical or scientific training. Its government is also focused on export promotion and attracting international business. Singapore is significantly more business friendly and internationalized than Malaysia. On the other hand, Malaysia has a larger population, cheaper land and lower wages, making large-scale manufacturing more feasible. B. Braun, for example, has several large manufacturing centers in Malaysia.

The Malaysian Industrial Development Authority (MIDA) (www.mida.gov.my) has identified medical devices as a priority sector for further promotion and development. A strong establishment of supporting industries, such as sterile medical packaging and precision engineering, positions Malaysia as a potential hub of medical device manufacturing. There are currently more than 180 medical device manufacturers in Malaysia.

Malaysia's medical industry is currently concentrated in rubber-based products, as the country is the world's leading producer of medical gloves and catheters. The Malaysian government hopes to encourage the development of higher-end medical devices, as the manufacturing value chain expands from basic processes to R&D, design and prototyping, distribution and logistics. They are particularly interested in increasing production of devices in these areas: Cardiovascular, orthopedic, in-vitro diagnostic, wound care, ophthalmic, home care, and electromedical equipment.

In March 2012, the Ministry of Health (MOH) established the Medical Device Act (Act 737), setting new regulations for medical devices that now require mandatory registration. To be phased in over the next two years, it requires both imported and locally manufactured devices to be registered with the Medical Device Control Division (MDCD). In addition, all medical device establishments are required to register and obtain licenses from the MOH. This new act is meant to promote further development and better regulation standards for Malaysia's medical device market. Separate legislation set up a new Medical Device Authority, which is responsible for enforcing Malaysian medical device regulations.

Through MIDA, the Malaysian government offers incentives to foreign medical technology companies manufacturing and investing in Malaysia.

Malaysia also has many free trade zones of different types. There are over 200 industrial parks developed by private developers or government agencies, such as State Economic Development Corporations (SEDCs) or Regional Development Authorities (RDAs). In April 2012, the first joint China-Malaysia Industrial Park was unveiled in Qinzhou, China. This project is expected to begin operations in 2014. There was a groundbreaking ceremony for a second park, the Malaysia-China Kuantan Industrial Park, in February 2013. Both projects are projected to cost almost \$1 billion each. There are also Free Industrial Zones and Free Zones.

In a Free Industrial Zone (FIZ), exports of finished products and imports of raw materials mostly bypass Malaysian customs (except for goods prohibited for import); there are currently 18 FIZs. To be located in an FIZ, at least 80% of production must be exported, with raw materials mainly imported.

A Free Commercial Zone (FCZ) has the same customs exemption, but allows both manufacturing for export and commercial activities such as trading, repacking, and reshipment. The first FCZ opened in Klang (the port serving the Kuala Lumpur area) in 2006. There are now 17 FCZs in Malaysia.

In August 2009, Malaysia launched its first special economic zone in the East Coast Economic Region (ECER). Although the SEZ only covers 5% of the ECER's total area (about 3,500 square kilometers), the government's 12-year Master Plan aims to create more than 200,000 jobs and attract RM90 billion (about US \$26 billion) worth of investments by 2020. The SEZ is projected to contribute RM20 billion (about US \$6.5 billion) to the national GDP.

The SEZ is modeled after the Shenzhen SEZ in China. Focus is on manufacturing and industrial activities. It offers customized incentives, such as higher expatriate hiring rates for management positions, 10-year tax exemptions, 100% investment tax allowances, and import and export duty exemptions. Studies are also underway for establishing a second SEZ in the ECER region. This is to encourage integrated development. There are also several planned projects in the SEZ, including an Herbal & Biotech Product Cluster.

Vietnam

Vietnam has become a viable and lower cost alternative to China as a sourcing/manufacturing location. Vietnam is beginning to play the same role to China that China once did to the more developed countries. It offers a large population and very cheap labor, up to one-third cheaper than in China. Vietnam also has a business environment that has a more lax regulatory enforcement. Despite an increase in the minimum wage announced at the end of 2013, Vietnam's wages are still competitive regionally.

Since China's accession to the WTO, it has been forced to take regulations on intellectual property and environmental standards more seriously. While labor standards in China's

factories are quite low, those in poorer countries like Vietnam can be even lower. This is particularly so as economic development and rising living standards push up wages in the traditional manufacturing areas of coastal China. This adds up to lower costs. Many Chinese business owners have begun to relocate some factories to Vietnam.

Vietnam offers an advantage because it is undergoing a similar transformation to that of China, from a central economy to a market economy. However, Vietnam is at an early stage of this transformation. Many Taiwanese-owned companies, which gravitate quickly to cheaper manufacturing sites, are now moving to Vietnam from mainland China.

Most domestic Vietnamese medical device makers focus on low-end products, such as medical disposables, hospital garments, and hospital furniture. There are only a few foreign-owned or joint-venture firms making higher-end devices such as imaging equipment. Most local demand for sophisticated products is met by imports. However, with economic growth at levels almost as high as China's, this will probably change in the future as infrastructure improves and local demand increases.

In early 2007, Vietnam officially joined the WTO. As part of the entry requirements, intellectual property laws were overhauled to comply with international standards in mid-2006. However, as in China, enforcement of these laws remains weak, and careful internal procedures are necessary to protect IP.

Vietnam has a variety of industrial and economic zones around the country, which have received over \$100 billion in foreign direct investment and combined export production worth almost half of Vietnam's total export turnover.

Vietnam has 289 Industrial Parks, 4 Export Processing Zones, and 3 Hi-Tech Zones. They are concentrated in the south around Ho Chi Minh City, in the north around Hanoi, and along the central coast between provinces Thea Thien (Hue) and Khanh Hoa. In these zones, enterprises can receive a 2 to 4 year corporate income tax holiday, and pay a 50% reduced tax rate for 6 - 9 years thereafter. These benefits can also be available to companies outside investment zones in promoted industries. Many import duties and value-added tax on equipment and materials can also be exempted or refunded. Decree 164, which went into effect January 1, 2014, updated some regulations for Industrial Parks and Export Processing Zones -- in particular, regarding domestic sales, construction materials, and trading licenses.

Vietnam also has 15 Economic Zones and 28 Bordergate Economic Zones. On May 1, 2009, Vietnam increased incentives for companies investing in Bordergate Economic Zones. Large construction projects investing in important infrastructure and public works will be considered government projects. These projects will be eligible for a portion of the state budget and land rental exemption. Other projects invested in the zones will be exempt from land rental for 11 years, with some up to 15 years.

New projects will receive a priority tax level of 10% within 15 years and a four-year income tax exemption. Products and services which are made, consumed, imported, or exported from these zones will be exempt from the value added tax (VAT). Vietnam plans to more than

double the number of Bordergate Economic Zones by 2020. In April 2012, a plan to construct a new Bordergate Economic Zone was approved. The Thanh Thuy Bordergate Economic Zone is to be constructed in the Ha Giang province and completed by 2030. Recent regulations, effective from January 15, 2014, addressed income taxes, land use levies, and land rent payments in Bordergate Economic Zones.

In the meantime, Vietnam is reconfiguring several of its existing zones. Vietnam's overall foreign investment has burgeoned, tripling between 2009 and 2012 to over US \$80 billion. Master plans were revised to turn Dung Quat Economic Zone in central province Quang Ngai and the Moc Bai Bordergate Economic Zone in southern province Tay Ninh into economic, cultural and technological centers within 10 to 15 years.

The Dong Dang Bordergate Economic Zone in the northern Lang Son province is home to two international border gates and seven border markets. Located near Hanoi and advantageous for cross-border trade, the zone has not yet achieved its potential in foreign investment. Development for the Lang Song region is projected to continue until 2020, including a plan to cooperate with Guangxi, China in the Dong Dang – Pingxiang border region.

Hence, the Department of Planning and Investment (www.dpi.hochiminhcity.gov.vn) is increasing access to information by allowing investors to register online. New logistics, such as a highway connecting Hanoi and Lang Son's Huu Nghi international border gate, and a railway route between Vietnam and China's Nanning City are in the works.

In addition, the Lang Son People's Committee stated that investors would enjoy minimal land lease taxes as low as 1% the normal rate, as well as simplified business procedures. The province will offer training subsidies for local workers for new investment projects. In an effort to promote advertising in provincial media outlets, large technology transfer projects are also eligible to receive a VND500 million (about US \$27 million) subsidy. Lang Son province has almost 50 foreign-investment projects.

The Vietnamese Prime Minister has also been approving plans for new economic regions. For instance, a new economic zone specializing in biotechnology is being built in the Mekong Delta. The zone will include Can Tho City and three provinces: An Giang, Kien Giang and Ca Mau. There is also a two-phase plan to develop an economic belt along the northern coast. The first phase focused on establishing basic infrastructure from 2009 to 2010. During the second phase, key projects, such as an airport, three ports, tourist and entertainment centers, and one economic zone by the Chinese border, will be built. This phase will last from 2011 to 2020. With the construction of this economic belt, the northern coastal region's economic growth is expected to be 1.5 times higher by 2020, contributing up to 7% of Vietnam's GDP.

Indonesia

Indonesia, a country of over 250 million people, is developing rapidly. However, the growth of medical device manufacturing is still at a fairly low level. A large proportion of the medical device market is made up by imports, and domestic manufacturing is dominated by disposable

commodities such as hypodermic needles. However, it is the site of some foreign production. An example is Paramount, a major Japan hospital-bed maker which has a large factory near Jakarta.

100% foreign investment is allowed for most manufacturing activities in Indonesia, including medical devices. However, foreign ownership of distributors is not allowed. Selling devices in the Indonesian market requires the help of a local distributor.

There are a number of tax benefits available to manufacturing enterprises, though they are not as favorable as in some other Asian countries. If approved by the Investment Coordinating Board (BKPM) (www.bkpm.go.id) or a local Office of Investment, new or expanding companies can have their taxable income reduced by 30% for 2-10 years, receive a tax credit for 5% of capital investment, and have their import tariffs capped at 5% of value. Exporting enterprises and enterprises in “bonded zones” (free trade zones) can also get exemption from import duties and sales taxes on raw materials.

In September 2009, the Indonesian government enacted the Special Economic Zones (SEZ) Law, an extension of a 2007 law on free trade zones. The law establishes a new government body, the National Council on SEZs, to oversee the development and promotion of those regions.

Indonesia currently only has Free Trade Zones (FTZ), located mostly near Singapore, including Batam, Bintan and Karimun islands (BKK), and Sabang Island, the oldest FTZ. The law also envisions eventually transforming the FTZs into SEZs. In November 2011, the government released a plan to develop at least five more SEZ before 2015, targeting the regions of Mandalika, West Nusa Tenggara, Bitung, North Sumatra, and Banten.

The SEZs will offer greater incentives than those offered in the FTZs. Companies will be exempt from paying value added tax (VAT), sales tax on luxury goods, and import duties. Investors may qualify for lower land and property taxes, which is currently set around 0.5% of the taxable value. Firms will no longer be exempt from import duties on raw materials and exports of finished products as they are in FTZs. However, goods produced in SEZs can be sold in the domestic market.

V. Medical Device Companies That Have Outsourced in Asia

Over the past two decades, numerous medical device companies have decided to source products from Asia or go overseas to invest in joint ventures or set up their own manufacturing facilities. Included below are some companies that have recently begun or expanded sourcing or manufacturing operations in Asia.

Accellent (Wilmington, MA) opened a 65,000 sq. feet medical device manufacturing facility in Penang, Malaysia in November 2011. The company purchased and outfitted the plant in less than 12 months thanks to support from the Malaysian Industrial Development Authority, Invest Penang and several departments within the State Government of Penang.

B. Braun Melsungen AG (Melsungen, Germany) began constructing a new medical production facility in Hanoi, Vietnam, in September 2008. The facility is a two-story structure with 15,200 square meters of space. The annual production capacity was expected to double from 100 million to 200 million IV administration sets between 2010 and 2012.

B. Braun also has significant operations in India. In 2007, it established a manufacturing plant in the Chennai area in southern India, making IV sets and sutures as well as heart catheters. It planned to invest a further \$10 million in this plant over 2009-2010 to expand production.

Becton Dickinson (Franklin Lakes, NJ) opened a new facility in Suzhou, China in April 2008 to manufacture rapid diagnostic products for flu and viral infections, expanding to more diseases later.

Another BD facility in Suzhou, which currently makes retaining needles and other products, is slated to receive additional investment of over \$40 million over the next 10 years. The investment will add new production lines and more than double the facility's capacity to become BD's largest production base in Asia.

Biomet Inc. (Warsaw, IN) began building a new manufacturing base in Changzhou, Jiangsu province, China, in July 2008. The plant is Biomet's second in China, and manufactures orthopedic equipment and supplies.

Boston Scientific (Natick, MA) announced in 2012 that it would invest \$150 million over the following four years to expand manufacturing, training and marketing facilities in China. In addition, the number of R&D and clinical study employees in China is set to increase from 200 to 1,200. Revenues are expected to reach \$500 million by 2016.

Brunk Industries, Inc. (Lake Geneva, WI) opened its Asian headquarters in Beijing, China.

Edwards Lifesciences (Irvine, CA) opened its first Asian facility in May 2008, a heart valve factory in Singapore with an investment of over \$20 million. This plant will also serve as Edwards's new Asian regional headquarters.

Flextronix/Avail (Singapore) opened a 600,000 sq. feet medical device manufacturing facility in Shenzhen, China and an 180,000 sq. feet medical device manufacturing facility in Malaysia to support rising demands from medical OEMs.

Hewlett-Packard Company's Medical Products Group (Palo Alto, CA) expanded its manufacturing operations in China by opening Hewlett-Packard Medical Equipment Products (Qingdao), Ltd. in a high-tech corporate park in Shandong Province in eastern China. This is a 12-year joint venture with the China National Corporation of Medical Equipment Industry (CMIC). It manufactures a variety of medical products, including patient monitors, cardiographs, ultrasound systems kits, and printed circuit assemblies. Forty percent of production is sold in the local market, and the remainder is for export, mostly to the Asia-Pacific market.

Johnson & Johnson (New Brunswick, NJ) opened a major medical device manufacturing base in Suzhou, China in April 2008. Representing a starting investment of \$100 million, this facility manufactures orthopedic products and expand to other products. It is one of J&J's largest plants worldwide. The company estimates that operating in China will reduce its manufacturing costs by one-third. J&J Ethicon has an existing 5,000 square-foot plant in Shanghai making silk sutures.

Medtronic (Minneapolis, MN) paid \$816 million for China Kanghui Holdings in 2013. Kanghui is one of the leading orthopedic device providers in China. The acquisition will give Medtronic a strong position in China's growing orthopedics market and other emerging markets, along with established manufacturing plants, R&D facilities, and Kanghui's orthopedic product portfolio.

Medtronic also set up an R&D center in Shanghai in 2012 to move towards local product development and commercialization in China. The company plans to hire 1,000 additional employees over the next 5 years, many of whom will be placed in the R&D center.

In 2009, Medtronic established a new manufacturing facility in Singapore, anticipating significant growth in the Asia medical device market, particularly for cardiac devices. The company began producing Cardiac Rhythm Disease Management (CRDM) devices in 2011, and had plans to hire more than 100 staff in 2011 and 2012.

Olympus Corporation (Tokyo, Japan), a manufacturer of various precision machinery and imaging systems including medical devices, opened a new factory in Vietnam's Dong Nai province in October 2008, making endoscopy equipment as well as digital camera lenses. The factory has over 3,000 workers.

Omron Healthcare Co. (Kyoto, Japan), a leading Japanese medical device factory, has built factory for home-use blood pressure monitoring devices in Vietnam. This factory, in an industrial park near Ho Chi Minh City, began operations in March 2008, and represented an investment of about \$2.5 million. It planned to increase from 150 employees at opening to about 400, selling its products for export to the world market.

Philips Healthcare (Best, Netherlands), expanded its already large Asia manufacturing presence in 2008 by purchasing Shenzhen Goldway Industrial, a large manufacturer of patient monitoring solutions, to export Goldway's products to other emerging markets and help market Philips's products in China.

Philips also acquired Alpha X-Ray Technologies, an India-based company, in 2008. Alpha manufactures a cardiovascular x-ray system. This medical area is predicted to be the fastest growing segment in the multi-billion dollar global cardiovascular x-ray market.

Roche (Basel, Switzerland) opened its first biologics manufacturing site in Asia in November 2009. The 12.6 hectare site in Tuas Biomedical Park, Singapore, is comprised of a microbial-cell facility and a mammalian-cell facility. The first received FDA licensure several years ago to manufacture Lucentis, an injection used to treat a certain cause of blindness. The second facility, purchased from Lonza in August 2009, manufactures Avastin, which is used to treat various cancers, including colorectal, lung and breast cancers.

Sanmina SCI (San Jose, CA) invested \$10 million in building a new factory in the city of Suzhou, Jiangsu province in China in May 2010. The plant develops and manufactures high-tech medical device systems for leading global companies such as General Electric, HP, Philips Medical Kodak and Applied Materials. The company hopes that the new Chinese plant will help it reach sales of \$200 million in the next five years.

Sanmina SCI acquired an optical facility in Shenzhen, China in 2009. The facility belonged to JDSU, a leading provider of optical products. Under the terms of the agreement, Sanmina manufactures JDSU products and acquire certain manufacturing assets, inventories, and employees in Shenzhen.

Siemens Medical Solutions Group (Munich, Germany) and Sysmex Corporation, a Japan-based company, renewed a five year contract agreement in 2009. Siemens' clinical laboratory customers will continue to have access to a wide array of coagulation instruments, tests, and new technology.

Smith & Nephew (London, UK) transitioned its manufacturing facility for high-tech wound care products from Florida to Suzhou, China, in 2009. The facility exports its products, including the ALLEVYN ADHESIVE dressings used to treat geriatric and diabetic ulcers, to 65 countries. The plant is located in Suzhou International Park, one of the fastest-growing industrial zones in China with over 3,000 foreign companies. In addition, the company opened a 10,000 sq. feet orthopedic manufacturing facility in Beijing, China.

Spacelabs Healthcare (Issaquah, WA), a medical device-making subsidiary of OSI Systems, opened a new manufacturing facility in Suzhou, China in March 2008. Spacelabs specializes in patient monitors, anesthesia delivery, and cardiac diagnostic systems. The company says that the factory focuses on making products for emerging markets.

Stryker Corp. (Kalamazoo, MI) acquired China's Trauson Holdings in 2013 for \$764 million. Trauson is the largest trauma product manufacturer in China, supplying almost 3,000 hospitals.

Stryker will gain access to Trauson's distribution network and orthopedic product market share in China.

Synergy Health (Swindon, England) announced the acquisition of the Malaysian company Sterilgamma in July 2011. This purchase increases Synergy Health's medical device sterilization capacity in Malaysia.

Thermo Fisher Scientific (Waltham, MA) set up a new medical device factory in Suzhou, Jiangsu province in China in 2011. The factory is developing medical device products for the local market.

VI. The Sourcing Process: Getting Started

Completing a cost-benefit analysis, which takes into account factors such as the technical complexity of the medical device and sustainable order volumes, is necessary before even considering sourcing or manufacturing in Asia. Sourcing must allow you to realize significant cost savings that will significantly outweigh the costs and risks of going overseas. Some of these potential costs include: overseas travel and communication, potentially longer lead times, or product adjustments (for prototypes).

Medical devices that are standard or commodity products will obviously be easier to source, while other devices that need a new design or mold in order to fit your specifications may require greater investment in terms of time and money. Many Asian manufacturers may be able to make commodity medical products, but more complex medical products that need more prototypes, sampling, testing will be harder for others to do. Thus, sourcing unique medical products will create a longer-term competitive advantage (barriers to entry), while sourcing commodities may make it easier for new competing groups to enter your market segment. It is important to keep all of these factors in mind when making the sourcing decision.

Identifying Manufacturers

The first step in the sourcing process is identifying appropriate manufacturers for your medical device. Referrals, business-to-business directories, trade catalogues, trade shows, or the internet are all sources for beginning a manufacturer search. There are numerous business-to-business websites listing manufacturers all over the world, some of which are listed in Appendix A. Knowledge of an Asian language can be especially helpful for navigating websites that do not have English versions, which is often the case for Asian manufacturers that serve primarily domestic markets. Translating the name of the medical device or other terminology (i.e., the medical sector you are interested in) into an Asian language is crucial when searching on the internet. It is important to keep in mind that while there is a wealth of information on the internet, this should not be the only source for your search.

Once you have a list of potential manufacturers for your product, explore all of their websites to learn more about them. You should look through each website thoroughly for content as well as for clues about its reliability as a supplier. Oftentimes, a manufacturer may be listed in a directory as a good prospect for your product, but when you actually visit the company website, you may find that the product offered is not actually listed, or that it is not as you expected. This is common, so watch out for any misleading information. Many Asian manufacturers, particularly the smaller companies that tend to be more focused on the domestic market, may have the bulk of their company information in their native language, with only very basic information in English. For this reason, it is advisable to have someone who understands the Asian language peruse all of the websites. Detailed information about the company, its facilities, production processes, and quality certifications may not be listed in English.

Some specific things to look for when doing company research include: any quality certifications such as ISO or FDA/EU certifications, any mention of US or European customers, or GMP standard production.

In examining different companies, you may find that a number of prospective manufacturers are concentrated in one region. There may be advantages to choosing a manufacturer in this region because there will be an accessible local pool of technical staff with experience in the same field.

If you need a “niche” product that is particularly specialized and requires expertise, be aware that some Asian companies are very interested in getting the higher prices available for niche products, whether or not they ever provided such a product before. Therefore, be alert for company’s business profiles mysteriously starting to better fit your needs *after* they learn what you want in detail.

Differentiating Trading Companies from Manufacturers

One of the key things to be aware of when conducting a manufacturer search is the difference between a manufacturer and a trading company. Manufacturers perform the actual design and production of the goods, while trading companies purchase the goods from the manufacturer and sell them to foreign buyers. Trading companies act as agents for manufacturers, bringing them together with potential buyers; a service that the manufacturers may not be equipped to handle on their own. Many Asian companies operate through trading companies because they do not have the language skills or expertise to conduct international sales.

A company may claim to manufacture its own products, but if its product lines vary widely (say, simple disposable plastics to more sophisticated products like stents or surgical instruments) and require very different manufacturing competencies, it is likely that the manufacturer did not actually produce all of these products. Instead, the company may be posing as a manufacturer or it may provide the storefront for other companies that actually do the production. Or, it may actually do production of some of the product lines itself while only selling the other lines. Trading companies can sometimes be identified by their names; for example, ABC Import & Export, or XYZ Trading and Investment Co.

There are a number of advantages to dealing with a trading company. For example, if you want to source several types of product lines or source from many different countries, it may be easier to deal with a trading company. The amount of company time and resources that would be required to undertake such a project (i.e. traveling overseas to meet with manufacturers, factory visits, technical discussions, and negotiations with several vendors) can be significant. Rather than having to build relationships with each individual manufacturer from scratch, working with a trading company essentially allows you to step right into a pre-existing network of business relationships between the trading company and its suppliers, “cutting out” the local ground work you would otherwise have to do. It also gives you access to the pricing or other arrangements that have already been established between the trading company and its many suppliers.

Trading companies are also very accustomed to dealing with foreign customers and working with foreign companies, whereas some local manufacturers that generally serve the domestic market may not have much exporting experience at all. Working with a trading company may also give you access to smaller Asian companies that you may not have come across otherwise on your own. You benefit from a trading company's ability to interface in both English and Asian languages.

The nature of the products you want to source also influences your choice of working with a trading company versus a manufacturer. If you are sourcing standard commodity products (or products that are easily customizable), have basic product features, and want to take advantage of cost savings in the short term, it is easier to go with a trading company.

The major disadvantage of this strategy is that while it is relatively easy to enter the relationship with a trading company, it can also be easy for the trading company to disentangle itself from your business. Because you do not have close ties to the manufacturers, you may be beholden to the discretions of the trading company.

Another critical disadvantage of trading companies is their handling of quality control. Once a deal is in place, trading companies will commonly inspect the first shipment of products, but only make irregular checks afterwards. Working directly with a manufacturer can make strict QC easier.

Finally, trading companies often purchase the same product from multiple suppliers. Because of this leeway, when they have problems with a supplier, they may switch suppliers without notifying their customers.

Working with a trading company is also not the best path to take if you have a more sophisticated product that requires substantial redesign or worker training in order to produce correctly. In this situation, you will need to have direct interaction with the manufacturer.

Working directly with the manufacturer makes sense if you are sourcing very specific or complicated products, or if you want more control of the design process. While it will take more start-up time and effort to develop trust between parties and to establish a good working relationship, it is generally worthwhile in the end. As your business relationship develops, you will have more leverage to negotiate prices or any other arrangements.

In addition, when you work with manufacturers, you eliminate the so-called "middleman," so any concerns or product adjustments you have can be communicated directly with the engineers or technicians who are making your product. The relationship is more stable because there are no third parties (like trading companies) who also have to be part of every negotiation. Since you are working *directly* with the suppliers, there is no worry that the trading company will suddenly cut off your supply.

In conclusion, the route you choose to take depends greatly on your strategic business needs, and it is important to be aware of the type of company you choose to do business with.

Initial Investigation

The next step is initiating contact with the manufacturers or trading companies to make some basic inquiries in order to determine which companies are viable choices for sourcing your device. The purpose of this initial investigation is to screen out the unviable candidates, narrowing the field down to those companies that have the capability to make or source your device at a satisfactory price. In addition, these initial inquiries give you the opportunity to interact with an actual person and begin developing that business relationship.

Initial contact is commonly made via phone calls or email correspondence. Since there is a great deal of variation in English speaking ability among Asian companies, it is a good idea to have a bilingual person as the main point of contact. Many Asian companies will have sales people or product managers that speak English very well, while other companies, particularly the smaller ones, may not. Once you begin discussing more technical or detailed issues, communicating in English may become difficult for them; still, you should be persistent in expressing your needs. It may take longer to get things off the ground when working with Asian companies. If the company is small, it may not be fully staffed in the same way that a large corporation would. For example, oftentimes the owner or manager is the decision-maker, so if he/she is not available, it may be difficult to get concrete information or decisions from staff people. Also, things may take a day longer to get done because of the difference in time zones.

When making these initial inquiries, you should ask some basic questions about the manufacturer's production capabilities. First of all, does (can) the manufacturer make your product? Second, can it make your product to the level of accuracy that you need – that is, can it handle your specifications, standards, and requirements? Third, is its pricing acceptable? Any company that you decide to engage with further must be able to meet these basic qualifications. You should take this opportunity to also ask any other questions you might have about the company's history, facilities, quality certifications, customer base, etc. to get an idea of the way the company operates.

A key element of your initial investigation, especially if you are sourcing non-commodity products, is a discussion of the technical specifications for your product. If you are satisfied with the manufacturer's existing product and do not expect to make any changes to it, then this is probably less important. However, if you do expect to make changes to the existing product, it is very important to determine whether the manufacturer can handle adjustments to the product specifications. Although some adjustments will not be difficult, others may require significant changes in technology or skills; for example, new types of production processes, new equipment, redesigns, etc. Does the company have the manufacturing process know-how and the right equipment to make what you need? One thing to keep in mind when discussing product specifications with Asian companies is that they tend to use the metric system of measurement, so you should be prepared to provide conversions from the English system.

In addition to asking companies about their manufacturing capabilities, you should also request product samples so that you can actually see what they can make. These samples can then be analyzed and compared to your own or other competing products. Particularly for more advanced or sophisticated products, it is useful to use an independent testing lab to see if the quality of the imported product is up to your standards.

If you are looking to source a product with unique specifications that require the manufacturer to make changes, the first sample you receive for your product may not be right for your needs. For example, it may take your specifications into account but be based on a slightly different product category. However, this sample can still be used to get an idea of the manufacturer's quality level, technological sophistication, and so forth.

However, if your sample contains significant intellectual property, it should not be sent until a later stage, when potential partners have been qualified. If it is sent to unreliable partners, they could well try to reverse-engineer its technology. If successful, they could then bring a copy product on the market very quickly. Even with qualified partners, a nondisclosure agreement should always be drawn up before any intellectual property is divulged (if a contract has not yet been signed).

Obtaining price quotes for commodity products should be a relatively straightforward process. However, you should be prepared to give an estimate of your purchase volume, as companies will usually give volume discounts. If you have a more complicated non-standard product, a price quote will probably not be very meaningful or useful until you lay out in more detail what you want, including specific features or specifications and order quantities. Keep in mind that many companies will give price quotes that are only valid for a certain period time.

You should ask about any additional costs, such as for customized packaging or printing, if this is something you will want. Companies often include a certain amount of artwork with the initial price quote such as one color printing or black and white printing, but anything more sophisticated than that will incur additional charges. There is usually a fixed cost for the design and production of the printing plate, for example, plus an additional per-unit charge for the printing.

When looking at the initial unit price, you should always remember that the total cost per unit to you will always be a bit higher, after taking into consideration the added costs of packaging and printing, freight, and customs duties. In particular, medical devices or products that are required to be sterile will add to the final unit cost.

Aside from the key issues, you should also be looking to determine whether the manufacturer would be a good fit for your company. For example, if it is a large company, it is probably not the right manufacturer to do small specialty device production. Does it have a lot of experience in the medical device industry? During the course of the initial investigation, there may be some "make or break" issues that will eliminate a company from the running. Other issues, however, may be overcome. There may also be other issues that are not of immediate concern, but could potentially become so down the line. It is important to be aware of all of these issues.

Qualifying the Manufacturer

After doing an initial investigation of potential manufacturers, you will likely have narrowed the field down to a handful or so of serious candidates. However, there is still a long way to go before putting any money on the table. It is very important to qualify every manufacturer that you may have any dealings with prior to entering into a business agreement or contract. This evaluation process will be much more rigorous and will entail due diligence and background checks. At the end, you will hopefully have several companies that are promising enough for you to visit.

Investigating companies in Asia is a much more challenging undertaking than in the US. Many Asian manufacturers do mostly domestic business, and may have no more than one or two pages in English available on their websites. Even if there is information on the websites, there will be few references to cross-check the information against.

In the case of China, there are now online services which let you search Chinese business registration records to make sure a company is in fact registered with the government, and even get its credit report. This service is an important starting part of due diligence. GLOBIS (<http://www.glo-bis.com/>) is one such service provider.

However, there is much important information that company profiles, even when available, do not address. Who really owns the company? Who owns the manufacturing licenses for the devices produced? How financially stable is this company, and will it still be in business in five years? Many manufacturers of medical products are very new and do not have a long history, and it is very difficult to get a good picture of the companies' finances.

To get answers to these questions, you must conduct additional due diligence. Start with the manufacturer itself and try to get much information as they are willing to give you. The manufacturer should be able to supply names of previous customers as a reference. Companies that export to the US, Japan, or Europe (especially Germany, France, and England) will generally have higher quality products.

Ideally, any company you work with should have all of the major quality certifications, such as ISO or GMP. You should ask for copies of any quality certificates they have earned, as well as FDA or EU registration information. Keep in mind that GMP standards in most of the Asian countries are common, but the qualifications of GMP are not all the same. For example, US GMP is different from Chinese GMP. China may have its own guidance for Good Manufacturing Practice that are based on existing GMP standards in use by other countries, but in practice those standards may not be at the same level as the internationally accepted standards that the US, Europe, and Japan adhere to. International harmonization of standards is in theory the goal, and it is occurring, but the process is slow.

China's Food and Drug Administration issued various medical device GMP regulations in December 2009. These regulations include detailed GMP rules for sterile and implantable medical devices and GMP inspection standards for sterile and implantable medical devices. In January 2011, the Chinese FDA released “Quality Management System Regulations for Medical Devices” and “Requirements for Medical Device Quality Management System Inspection.” By July 2011, manufacturers of implantable and sterile devices were required to obtain GMP certification before they filed for initial registration or re-registration.

In December 2013, the Chinese government a draft version of revised GMP inspection assessment standards. If adopted, this regulation will make the manufacturing certificate approval system more standardized and strengthen government supervision of medical device manufacturing.

Some products, such as disposable medical products, require sterilization. Finding out the type of sterilization done on products is an important part of due diligence. Out of the common types of sterilization (EtO, gamma, plasma, etc.), some may be inappropriate for your particular product. Ideally, the sterilization type should match the type currently done on the products to be sourced.

In some countries, sterilization is often outsourced to a third party service provider. The reputation, experience, and quality of this provider should always be assessed. In China, many medical schools and universities have sterilization centers which private enterprises may use. You should not assume that this is an inferior option. In fact, such centers are often superior to independent sterilization companies, and manufacturers sometimes boast about using them. The logistics of contract sterilization should be examined, to make sure that the sterilization is well-coordinated and will not hold up the flow of products from the manufacturer to you. Finally, whoever does the sterilization should be properly licensed.

In some cases, it may make sense to sterilize the sourced products yourself. This may also be necessary in the short term before a stable and reliable in-country sterilization process has been arranged. For this purpose, a list of Western sterilizers is included in the appendices.

Any local Asian business partners or contacts in your line of business should be consulted for their opinions on a particular manufacturer. It is best to enlist a local person to conduct further investigations into the company and to find out more about the company's reputation. This begins with basic things like checking to see that the factory exists at the location listed on the website. You should make sure that the company has the proper business operating licenses and permits to conduct its business operations at all levels of government, and that these licenses are up to date. If, for example, you do want to work directly with a manufacturer, these initial site visits will be able to provide confirmation of the existence of the factory, as opposed to an office storefront (as may be the case for a trading company).

A local contact or consultant should also visit the factory and meet with the international sales people to get a feel for their operations. If possible, ask him or her to take photographs of the facilities. The partner should take careful note of the condition of the factory. For example, is the equipment new? Is the factory clean and organized? Are the workers treated fairly? How

much work is done with machines and how much is done through manual labor? What is the frequency of interruptions to production such as power failures? Would the facility be acceptable to your own quality control people? If there is a cleanroom, does it have adequate washing facilities, and do employees seem to be following correct procedures in passing in and out of the cleanroom? Your local contact or consultant can also check to see what type of equipment the manufacturer uses and whether it is similar to the equipment that you or your competitors use to make the product. Also, if a great deal of manual labor is being used, it may be more difficult to maintain quality control.

Having local contacts and consultants investigate manufacturers is extremely useful as a screening process. You will eventually be visiting the factories yourself, but it is good to have help in making the first cut, since factories that look good on paper may not always be so good in reality.

When deciding which manufacturer to pursue, evaluating its reputation is almost as important as assessing its production capabilities. In general, it is always better to work with companies that either are familiar to you or have been referred to you. Therefore, you must get feedback from the manufacturer's previous customers to get an idea of how reliable and honest the manufacturer is. Positive feedback on a potential manufacturer from a company that you trust is even more valuable.

Factory Visits

By now, you have a couple of Asian suppliers that are solid candidates for sourcing your device, and it is time to take a visit to the factory. Any factory that you visit should clearly have the capability to produce your device to your specifications and at prices that make importing attractive. In addition, you should be reasonably confident that the company is honest, stable, and operating legally.

Face-to-face meetings are an important part of developing a business relationship with Asian companies, so you should plan carefully for your first visit to the factory and offices. The Asian company will normally have its senior management at the meetings. If you send a low-level junior associate to meet with the head of an Asian company, it will be seen as disrespectful. You should also prepare small gifts for the people you meet with. Once you arrive at the factory, you should meet with all of the key personnel and spend time getting to know all of them well.

At the factory, ask the same questions that your local partner did during his preliminary investigation. Learn about the company's history, the state of its finances, production processes, quality control, research and development, working conditions, etc. Ask to see their licenses and any quality certifications they have. If you have a highly complicated device, look for the specific types of machinery required in order to be make it correctly. While you should have much of this information already from your local partner's investigation, it is good for you to make these requests yourself to show your interest and desire to get to know the

manufacturer. It is important for you to get your own impression of the quality of the facilities and equipment.

You should also get an idea of where the factory gets its components and raw materials. The factory should go through a qualification process with its own suppliers and test its purchases. It may be a bad sign if suppliers change frequently without oversight. Many Asian quality scandals, such as the deaths from China-sourced heparin in 2008, took place even though Western buyers had thoroughly vetted their suppliers' quality control and trustworthiness. In the heparin case, the China supplier, Scientific Protein Laboratories (SPL), was an American joint venture with a very Westernized quality management system. However, SPL relied on two Chinese companies (one of which was its JV partner) to source raw heparin, and it was these companies that reportedly bought adulterated heparin from multiple small processors.

The factory visit can also serve as an opportunity to see how strictly the company manages the cleanroom. Since you are guests, and are supposed to be treated well, your guides may choose to bend the rules and let you into the cleanroom without following all the proper procedures.

In addition, it is also important for your company to make a formal face-to-face visit to the factory to further cement your relationship. The personal interaction is valuable, as you will be able to develop an opinion on whether the managers and employees seem trustworthy and reliable. Your presence also communicates that you are serious. Business in Asia requires face-to-face meetings, dinners, and lunches together, as well as sometimes socializing outside of the office.

After factory visits, it is a good idea to summarize the meetings and follow-up points and distribute them to all participants so that both parties are on the same page.

VII. Contracts

Once you have found a manufacturer that you want to do business with; i.e. a company that is capable of and willing to sell you the product you want and has passed all of your background checks, the next step is drawing up a contract. The contract establishes the basic terms of the business agreement; mainly, price, quantity, and product. It will also address other issues such as disputes and return policies. The contract should be clear and concise and should keep foreign “legalese” to a minimum. It should be specific enough to avoid ambiguity and misinterpretation, but it should not be too overwhelming either.

It is important to keep in mind that while Westerners view the contract as a binding agreement, Asians may view it as only a starting point from which to negotiate. For example, some Asian manufacturers’ contracts might be shorter and simpler than a standard Western contract, leaving much to chance. If a clause states that “the manufacturer will provide XX number of products at YY price in accordance with the buyer’s requirements,” you should make sure that those requirements are actually listed in the contract as well as the purchase order.

Of course, this may not be the case in every country in Asia, as there is a great deal of variation in cultural and business practices within Asia, but it is true in some Asian countries. In China, for example, business has commonly been conducted based on personal relationships (called *guanxi*), whereby it is expected that you use your connections to get ahead. In contrast, in Western societies, rule of law is normally the governing system. Each entity is treated equally before the law and the law is applied to everyone equally. Laws govern the functioning of business and nobody gets special treatment. If someone uses his personal connections and it results in unfair treatment, this may be punished or frowned upon in the West. In China, this is considered part of normal business. Obviously, there are exceptions to this rule.

This is not to say that a contract is not useful, however; it is still important to get everything in the agreement down in writing. It just may *not* be viewed by the Asian company in the same regard as another US or European company might. For this reason, you should make sure that the terms of the contract are specified as clearly and as precisely as possible, especially when it comes to issues like payment terms, quality standards, lead times, etc. If there is any doubt about something, put it in writing. It is important to note that translating your contract into the local language may also be required.

At the stage of contract negotiations, you should be careful to avoid thinking, “We’ve done all this work and come all this way, so we have to come out of this with an agreement.” After the long process of identifying manufacturers, it can be embarrassing to discover that your prospective partner is actually not honest or capable enough. Because of this sense of investment in the process, buyers can be reluctant to quit in the later stages of talks. This problem is common to all negotiations, but it is especially common in Asian deals because of the perception that “Asia is the future” and that using Asia is vital to your company’s survival.

Asian companies are aware of this reluctance and may take advantage of it in negotiations. But a bad supply agreement can be worse than no agreement at all, when it results in poor-quality

or delayed products. You should always go in willing to abandon a deal if necessary. This is another reason it is important to maintain qualified backup suppliers.

Price and Quantity

In Asia, price is almost always negotiable. The rule of thumb is simple: the more you buy, the more leverage you will have. Clearly, bringing in large volumes will command more favorable prices, while a small order will not be as persuasive. However, the promise of subsequent orders or long-term contracts that are contingent upon performance may offer some leeway. Over time, you should try to negotiate price adjustments as you increase your orders. You can also initially place smaller orders of less complicated products to see how the manufacturer performs, and then transition to larger orders of more advanced products as the supplier proves its capabilities.

Remember that there may be additional charges for other aspects of your product, such as packaging. You should make sure that these are included in the purchase order contract as well.

1.1 The contract price shall be inclusive of all charges for packaging and packing as indicated in Schedules 1, 2, and 9.

The above contract clause refers to Schedules 1, 2, and 9, which are part of the purchase order attached to the contract. The purchase order contains all of the actual figures and details for the pricing, as well as all other specifications. The following chapter on purchase orders will discuss these specifics in greater detail.

When deciding on order quantities, you should think about existing inventory, shipping lead time, and how long it might take to switch buyers from one product to another, etc. It may also be useful to include a clause stating that you will only be financially responsible for the quantity of units you requested in your initial order:

3.4 SELLER guarantees that it will ship the exact number of widgets requested by BUYER in Schedule 1 and will not add additional widgets. If SELLER ships additional widgets in excess of the amount stipulated by BUYER Schedule 1, BUYER shall not be responsible for these costs.

It is possible that the manufacturer may ship additional units or devices that you did not order, and then bill you for the full amount on the assumption that you will keep them. Make sure that what you get is what you ordered.

Product

The contract terms that outline the device's product and quality specifications are the most crucial, so it is particularly important to have very clearly written terms. For example, a clause in an Asian contract may have the words "reasonable tolerance" with regard to specifications such as weight, measurement, quality, and color. Such a clause as "reasonable tolerance" may

be entirely too vague for your needs. What is considered to be a reasonable tolerance in measurement—0.5 cm, 1 cm, 10 cm? These figures should be included in the contract:

2.1 SELLER agrees to produce widgets in accordance with the information contained in Schedules 1, 2, 3, 4, 5, 6, 7, 8, and 9.

You can then specify and list any product specifications you feel are necessary in the attached purchase order; specifications can include things like size, color, materials, packaging, artwork, logos, user's manuals, acceptable tolerances, production processes, functionality, testing methods, etc.

It is also wise to include a clause to allow for your alterations or changes to the device:

3.7 SELLER must disclose any changes to the approved specifications, prior to making those changes, for review and approval from BUYER.

4.3 BUYER must inform SELLER of any changes to the attached specifications (see Schedules 1, 2, 3, 4, 5, 6, 7, 8, and 9) before placing order. Otherwise, BUYER should pay for the additional cost caused by new changes.

These two clauses ensure that the manufacturer will not make unilateral changes to your product without your consent; and they provide the manufacturer some relief from last-minute changes after the order has already been made.

It is also useful to include a clause stating that the manufacturer will produce samples or prototypes of your device to be approved by you before initiating the actual production run.

The purpose of including these product clauses in the contract is to have a document that the manufacturer can be held accountable to, so that the product coming off the production line will be exactly what you want.

Defective Goods

The possibility of receiving defective goods is inevitable, whether the products are imported from China, Japan, or England. Therefore, your contract should include a clause addressing warranties on the goods. Basically, you want to ensure that you will be given just compensation should the shipment of goods be unsatisfactory and fail to meet your quality standards. The following clauses address this issue:

3.8 SELLER shall be liable to BUYER for and indemnify BUYER against any liability, claim, action, demand, expense, cost, loss, or damage, whether foreseen or not (including but not limited to the recall by BUYER of any Goods or Services):

a) Caused by any defect in any Goods supplied by the SELLER or by their not complying with the appropriate specification;

3.9 Returned products may be sent by BUYER (at BUYER's expense) to SELLER for review. All products that are determined to have manufacturing faults as described in 3.8 will be repaired or replaced and shipped to BUYER at SELLER's expense. Where a dispute arises regarding returns due to manufacturing faults or other, an independent test house will be appointed, and the losing party will settle the costs of the independent test house.

3.10 BUYER may appoint an agent to carry out inspections of the product, the factory, and the facilities. Additionally, BUYER may appoint an agent to conduct a pre-shipment inspection. The traveling, accommodation and related expenses of the agent for this inspection will be borne by BUYER. The inspection agent will apply the following AQL levels – 4.0% for minor defects, 1.0% for major defects, and 0.0% for critical defects.

The clauses addressing this issue should specify an impartial method for determining whether the product is in fact defective if there is a dispute. For example, paragraph 3.9 above specifies that an independent test house will be appointed to resolve the dispute. Paragraph 3.10 lays out the criteria for what is considered to be an acceptable percentage of defects.

The contract should also prescribe what the compensation should be for defects (if necessary). For example, this may be in the form of a replacement product, credit against your next order, or a refund. Of course, the specific terms must be negotiated with your supplier.

Payment Terms

As you develop a business relationship over time, payment terms can be negotiated. In a cash transaction (without a letter of credit), it is common for the buyer to make an initial deposit payment, with the balance to be paid as soon as the goods leave the dock.

5.1 BUYER shall give SELLER 30% T/T within 10 days of signing the contract and 70% T/T within 48 hours of the transfer of the product to a freight forwarding company designated by BUYER. If SELLER does not receive 70% T/T within 48 hours of the transfer of the product to a freight forwarding company designated by BUYER, SELLER is entitled to stop the shipment and take back all goods.

In the above clause, 30% of the total order is remitted as a deposit and the remaining 70% balance is paid upon transfer of the goods to a freight forwarder (“T/T” means that the payment will be made in cash). However, if you are working with an unproven supplier, you may want to hold back some of the payment as an “insurance policy.” For example, you might have an arrangement of 30% as a deposit, 50% upon shipping, and 20% after receipt of the goods. Eventually, you may switch to a 50%/50% arrangement, or the supplier may even ship goods without requiring a deposit. When dealing with overseas suppliers, it is usually best to make payments electronically through wire transfer.

A more expensive but also highly secure option is to arrange for a Letter of Credit for the full payment with a Western bank. The issuing bank will guarantee payment to the seller upon receipt of documents showing shipment. Letters of Credit are more commonly used when the transaction is large.

In the event that you need the manufacturer to build a new mold or to purchase new equipment or materials to produce your device, you should expect to pay a deposit on these items as well.

If a prospective Asian supplier demands full payment in advance, this should be considered a warning sign. Requesting advance payment is a hallmark of scammers who disappear immediately after being paid. It is also not usually advisable to use services like Western

Union or PayPal, unless it is for the initial 30% deposit only, since payment through these services may not be recoverable.

Another issue to think about is the currency of sale, which is the currency in which the two parties will conduct business. You will most likely want to make payments in US dollars, while the Asian manufacturer will pay its employees and subcontractors in local currency. The currency of sale determines which party will shoulder the burden of currency fluctuation, if any.

Confidential Information

In any relationship with a subcontractor, maintaining the confidentiality of sensitive company information is a key concern. Confidential information includes things such as blueprints, production processes, financial information, etc. Though you are collaborating or working with this manufacturer, it is not part of your company, and it is almost impossible to ensure that it is not using your confidential information for other purposes. In certain Asian countries, for example, China and India, lax enforcement of intellectual property rights has been a notorious problem. It is important to include a clause on confidential information to make it clear that leaking your sensitive information outside the company is not permitted:

7.1 SELLER acknowledges that during the performance of this Agreement, it will have access to and become acquainted with information of a confidential nature that relates to BUYER's business ("Confidential Information"). Such Confidential Information includes, but is not limited to, BUYER's customer data, product data, inventions, trade secrets, innovations, business concepts, strategies and forecasts, budgets, marketing plans, tools, designs, financial information, personnel information, training methods and materials, manuals, forms and records. SELLER acknowledges that Confidential Information is not generally known by third parties, that it is used by BUYER to obtain a competitive advantage over competitors, and that protection of Confidential Information against unauthorized disclosure and use is critically important to BUYER. SELLER agrees that BUYER has the exclusive right, title and interest in and to Confidential Information, and that SELLER has no right, title, interest or license in or to Confidential Information.

Also, the following clause prohibits the violation of intellectual property rights of other companies to make sure that your manufacturer will not be shut down due to infringement on others' intellectual property:

3.6 SELLER warrants that the products it sells to the BUYER do not violate the intellectual or other rights of third parties.

It is important to have these clauses in the contract, but keep in mind that a 10-page document is not going to deter a company that is intent on exploiting confidential information. This has to do with the efficacy of contracts in different cultures. Even though stealing intellectual property is prohibited in writing, this does not mean that it will not happen. The key is that you have to trust the company, and trust takes time to build. Hopefully, by this point you will have gotten to know your supplier well enough to trust them not to violate your contract. In other words, you should not rely on the contract to ensure that your supplier behaves legally, but on your relationship and developed trust in the individuals at the company. However, it is

important to address all of these issues in writing so that you have recourse in the event that something does happen.

Finally, you should include a clause about maintaining confidentiality of the terms of the business agreement. One of the most important terms is the price you are paying for the goods:

4.2 BUYER AND SELLER should not inform the price in this contract to other companies.

You should communicate to your manufacturer the importance to you of keeping all pricing information private and out of the public domain.

Choice of Law

When doing business with Asian companies, it is also important to think about which jurisdiction, or which country's laws, will govern the contract. US companies will naturally want to operate by US laws, while Asian companies will want to operate by their own country's laws. In the case below, the contract is governed by the laws of the State of New York.

9.1 These terms shall be governed in all respects by the laws of the State of New York. All disputes relating to this Agreement shall be subject to the exclusive jurisdiction of the State of New York courts, to which the parties hereto agree to submit.

Some countries may have their own contract law; for example, China revised its PRC Contract Law in 1999 to be more efficient and more in line with international standards. However, it is generally best to use the Uniform Commercial Code (UCC), which is used in 49 of the 50 US states, or the UN Convention on Contracts for the International Sale of Goods (CISG), which is modeled after the UCC. It is possible to use the UCC even if the production or business activity takes place in Asia, as long as both parties agree to do so. If there is no clause regarding choice of law, and if both parties are subject to the UN CISG, then the contract would be subject to CISG. The CISG is the most commonly used standard for international contracts, and all countries that have ratified it are subject to its provisions.

In the case of China, it is often difficult to enforce a contract based on foreign laws. Courts may handle a contract case controlled by foreign laws, but this is time-consuming and uncertain. Also, if a contract specifies a foreign country as the *exclusive* venue, a judge may summarily throw the case out of court.

The Chinese legal system is now much more reliable and fair to foreign litigants than it was in the past. In addition, in major cities like Beijing and Shanghai, enforcement of judgments has become relatively reliable (as long as the defendant has assets). Therefore, it is now preferable to specify that a contract will be subject to Chinese law and will be litigated in Chinese courts.

The CISG, mentioned above, also has a good framework in the Chinese judicial system and can generally be relied on.

Dispute Clauses

The contract should include agreed methods for the resolution of any disputes. In Asia, it is much more preferable to attempt to resolve disputes through mediation or arbitration, if necessary, as opposed to bringing forth a lawsuit. It is best to first try to resolve a dispute through face-to-face meetings. However, in the event that talking the issue through does not work, you need to include a clause addressing dispute resolution. Commercial arbitration is the preferred next step. It is advisable to include a clause that prescribes the use of arbitration instead of litigation, which is always the last resort option. An example of a dispute resolution clause is below:

- 8.1 The Parties shall use their best efforts to resolve informally any disputes that may arise relating to this Agreement. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, that cannot be resolved by the Parties informally within thirty (30) days shall be settled by arbitration administered by the American Arbitration Association (“AAA”) in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof.

Technology Transfer

It may become necessary to transfer technology to an Asian supplier in order to make a product with the right level of quality, or to make it at all. Alternatively, once a sourcing relationship for lower-end goods has been established, the option of sourcing a higher-end product may open up later.

The consequences of a bad technology transfer are more severe than ordinary sourcing. A lot of time and money may be put in to train people in the new technology. And in countries like India and China, poor partners may abandon the partnership to copy the technology on their own, or sell it to another producer. If possible, if you already have been purchasing other goods from a supplier and feel you can trust them, it is good to try to use them.

A technology transfer agreement should specify exactly what form of assistance is to be given. This might include manufacturing equipment, blueprints, design specifications, quality control assistance, or capital investment. In the case of China, it is very common for in-person training to be a significant component as well. The types and/or quantities of equipment, assistance, or capital should also be detailed. Technology transfer should *not* begin before the agreement has been signed.

In creating a contract for technology transfer, it may be advisable to put stricter enforcement clauses in case of breach. Below is a sample clause specifying a compensation amount in advance.

Breach of Agreement: In the event of XYZ’s breach of the Agreement, it shall pay ABC liquidated damages in the amount of \$1,000,000 due to the difficulty in ascertaining the actual amount of the damages incurred to ABC; and ABC shall be entitled to an immediate injunction in both the US and [XYZ country] requiring that XYZ immediately discontinue its actions.

Effect of Termination: XYZ shall return to ABC any equipment or machinery purchased by ABC. XYZ may continue to sell the products globally, provided however, that it remits quarterly royalty payments of twenty percent (20%) of its gross sales for ten (10) years following the termination of the Agreement; XYZ shall not use any of ABC’s Intellectual Property to develop any competing product to ABC’s Product; XYZ shall not sell the Product outside of China; and ABC shall not sell either Product in China.

Sample Contract

This contract is made by and between ABC Enterprises, Inc., having offices at 123 Main Street, New York, NY 10000, USA (hereinafter referred to as “BUYER”), and XYZ Enterprises, Ltd., having offices at 456 Chang An Avenue, Beijing, China 100000 (hereinafter referred to as “SELLER”).

WITNESS

WHEREAS, BUYER is in the business of buying widgets and other items,

WHEREAS, SELLER is in the business of selling widgets and similar items.

Now, therefore, in consideration of the mutual covenants of the parties and for good and valuable consideration, the legal sufficiency of which is hereby acknowledged, the parties agree as follows:

I PRICE OF WIDGETS

- 1.2 The contract price shall be inclusive of all charges for packaging and packing as indicated in Exhibits A, B, C, D, E, F, G, and H.

II QUALITY OF WIDGETS

- 2.2 SELLER agrees to produce widgets in accordance with the information contained in Exhibits A, B, C, D, E, F, G, and H.

III. SELLER’S WARRANTIES

- 3.1 SELLER warrants that SELLER has all required permits, licenses and insurance to produce all products to be bought by the BUYER
- 3.2 SELLER agrees to supply BUYER upon request with all necessary declarations and documents requested by BUYER, including safety certificates and independent test house reports. Any documents requested in addition to those mentioned in 3.3 (US FDA 510(k) approvals and EMC test reports) will be supplied at BUYER’s expense.
- 3.3. SELLER warrants that all products are supplied with US FDA 510(k) approvals (listed in Exhibit E) & EMC from a recognized independent test house such as T.U.V. If a product is not approved for sale in the USA, SELLER, at its own expense, will secure the necessary approvals.
- 3.4 SELLER guarantees that it will ship the exact number of widgets requested by BUYER in Exhibit H and will not add additional widgets. If SELLER ships additional widgets in excess of the amount stipulated by BUYER in Exhibit H, BUYER shall not be responsible for these costs.
- 3.5 SELLER shall ensure (at its own cost and expense) that the goods are properly packed so that they are delivered free from damage and in perfect condition. If the goods are not so packaged BUYER may require SELLER (at SELLER’s cost) to repackage the goods.
- 3.6 SELLER warrants that the products it sells to the BUYER do not violate the intellectual or other rights of third parties.

- 3.7 SELLER must disclose any changes to the approved specifications, prior to making those changes, for review and approval from BUYER.
- 3.8 SELLER shall be liable to BUYER for and indemnify BUYER against any liability, claim, action, demand, expense, cost, loss, or damage, whether foreseen or not (including but not limited to the recall by BUYER of any Goods or Services):
- a) Caused by any defect in any Goods supplied by the SELLER or by their not complying with the appropriate specification;
 - b) Arising directly or indirectly out of any breach by SELLER; or
 - c) Arising from any claim that the Goods infringe or their importation, use or resale infringes the patent, copyright, design right, trademark or other intellectual property rights or any third party.
 - d) Arising from any claim that the products have not obtained US FDA 510(k) approval.
- 3.9 Returned products may be sent by BUYER (at BUYER's expense) to SELLER for review. All products that are determined to have manufacturing faults as described in 3.8 will be repaired or replaced and shipped to BUYER at SELLER's expense. Where a dispute arises regarding returns due to manufacturing faults or other, an independent test house will be appointed, and the losing party will settle the costs of the independent test house.
- 3.10 BUYER may appoint an agent to carry out inspections of the product, the factory, and the facilities. Additionally, BUYER may appoint an agent to conduct a pre-shipment inspection. The traveling, accommodation and related expenses of the agent for this inspection will be borne by BUYER. The inspection agent will apply the following AQL levels – 4.0% for minor defects, 1.0% for major defects, and 0.0% for critical defects.
- 3.11 If the returns level for faulty product exceeds 10%, or if BUYER instigates a product recall, this shall constitute an epidemic returns level. Under such circumstances, SELLER shall have 21 days to solve the problems. If the problems should have not been solved by SELLER within 21 days upon written notice from BUYER, BUYER is entitled to reject all goods in its possession, on order, or in delivery, and BUYER shall be entitled to a refund of its money and a claim for damages as described below in 3.12 and 3.13, a credit towards a future purchase equal to the value of the rejected goods, or a replacement of the damaged goods by SELLER, in which SELLER pays all freight forwarding costs.
- 3.12 For the avoidance of doubt, where SELLER is in breach of clauses 3.1-3.11 in respect of Goods, losses by BUYER may include: the cost price of the goods, the transportation costs, duty and administration costs.
- 3.13 Any reasonable money expended by BUYER so caused or arising out of breach of contract shall be reimbursed to BUYER by SELLER within 30 days.

IV. BUYER'S WARRANTIES

- 4.1 BUYER should present design, packing, and print information before placing order.
- 4.2 BUYER should not inform the price in this contract to other companies.
- 4.3 BUYER must inform SELLER of any changes to the attached specifications (see Exhibits A, B, C, D, E, F, G, and H) before placing order. Otherwise, BUYER should pay for the additional cost caused by new changes.
- 4.4 BUYER should check and receive products according to Exhibits A, B C, D, E, F, G, and H and bring forward any quality problems within 45 days after receiving goods. BUYER will designate the third independent party to review the quality problem. This third party shall attempt to resolve any differences between BUYER and SELLER without going to arbitration.

V. PAYMENT

- 5.1 BUYER shall give SELLER 30% T/T within 10 days of signing the contract and 70% T/T within 48 hours of the transfer of the product to a freight forwarding company designated by BUYER. If SELLER does not receive 70% T/T within 48 hours of the transfer of the product to a freight forwarding company designated by BUYER, SELLER is entitled to stop the shipment and take back all goods.
- 5.2 SELLER shall cover the air freight charges for delayed shipment upon demand by BUYER. This is effective only if the shipment is delayed 21 days after the shipment date specified in Exhibit G.

VI. EFFECTIVE DATE; TERMINATION

- 6.1 This Agreement is effective as of the Date of Acceptance below by BUYER. However, upon any material breach of this Agreement by a party, the other party may terminate this Agreement immediately by giving written notice to the breaching party.
- 6.2 Upon the termination of this Agreement, neither party shall have any liability to the other party, except for (i) compensation for any goods produced or expenses incurred by SELLER prior to termination, (ii) any prior breaches of this Agreement, or (iii) the breach of any provision of this Agreement that requires or reasonably contemplates the performance or existence of obligations by either party after the termination of this Agreement, including without limitation clauses 3 and 7.

VII. CONFIDENTIAL INFORMATION

- 7.1 SELLER acknowledges that during the performance of this Agreement, it will have access to and become acquainted with information of a confidential nature that relates to BUYER's business ("Confidential Information"). Such Confidential Information includes, but is not limited to, BUYER's customer data, product data, inventions, trade secrets, innovations, business concepts, strategies and forecasts, budgets, marketing plans, tools, designs, financial information, personnel information, training methods and materials, manuals, forms and records. SELLER acknowledges that Confidential Information is not generally known by third parties, that it is used by BUYER to obtain a competitive advantage over competitors, and that protection of Confidential Information against unauthorized disclosure and use is critically important to BUYER. SELLER agrees that BUYER has the exclusive right, title and interest in and to Confidential Information, and that SELLER has no right, title, interest or license in or to Confidential Information.

VIII. DISPUTES; ARBITRATION

- 8.1 The Parties shall use their best efforts to resolve informally any disputes that may arise relating to this Agreement. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, that cannot be resolved by the Parties informally within thirty (30) days shall be settled by arbitration administered by the American Arbitration Association ("AAA") in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The arbitrator(s) shall determine which party is the prevailing party in such arbitration and award that party the expenses it incurred in connection with the arbitration, including without limitation its reasonable attorneys' fees, AAA administrative and arbitrator charges, and expert witness fees, in addition to any other relief or damages awarded. The arbitration hearing shall take place in United States of America, in the State of New York. The Parties consent to the jurisdiction of the state and federal courts located in the State of New York for any motion or lawsuit related to the judicial confirmation of any arbitration award.

IX. APPLICABLE LAW/JURISDICTION

- 9.1 These terms shall be governed in all respects by the laws of the State of New York. All disputes relating to this Agreement shall be subject to the exclusive jurisdiction of the State of New York courts, to which the parties hereto agree to submit.

X. NOTICES

- 10.1 The points of contact for any notices under this Agreement are:

FOR BUYER:

ABC Enterprises, Inc.
Attention:
Fax:

FOR SELLER:

XYZ Enterprises, Ltd.
Attention:
Fax:

- 10.2 Any written notice under this Agreement shall be transmitted by fax, delivered personally, or delivered by an internationally recognized overnight courier, including without limitation Federal Express or United Parcel Service. Any notice given by fax shall be effective upon transmission by the sender. Any

notice delivered personally shall be effective upon receipt. Any notice delivered by overnight courier shall be deemed effective one (1) day after having been deposited with such courier by the party giving notice.

10.3 Either party may designate a different point of contact, address or fax number by giving written notice to the other party.

XI. SEVERABILITY

11.1 The terms of this Agreement are severable. If any term or portion thereof of this Agreement shall be determined to be invalid or unenforceable to any extent, the remainder of this Agreement shall not be affected thereby, and each remaining term or portion thereof shall be valid and enforced to the fullest extent permitted by law.

XII. NO WAIVER

12.1 Any failure to enforce any provision of this Agreement shall not operate as a waiver of such provision or of any other provision.

XIII. AMENDMENTS

13.1 This Agreement shall not be amended, changed or modified except in writing signed by both Parties.

XIV. AUTHORITY

14.1 Each of the individuals executing this Agreement represents and warrants that he or she is fully empowered and authorized to act for his or her respective party without any further approvals.

XV. FORCE MAJEURE

15.1 "Force Majeure" means any event beyond the reasonable control of the parties which was not reasonably foreseeable at the time and which prevents or hinders in any material way the carrying out by a party of its obligations under this Agreement, including but not limited to civil disturbance, war, terrorist acts, hostilities, strike, revolution, flood, fire, storm, earthquake, act of God, epidemic, destruction, or immobilization of manufacturing or warehousing facilities and governmental orders. A party shall not be liable or obligated to the others for its failure to perform obligations under this Agreement if and to the extent that any such failure is caused by an event of Force Majeure.

15.2 A party seeking to rely on an event of Force Majeure shall promptly notify the other party of its inability to perform and the nature, extent and likely effect of the event of Force Majeure. As soon as possible thereafter, the parties shall enter into discussions to try to agree a procedure to alleviate disruption caused by the event in question or to agree alternative arrangements to overcome the event or difficulties arising as may be reasonable.

XVI. ENTIRE AGREEMENT

16.1 This Agreement constitutes the entire agreement between the Parties with respect to the above matters and supersedes any prior oral or written agreements, representations or warranties. The Parties acknowledge that in executing this Agreement they are not relying on any representations, promises or statements that are not expressly set forth in this Agreement.

XVII. COUNTERPARTS

17.1 This Agreement may be executed in counterparts, each of which when executed shall be considered an original, and all of which when taken together shall constitute but one and the same instrument.

The parties hereafter execute this Agreement as of the _____ day of _____, 201_.

For and on behalf of:

ABC Enterprises, Inc.

XYZ Enterprises, Ltd.

Signature: _____
Name: _____
Title: _____

Signature: _____
Name: _____
Title: _____

VIII. Purchase Orders

The purchase order should be attached to the end of your contract. In addition to specifying which devices you are purchasing and at what price, the purchase order actually lays out all of the specifications and requirements that the manufacturer should adhere to when executing the contract. Here, you can list every product specification, including features such as prices, size, model number, colors, printing, logos, graphic design, packaging, and box dimensions.

Schedule 1 (Quantity and Price) outlines your order—how many units and cartons of each item you are purchasing, unit prices, and total (extended) price for the order. You may want to ship a small order via air transportation so that you can examine the goods before sending the whole shipment.

Schedule 2 (Pricing & Unit Packaging) outlines the unit prices and how the units will be packaged. This includes the number of units in a box and the number of units in a carton.

Schedules 3 (Unit Specifications) and 4 (Unit Color & Design) include details like the unit's weight, dimensions, materials used for components, etc. It also includes specifications for printing colors using the Pantone Matching System (PMS). Each color has an identification number that should be included in the purchase order to ensure that the color you want is exactly the color that is printed.

Schedules 5 (Box Specifications) and 6 (Box Color & Design) lists all of the specifications for the packaging of your device, including the dimensions and weight of the unit box and carton, color printing, and UPC codes.

Schedule 7 (FDA Approval & Registration) includes the FDA 510(k) numbers for each product that is registered.

Schedule 8 (Design Specifications) states that the manufacturer will adhere to the designs as specified by the buyer. It also includes acceptable tolerance in deviation of the dimensions of the device.

Schedule 9 (Printing Fees) lists the additional charges associated with color printing.

Schedule 10 (Shipment Date) lists when air freight and/or ocean freight will be shipped.

SAMPLE PURCHASE ORDER

Schedule 1: Quantity and Price

Air Freight Order

Item No.	Model	Size	Units	Cartons	Unit Price (US\$)	Extended Price (US\$)
ABC1122	1	XS	60	1	\$5.00	\$300.00
ABC1133	2	SML	60	1	\$6.00	\$360.00
Total Air Freight Order:			120	2		\$660.00

Ocean Freight Order

Item No.	Model	Size	Units	Cartons	Unit Price (US\$)	Extended Price (US\$)
ABC1122	1	XS	7,200	1,200	\$5.00	\$36,000.00
ABC1133	2	SML	36,000	6,000	\$6.00	\$216,000.00
Total Ocean Freight Order:			43,200	7,200		\$252,000.00

Total Order

Item No.	Model	Size	Units	Cartons	Unit Price (US\$)	Extended Price (US\$)
ABC1122	1	XS	7,260	1,201	\$5.00	\$36,300.00
ABC1133	2	SML	36,060	6,001	\$6.00	\$216,360.00
Total Order:			43,320	7,202		\$252,660.00

Schedule 2: Pricing & Unit Packaging

Item No.	Model	Size	Price (USD)	Packing		
				5 units/box	12 boxes/carton	60 units/carton
ABC1122	1	XS	\$5.00	5 units/box	12 boxes/carton	60 units/carton
ABC1133	2	SML	\$6.00	5 units/box	12 boxes/carton	60 units/carton

Schedule 3: Unit Specifications

Item No.	Size	Dimensions	Weight	Material	Case	Manual/Warranty	Display
ABC1112	XS	5" x 5"	1.5 lb		Plastic	Included	LCD
ABC1133	SML	6" x 6"	2.5 lb		Plastic	Included	LCD

Schedule 4: Unit Color and Design

Item No.	Size	Warning Label Text PMS Color	Display Label	Display PMS Color	Case Color	Button Color
ABC1122	XS	Red 185	Bottom center	Black 419	White	Red
ABC1133	SML	Red 185	Bottom center	Black 419	Gray	Red

Schedule 5: Box Specifications

Item No.	Size	Box Dimensions (cm)	Box Weight	Carton Dimensions (cm)	Carton Weight	Carton Print Color
ABC1122	XS	10 x 15 x 30	250g	50 x 75 x 75	9.5kg	Black
ABC1133	SML	15 x 20 x 45	400g	60 x 80 x 90	15.0kg	Black

Schedule 6: Box Color and Design

Item #	Model	Size	No. Colors	UPC Label		Shipping Mark	
				Color	Dimensions	Color	Dimensions
ABC1122	1	XS	4	Black & white	7 x 2 cm	Black & white	9 x 10 cm
ABC1133	2	SML	4	Black & white	7 x 2 cm	Black & white	9 x 10 cm

Schedule 7: FDA Approval & Registration

Item No.	Size	US FDA 510(k) Number
ABC1122	XS	A123456
ABC1133	SML	A123456

Schedule 8: Design Specifications

1. Design

1.1 Widgets

1.1.1 The design of the widgets should conform to the designs supplied by SELLER to BUYER.

1.1.2 SELLER shall apply a permanent rating label to all products. The label shall have a serial number consisting of the year and month of production and the chronological number of the unit. The design of the permanent rating label should conform to the designs supplied by BUYER.

1.2 Boxes

1.2.1 The design of the unit boxes should conform to the designs supplied by BUYER.

1.3 Cartons

1.3.1 The design of the cartons should conform to the designs supplied by BUYER.

2. Specifications

Item #	Model	Size	Length	
			Basic Dimension	Limit of Deviations

ABC1122	1	XS	5" x 5"	+ 0.1 inches
ABC1133	2	SML	6 x 6"	+ 0.1 inches

Schedule 9: Printing Fees

Item #	Model	Unit Box Dimensions	Printing Item	Film	Matrix	Total
ABC1122	1	10 x 15 x 30	4 color box	\$50.00	\$50.00	\$100.00
ABC1133	2	15 x 20 x 45	2 color box	\$50.00	\$25.00	\$75.00

Schedule 10: Shipment Date

1. Shipment Date

1.1 SELLER shall ship the Air Freight by the _____ day of _____, 2014.

1.2 SELLER shall ship the Ocean Freight by the _____ day of _____, 2014.

IX. Quality Control

Quality control is an important issue when sourcing from Asia. However, effective quality control begins much earlier than monitoring the production line. It starts with the initial product design and continues throughout the rest of the manufacturing process.

If you are sourcing a relatively simple device, the first step is ensuring that the product and quality specifications are correct and that they are clearly understood by the manufacturer. After signing the contract and making the first purchase order, the manufacturer should then begin producing the first prototype or sample of your device. You will then be able to evaluate and test the prototypes. It is very important that you approve a sample of the final product, including all of the appropriate packaging, labeling, and artwork, before you authorize the actual production run.

From this point forward, you will generally be monitoring quality control (QC) at the factory. Ideally, someone from your firm should be able to have an on-site presence at the factory. If you do not have the QC expertise in-house, you can use a local QC company to act as the QC representative (consultant to your firm) at the factory. It is obviously best to contract with a company that has experience in the medical industry.

Having your own QC representative on-site serves two purposes. The first is functional, so that you can have your own representative on the ground at the production site monitoring production runs and ensuring that everything runs smoothly. He or she should also perform random testing as the devices come off the production line to check product quality. The second purpose is more subtle—it is a signal to the manufacturer that you are serious about quality.

However, in selecting a QC representative, you should keep language issues in mind. Examining and critiquing manufacturing quality requires a large technical vocabulary, and a limited language ability can lead to serious miscommunications. It is ideal to send someone fluent in the local language. Otherwise, there should be an interpreter with a technical background who can translate accurately.

In conducting ongoing QC, it is helpful to keep the approved sample immediately available for quick visual comparison with later products. You may need to have two approved samples, one with your local QC representative and one in your home country where goods are received.

It may also be wise to have the products tested by an independent testing laboratory. You can authorize shipment of the goods to be contingent upon successful completion of a thorough inspection of product quality, which would include your own as well as third-party testing. There are a variety of testing labs throughout Asia. In addition, the QC representative can monitor the loading of goods into containers. Finally, if any quality issues arise after shipment, the representative should follow up with the manufacturer.

If you are sourcing a more complicated medical device, the quality control process may be more involved. During the product design process, your engineers and QC personnel should

ensure that all of the technical specifications and requirements are implemented accurately. They should also obtain more information about the existing quality checks and testing that the Asian supplier conducts on its products. Does it also use independent testing laboratories to test its products? If so, what testing labs does it use, and do the checks actually work?

Before any production begins, the two companies should then work to develop a formal quality assurance system that involves checks and testing during various parts of the production process. These checks should be agreed upon by both parties and should be clearly outlined so that the supplier knows how its products will be evaluated. This internal process should serve as the first level of your quality control program.

If your device requires any modifications during the design process, the manufacturer should send you samples of the redesigned device for your testing and review until the quality is where you need it to be. This may take a few iterations before you are satisfied. In addition, if your device required the creation of a new mold, you should also ask to see and approve the molds. In the case of complex medical devices, it is even more crucial to see final prototypes before authorizing the production run.

It is useful to have a quality control checklist to guide both your QC representatives and your manufacturer's own QC personnel in their inspections. Sample items that should be included on a quality control checklist are listed below:

- Do the devices perform as expected when tested?
- Do the finished products fall within the acceptable range of variance for specific specifications such as length, width, weight?
- If the devices are sterile, do they pass tests for sterility?
- Is the device properly labeled to meet customer and regulatory requirements?
- Are the workers properly trained to operate the production equipment, and are they operating the equipment correctly?
- Does the production equipment function properly (as expected)? Does the equipment undergo periodic maintenance, recalibration, cleaning, etc.?
- Are the devices packaged correctly?
- Have all of the components and raw materials been checked?

Quality control regulations for medical devices are constantly changing in Asian countries. For example, recent regulations for quality control in China include:

- Provisions for Implementation of the Special Regulations of the State Council on Intensifying Safety Control of Food and Other Products
 - Among other measures, it makes it mandatory to recall unsafe devices and sets large fines for companies which use fake certificates to export their products.
- Requirements on the Compilation and Revision of Medical Device Industrial Standards
 - Regulates the issuance of new industrial standards for medical devices.
- Eight Prohibitive Rules for Personnel Involved in Food and Drug Supervision

- New ethics rules banning CFDA employees from several activities associated with corruption like owning stock in medical-related companies, collecting consulting or lecturing fees, divulging trade secrets, etc.
- The Chinese FDA's National Sampling and Testing of Medical Device Quality has increased in scope.
 - Added medical device product types to be collected from manufacturers and tested.
 - Surprise inspections for medical device manufacturing facilities
- Chinese government is investing the equivalent of over \$1 billion dollars to improve the food and drug regulatory infrastructure, especially its underequipped testing centers.

X. Intellectual Property

Lax enforcement of intellectual property (IP) rights throughout Asia (especially China, Indonesia, the Philippines, and India) is a well-known problem. First of all, the IP laws must be comprehensive and tough enough to be meaningful. Second, the laws must be enforced fully and uniformly in order to be a significant deterrent to theft of intellectual property. In reality, neither of these criteria has been met satisfactorily on a wide scale in Asia.

India, for example, has come to be recognized as a generic drug manufacturing base due to its loose patent infringement laws that only granted patents on processes rather than final products. As a result, dozens of Indian companies were able to patent different “processes” to make essentially the same drug as a branded drug. As long as a company could cite a different process, it was permitted to copy the drug. In 2005, the Indian government passed a patent law that permits patents on the end product. However, generic manufacturers are not completely banned from making drugs—they pay royalties and must wait three years after a patent has been granted before they can begin to copy the branded drug.

After this law came into effect, the government did step up IP enforcement, but mostly in the area of trademarks, rather than patents. There are also charges of corruption in the patent process and delays due to understaffing. More than 1,000 drug patents were issued in India in 2012, though almost 80% of these were for foreign products. Overall, the IP environment in India is changing only slowly. Domestic Indian manufacturers are still largely focused on production rather than innovation as a business strategy, so there is still a great temptation to copy others’ products.

China is another country where enforcement of IP rights has historically been lax to nonexistent. China has a huge counterfeit goods industry that is not limited to the usual products like DVDs, CDs, computer software, and designer handbags—it can extend to drugs and medical devices as well. However, China has taken steps towards improving its intellectual property regime. Now that it is a member of the WTO, China must adhere to TRIPS, the WTO rules on intellectual property rights. The government also recently revised its patent enforcement laws to make it easier for foreign firms to file for compensation against IP right infringements. The government authorities have pledged to be more stringent when it comes to enforcing these rules, but it may take some time until full enforcement occurs.

In contrast, Singapore takes intellectual property protection very seriously, and markets itself as an ideal location for “IP commercialization.” Singapore is ranked as the top location in Asia for IP protection by the World Economic Forum, and the lowest in IP risk in Asia by the Political and Economic Risk Consultancy. In 2002, it established a specialist IP court with dedicated IP judges; and in 2003, it established the IP Academy. Singapore has made a significant effort to develop the strength of its IP regime, which Western companies find highly attractive.

Regardless of which country your manufacturer is located in, you should take proactive steps to prevent theft of intellectual property. The first thing to do is to make sure that you include a

confidentiality clause in your contract. Whether or not the contract will be strictly adhered to is another matter, but you should have in writing that the violation of intellectual property rights or any illegal use of your confidential information is expressly prohibited.

Second, it is a good idea to register your patents, trademarks, or copyrights with the local patent or trademark office. You should do this before the manufacturing process begins so that the local government has a record of your ownership of the intellectual property.

Third, you should try to compartmentalize the manufacturing process so that the Asian supplier does not have access to the entire blueprint or all of your sensitive data. For example, you might only give the supplier one module or process to oversee, and then perform the product assembly in another facility, where you have tighter control of the flow of information. Access to any critical information should only be given to those employees who you trust, and who have been screened and cleared. It is also wise to provide training for your local staff on the importance of intellectual property right protection so that they understand the need for security.

Fourth, you should look into defending intellectual property widely by registering variations or derivatives. For example, in China and other countries with their own writing systems, registering an English trademark may not protect you against other companies using equivalents of the trademark in their own alphabet.

Fifth, you should be constantly alert for any infringement by a partner. In 2007, Groupe Danone, a French food conglomerate, sued its joint venture partner Wahaha, a famous Chinese beverage maker. Wahaha has admitted that it failed to transfer its IP to Danone's name, as specified by the contract. Not only that, even though Danone owned a majority stake in the JV, Wahaha apparently set up shadow factories making Wahaha drinks without Danone knowledge or revenue-sharing. This illustrates that even a high-profile agreement with a reputable firm may be ignored. (It is this kind of experience that has made JVs less and less popular in China now that full foreign ownership is legal in most cases.)

XI. Other Issues

There are several other issues that are important to consider when sourcing in Asia. These include logistical issues like customs, freight, and insurance, as well as other regulatory compliance issues.

US Import Documentation

When shipping your products, the manufacturer should include a *commercial invoice*, which is the actual bill of sale for the goods. Although you will not be responsible for issuing this document, you should agree to the contents before the goods are sent. Generally, the manufacturer will send you a pro forma invoice upon making the initial order. In the interim between the time of order and the time of shipment, there may be a change to the order; the final copy is the commercial invoice that is enclosed with the actual goods.

It is important for the information on the commercial invoice to be clear and concise and provide comprehensive information, since it will be used by the customs authorities in the importing country to determine the proper classification of the goods being shipped. This is done for the assessment of duties and taxes, and for determining eligibility of entry into the commerce of that country. A shipment of non-document goods to the US must include the original commercial invoice, as well as two copies.

Commercial invoices must include the following information:

- Shipper's name, contact name, address, and telephone number
- Consignee's name, contact name, address, and telephone number
- Federal Tax Identification Number (EIN) for a company or social security number for an individual
- Complete description of goods
- Intended use of commodity
- Country of origin for all commodities
- Unit values (if the item was sent for repairs, list the original value plus the cost of the repair)
- Extended values
- Currency in US dollars
- Terms of sale
- Weight of shipment
- Any commodity-specific information

The US Customs Service does not require importers to have a license or permit, but other agencies may require a permit, license, or other certification, depending on what is being imported. Customs entry forms do ask for your importer number, which is either your IRS business registration number, or your social security number if your business is not registered with the IRS or if you do not have a business.

Terms of Sale

The INCO terms, issued by the International Chamber of Commerce, define the various arrangements used in international trade. FOB and CIF are the most common terms.

FOB (Free on Board, named port of shipment) means that the seller has fulfilled its obligation to deliver once the goods have passed the ship's rail (i.e. delivered on board the ship) at the port of shipment. The buyer bears the cost and risk of potential loss or damage to the shipment from that point onward including insurance and freight. The seller is responsible for clearing the goods for export. This term can only be used for sea and inland waterway transportation.

CIF (Cost, Insurance, and Freight, named port of destination) means that the seller has fulfilled its obligation to deliver the goods once they pass the ship's rail at the port of shipment. The buyer bears the risk of loss or damage to goods from that point onward, but the seller must pay for the cost, freight, and insurance of bringing the goods to the port of destination. This term can only be used for sea and inland waterway transportation.

Freight Forwarders and Shipping

International freight forwarders are the most important part of the overseas transportation process. Freight forwarders act on behalf of exporters (or importers) in arranging transportation services. Most freight forwarders handle both ocean and air transportation, but usually in separate departments. They are familiar with the import rules and regulations of foreign countries, methods of shipping, US government export regulations, and documents connected with foreign trade.

Freight forwarders provide a number of services. At the beginning of a sale, they can provide quotations on freight costs, port charges, consular fees, special documentation costs, insurance costs, and freight forwarder's fees. This information can be used in the preparation of an overall accurate price estimate. At the shipper's request, freight forwarders can make the actual arrangements and provide the necessary services for expediting the shipment to its overseas destination. This can include:

- Booking space with the carrier;
- Completing export documentation;
- Arranging for cargo insurance;
- Advising on foreign import regulations;
- Providing guidance on packaging, marking, and labeling;
- Arranging for products to be packed and containerized at the exporter's request;
- Export clearance.

Some freight forwarders are also freight consolidators, but this is not a standard service. Freight forwarders operate on a fee basis paid by the exporter (or importer). The forwarders' fees consist of an agreed-upon amount, plus documentation charges. The cost for their services should be figured into the price charged to the customer. Freight forwarders also collect a percentage of the freight costs from the carrier.

Insurance

Insurance will generally be a necessary part of importing devices from Asia. A common term of sale is FOB (Free on Board), which transfers the risk and cost of loss or damage to the goods to the buyer once the goods reach the ship. Therefore, the buyer should purchase insurance on the goods. In general, insurance costs include basic invoice costs as well as additional charges in the invoice such as export packing, inland freight, consular and other fees, ocean freight, insurance premiums, and anticipated profit.

The most basic type of insurance coverage is “Free of Particular Average” (FPA) coverage. It is the narrowest coverage in common use. This clause provides that in addition to total losses, partial losses resulting from perils of the sea are recoverable, but only in the event that the carrying vessel has been stranded, sunk, burnt, on fire, or in collision.

Certain types of losses are excluded from insurance coverage, despite having an “all risks” clause. The “all risks” clause is not actually all-inclusive; it covers only physical loss or damage from external cause(s) and does not include war risks, strikes, riots, or civil commotions. These risks would have to be included in a separate policy for an additional premium.

The “delay” clause is also common; it excludes claims for loss of market and for loss, damage, or deterioration arising from delay. A market loss is an indirect or consequential damage; it is not a “physical loss or damage.” This exclusion appears in almost every cargo policy.

Unlike most other types of insurance rates, the rates for marine insurance are not standardized. Rather, they are generally determined by the cargo, experience of the risk, and the judgment of the underwriter. As experience under an open policy develops, the premium and loss record will be reviewed at intervals, and rate adjustments will be made, if the record and existing circumstances justify such action in the opinion of the underwriter. Insurance is typically handled through a freight forwarder.

Packing is an integral part of the cargo shipped, and damage caused by the original packing—or lack thereof—does not arise from an external cause. It is excluded no matter when the damage itself may occur. For instance, nails may be driven by a careless packer into the contents of the package.

Customs Issues *(for formal entry)*

Surety Bond: a bond is like an insurance policy that is payable to Customs in the event that the importer does not comply with import requirements. Having a bond on file allows an importer to take possession of his merchandise before the payment of duties, taxes and fees. Bonds can be obtained from a surety, which is an insurance company that has been authorized by the Treasury Department to write Customs bonds.

Formal Entry of Goods' documentation: Importing these products from a Chinese manufacturer will be classified as a formal entry of goods, since it is not a personal shipment and since it will be valued at more than \$2,000. Formal entries require four different types of documentation:

- A bill of lading, airway bill, or carrier's certificate (naming the consignee for customs purposes) as evidence of the consignee's right to make entry.
- A commercial invoice obtained from the seller, which shows the value and description of the merchandise.
- Entry manifest (Customs Form 7533) or Entry/Immediate Delivery (Customs Form 3461).
- Packing lists (if appropriate) and other documents necessary to determine whether the merchandise may be admitted.

Classification: All goods that enter the United States are categorized according to the Harmonized Tariff Schedule of the United States (HTSUS) (<http://hts.usitc.gov/>).

Classification determines how much duty will be collected. Classification is more than simply looking up an item in an index. It is a very complicated process requiring the application of the General Rules of Interpretation; the section, chapter and subheading notes; and the Explanatory Notes. The importer is responsible for properly classifying his merchandise before entry. If he is not sure how to properly classify an item, he can submit a request, in writing, for a binding classification ruling to the National Commodity Specialist Division, US Customs, Attn: Classification Ruling Requests, New York, NY 10048.

The rulings will be binding at all ports of entry unless revoked by the Headquarters' Office of Regulations and Rulings. If an importer is not satisfied with the binding ruling received from New York, he or she can appeal it to the Headquarters' Office of Regulations and Rulings, Washington, DC 20229. The Customs Service will not issue binding rulings in response to oral requests. Import Specialists can give oral advisory rulings but the classification-related opinions or advice of Customs Service personnel at one port are not binding on the Customs ports elsewhere. Oral inquiries may be made to Customs offices regarding existing binding rulings that might cover your importation. Binding rulings may also be researched on the Customs web site at <http://www.cbp.gov/>.

Declaration of Merchandise's Dutiable Value: The importer must declare the dutiable value of merchandise. The final appraisement is fixed by Customs. Several appraisement methods are used to arrive at this value. The transaction value serves as the primary basis of appraisement. Transaction value is the price actually paid or payable by the buyer to the seller for the goods imported. Other factors may also add to the dutiable value of merchandise, such as packing costs, selling commissions, royalty or licensing fees, etc.

When the transaction value cannot be determined, then the value of the imported goods being appraised is the transaction value of identical merchandise. If merchandise identical to the imported goods cannot be found or an acceptable transaction value for such merchandise does not exist, then the value is the transaction value of similar merchandise. Similar merchandise means merchandise that is produced in the same country and by the same person as the

merchandise being appraised. It must be commercially interchangeable with the merchandise being appraised. The identical or similar merchandise must have been exported to the United States at or about the same time the merchandise being appraised is exported to the United States.

Duties and processing fees: The importer must pay estimated duties and processing fees if applicable. Customs makes the final determination of the correct rate of duty. The duty rate of an item is tied to its classification number. The HTSUS provides several rates of duty for each item: general rates for countries with which we maintain normal trade relations (NTR); *special* rates for special programs (free, or lower than the rates currently accorded NTR countries); and *column 2* rates for imports not eligible for either general or special rates. Customs duties are generally assessed at *ad valorem* rates, a percentage of which is applied to the dutiable value of the imported goods. Some articles, however, are dutiable at a *specific rate* (so much per piece, liter, kilo, etc); others at a *compound* rate of duty (i.e., combination of both ad valorem and specific rates).

All products shipped across international borders are subject to additional fees such as duties or taxes. These fees are assessed by the importing country and generally collected by the shipping/freight forwarding company.

Admissibility Requirements: It is the importer's responsibility to ensure that his or her goods being imported meet admissibility requirements (such as proper marking, safety standards, etc.) and that the proper permits, if required, have been obtained in advance of the goods arriving in the United States (i.e., the goods must meet FDA requirements if necessary).

US FDA Regulations for Importing Medical Devices

If you are sourcing or manufacturing medical devices in Asia to be imported into the US, there are several FDA regulations you need be aware of.

Classification

The starting point of importing medical devices is determining the device's classification. If the device is classified as a Class I device (i.e. low-risk), then it is exempt from pre-market notification, also known as 510(k). This will make them much easier to import.

Devices classified as Class II (medium-risk) are slightly more complicated, since some Class II devices are from pre-market notification, while others are not. For example, dressings, gauze/sponges (internal), and blood pressure monitors are not exempt from 510(k) requirements. Class III (high-risk) devices require 510(k).

510(k) forms

If the device requires a 510(k), this should not be a big obstacle to importing it. The 510(k) is intended to demonstrate that the device is safe and effective.

A device is considered to be substantially equivalent if, in comparison to a predicate device it:

- has the same intended use as the predicate device; and
- has the same technological characteristics as the predicate device; or
- has different technological characteristics, that do not raise new questions of safety and effectiveness, and the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

Applicants must compare their device to one or more similar devices already on the US market and make and support their substantial equivalency claim.

Establishment Registration

Foreign establishments that manufacture devices for export into the US are required to register their establishments with the FDA on Form FDA-2891. Registration does not mean that the FDA has approved the manufacturer or its devices, however. There is no fee for registration.

In addition, the foreign establishment must provide the FDA with the name of the United States agent representing its establishment. Foreign establishments must also continue to list the devices that they export to the US on the listing form FDA-2892.

Medical Device Listing

Most foreign medical device establishments required to register with the FDA must list the devices they have in commercial distribution. Medical device listing is a means of keeping the FDA advised of the generic category(s) of devices an establishment is marketing. Importers cannot submit the listing form FDA-2892 for foreign establishments; foreign manufacturers should submit the form signed by the foreign establishment's official correspondent.

Listing of a medical device does not mean that the FDA has approved the establishment or the device. Unless exempt, pre-market clearance (i.e. 510(k) approval) is required before a device can be marketed (placed into commercial distribution) in the US.

General Legal Compliance

In many developing Asian countries, the rule of law is not well established. Depending on the country, some corrupt or illegal practices may be routine even with reliable manufacturing partners. However, you should avoid following their lead, because foreigners, as a rule, will be held to higher standards.

In China, there is a long history of foreign businesses skirting the law. For example, there are thousands of representative offices that are not registered with the government and do not pay

taxes. Some Western businesses in China do things they would not normally do on the advice of their partners, such as issuing false receipts. You may be told by your partner that these practices are standard and the laws are never enforced. This may be true for them, but it is still not safe or advisable. Unregistered representative offices, for example, are now being cracked down on in many cities.

Your partner may explain that its connections (*guanxi*) will protect you from legal risk. *Guanxi* is certainly important, but it is not a get-out-of-jail-free card. In one well-known case, Lai Changxing, a successful Fujianese businessman, cultivated many friends at high levels of government. But when top officials chose to make an example of him on smuggling charges, these friends were unable to help him. His family was arrested, and he fled to Canada.

Ethical standards in business are rapidly rising in China, and this is especially true for foreign businesses. Illegal activities by foreigners may be labeled as “taking advantage of” China and the Chinese people. Exposing them can enhance the reputation of the government officials or journalists responsible. Companies and persons in the US are also barred from bribery abroad by the Foreign Corrupt Practices Act. Because of this, it is very important to stay within the law at every opportunity.

Asian Business Culture

When you go to Asia to inspect partners, make deals, or keep up relationships, you should be aware of how to take local people’s culture into account. Although some characteristics are common to Asians in general, there are significant differences from country to country that should be considered.

In general, no matter the country, avoid being the “brash American.” In the US, we are encouraged to be direct, bringing up problems openly. In Asia, this is offensive because it causes people to lose face in front of their colleagues. Problems should be mentioned obliquely or in private.

Not just in China but across Asia, relationships are key to business success. Traditionally, Americans think of business as defined around laws, rules, and self-interest. In this view, a person chooses to take a job or sign a contract because he has decided that the rewards in the agreement outweigh the risks. In Asia, people’s relationships are the framework, and written agreements are incidental to those relationships. A person makes a deal with someone else in order to help them out, and expects to be helped later in return. Until these relationships have been forged over time, business can be done, but it will be more difficult.

People from Korea or Japan are especially group-oriented and tend to seek consensus solutions among their group before moving forward. This is less true in China and Southeast Asia, where there is still a group orientation, but decisions may be made more unilaterally.

In much of Asia, there is a less strict attitude toward punctuality than in the US and Europe. When a contact is somewhat late for an appointment in Southeast Asia or (to a lesser degree) in

China, this should not be taken as a sign of incompetence or as an insult. On the other hand, Japanese and Koreans are extremely time-sensitive, comparable to Germans, and you should make every effort to be punctual.

Sourcing: The Big Picture

The greatest worry for most Western companies looking to source their products is that the supplier may eventually develop the capacity to produce and promote products on its own, cutting you out of the loop. If a long history of development and evolution is behind your product, there is the risk that your supplier will internalize that knowledge and experience to become your competitor – even if they do not steal your intellectual property. In these cases, if you choose to source, you should consider making a closer, longer-term relationship with less risk that integrates the manufacturer into your strategy.

The sourcing process should bear in mind the future when the Asian countries are fully developed. What is your company's core competency – marketing, design, R&D, or something else? You should make sure that your sourcing will not erode that competency over time.

Summary

This report has tried to familiarize the reader with information related to sourcing and manufacturing in Asia. Many people hear about the promise of Asia and assume that sourcing there is bound to be quick and cost-effective. However, many manufacturers are unscrupulous or have hidden drawbacks, so comprehensive due diligence and quality control is indispensable. The entire sourcing process from beginning to end might actually take *longer* than it would to use a Western contract manufacturer. However, once you have made the proper effort, the financial reward can be considerable.

XII. Appendix A: Websites for Manufacturer Searches

- a. <http://www.alibaba.com>
- b. <http://www.made-in-china.com/>
- c. <http://www.ecplaza.net/>
- d. <http://ec21.com>
- e. <http://www.manufacturers.com.tw>
- f. <http://www.tradebig.com>
- g. <http://trademama.com>

XIII. Appendix B: Selected Contract Sterilization Companies

Centurion Sterilization Services

Address: 301 Catrell Dr., Howell, MI 48843-0170
Phone (517) 545-3748; (866) 386-0530
Fax: (517) 546-3356
Email: contractsterilization@tshsc.com
Website: <http://www.centurionsterile.com>
Locations: Michigan, North Carolina, Arizona

Ethox STS Life Sciences Division

Address: 7500 W. Henrietta Rd., Rush, NY 14543
Phone (585) 533-1672; (866) 836-4850
Fax: (585) 533-1796
Email: info@sts.ethoxint.com
Website: <http://www.stsduotek.com>
Locations: New York, Pennsylvania (Ethox International, Inc.)

Life Science Outsourcing Inc.

Address: 830 Challenger St., Brea, CA 92821
Phone (714) 672-1090
Fax: (714) 672-1093
Email: info@lso-inc.com
Website: <http://www.lso-inc.com>
Locations: California

North American Sterilization & Packaging Company

Address: 19 Park Drive, Franklin, New Jersey 07416
Phone (973) 209-4388; (800) 392-6310
Fax: (973) 209-6374
Email: info@naspco.com
Website: <http://www.naspco.com>
Locations: New Jersey

Shoney Scientific Inc.

Address: W223, N720 Saratoga Drive, Suite 120, Waukesha, WI 53186
Phone (262) 970-0170
Fax: (253) 650-6972
Email: suryshoney@gmail.com, shoney53186@yahoo.com
Website: www.shoney.com
Locations: Wisconsin, India

Sterigenics

Address: 2015 Spring Rd., Ste. 650, Oak Brook, IL 60523
Phone (630) 928-1700; (800) 472-4508
Fax: (630) 928-1701
Email: info@sterigenics.com
Website: <http://www.sterigenics.com>
Locations: US, Canada, Mexico, China, Thailand, UK, France, Belgium, Netherlands, Germany, Denmark

Sterilization Services

Address: 6005 Boat Rock Blvd., Atlanta, GA 30336
Phone (404) 344-8423
Fax: (404) 344-8665
Email: tfisher@sterilization-services.com
Website: <http://www.sterilization-services.com>
Locations: Tennessee, Georgia, Virginia

STERIS Isomedix Services

Address: 5960 Heisley Rd., Mentor, OH 44060
Phone (877) 783-7479
Fax: (440) 354-2600
Email: kevin_cmiel@steris.com
Website: <http://www.isomedix.com/>
Locations: California, Utah, Arizona, Texas, Illinois, Minnesota, Ohio, South Carolina, New Jersey, New York, Massachusetts, Puerto Rico, Canada

XIV. Appendix C: Selected Freight Forwarding Companies

AIT Worldwide Logistics, Inc.

Address: 701 N. Rohlwing Rd., Itasca, IL 60143
Phone (800) 669-4248, (630) 766-8300
Fax: N/A
Email: Info@AITWorldwide.com
Website: <http://www.aitworldwide.com>

Alba Wheels Up International, Inc.

Address: 150-30 132nd Avenue, Jamaica, NY, 11434
Phone (718) 276-3000
Fax: (718) 712-1222
Email: jfk@alba-wheelsup.com
Website: <http://www.albawheelsup.com/>

AVIO International Forwarders Corp

Address: 337 Merrick Road, Suite # 1, Lynbrook, NY 11563
Phone (516) 872-8800
Fax: (516) 872-8811
Email: avio@aviofreight.com; jfk@aviofreight.com
Website: <http://www.aviofreight.com>

Berklay Freight Services

Address: 14 Bond Street, Suite 223, Great Neck, NY 11021
Phone (516) 872-3335, (800) 254-4422
Fax: (516) 872-3331
Email: info@berklay.com
Website: <http://berklay.com>

Cargo International Logistics Inc.

Address: Willow Creek Executive Office Center, 3729 Union Road Suite 20,
Cheektowaga, NY 14225-4246
28 E. Jackson Blvd., 10F #M633, Chicago, IL 60604
Phone (905)-524-2112
Fax: (905)-524-0099
Email : info@cargoagents.net
Website: <http://www.cargoagents.net>

Certified Packaging & Transport, Inc.

Address: 10305 Guilford Rd, Jessup, MD 20794
Phone (800) 891-2147; (301) 604-2147
Fax: (301) 604-0324
Email: mark@certifiedpackaging.com
Website: <http://www.certifiedpackaging.com>

Coppersmith Global Logistics

Address: 800 S. Hindry Ave, Unit A, Inglewood, CA 90301
Phone (310) 215-8282
Fax: (310) 649-0324
Email: salesquotes@coppersmith.com
Website: <http://www.coppersmith.com>

COSCO Container Lines Americas, Inc. (New York)

Address: 100 Lighting Way, Secaucus, NJ 07094
Phone (201) 422-0500; (800) 242-7354
Fax: (201) 422-8956
Email: webcontact@cosco-usa.com; dsandgrund@cosco-usa.com
Website: <http://www.cosco-usa.com>

DB Schenker

Address: 150 Albany Ave., Freeport, NY 11520
Phone (516) 377-3000; (800) 225-5229
Website: <http://www.dbschenkerusa.com>

Genesis Forwarding Services

Address: 800 Hindry Avenue #B, Inglewood, CA 90301
Phone (310) 338 8888
Fax: (310) 338 0433
Email: ImportsLAX@genesis-forwarding.com
Website: <http://www.genesis-forwarding.com>

John S. Connor, Inc.

Address: 799 Cromwell Park Drive, Suite A-G, Glen Burnie, MD 21061
Phone (410) 863-0211
Fax: (410) 863-1377
Email: info@jsconnor.com
Website: <http://www.jsconnor.com>

Mediterranean Shipping Company

Address: 40 Avenue Eugene-Pittard, CH-1206, Geneva, Switzerland
Phone +41 22 703 8888
Fax: +41 22 703 8787
Email: info@mscgva.ch
Website: <http://www.mscgva.ch>

Rosemark Shipping LLC

Address: 3491 Long Dr., Minden, NV 89423
Phone (775) 267-0970
Fax: (776) 267-0972
Email: joc@rosemark.com

Schaefer Trans. Inc.

Address: 580 Atlantic Ave., East Rockaway, NY 11518
Phone (516) 561-2800
Fax: (516) 561-2870
Email: andre.krawentek@schaefertransinc.com
Website: <http://www.schaefertransinc.com>

Seaborne International, Inc.

Address: 406 North Oak Street, Inglewood, CA 90302
Phone (800) 662-6722; (310) 330-9020
Fax: (310) 330-1180
Email: sar@seaborne-intl.com
Website: <http://www.seaborne-intl.com>

XV. Appendix D: Medical Device-Related Trade Shows in Asia

China

International Medical Instruments and Equipment Exhibition (China Med)

Frequency: Annual
Next Show: March 21-23, 2014
Location: China National Convention Center, Beijing, China
Website: www.chinamed.net.cn

Dental South China International Expo

Frequency: Annual
Next Show: March 6-9, 2014
Location: China Import and Export Fair Pazhou Complex, Guangzhou, China
Website: <http://www.dentalsouthchina.com/En/>

China International Medical Equipment Fair (CMEF)

Frequency: Semi-annual
Next Show: April 17-20, 2014
Location: Shenzhen Convention & Exhibition Center, Shenzhen, China
Website: <http://en.cmf.com.cn>

China Exhibition and Conference on Analytic and Laboratory Equipment (CECIA)

Frequency: Annual
Next Show: March 12-14, 2014
Location: Guangzhou Poly World Trade Center, Guangzhou, China
Website: www.chinacecia.com

MEDTEC China

Frequency: Annual
Next Show: September 25-26, 2014
Location: Shanghai World Expo Exhibition & Convention Center, Shanghai, China
Website: www.canontradeshows.com/expo/shanghai10/when_where_en.html

China International Optics Fair (CIOF)

Frequency: Annual
Next Show: September 3-5, 2014
Location: China International Exhibition Center, Beijing, China
Website: www.ciof.cn

China International Exhibition & Symposium on Dental Equipment, Technology & Products (Dentech China)

Frequency: Annual
Next Show: October 22-25, 2014
Location: Shanghai World Expo Exhibition & Convention Center, Shanghai, China

Website: www.dentech.com.cn

Hong Kong

Hong Kong International Medical Devices and Supplies Fair

Frequency: Annual
Next Show: May 7-9, 2014
Location: Hong Kong Convention and Exhibitions Center, Hong Kong
Website: <http://www.hktdc.com/fair/hkmedicalfair-en/>

India

India Lab Expo: International Exhibition on Laboratory and Scientific Instruments

Frequency: Annual
Next Show: November 6-8, 2014
Location: Hitex Exhibition Center, Hyderabad, India
Website: www.indialabexpo.com/index.asp

Medicall: Hospital Needs Expo

Frequency: Annual
Next Shows: August 1-3, 2014
Locations: Chennai Trade Centre, Chennai, India
Website: www.medicall.in/

Medical Fair India: International Exhibition and Conference on Diagnostics, Medical Equipment and Technology

Frequency: Annual
Next Show: March 14-16, 2014
Location: Pragati Maldan, New Delhi, India
Website: <http://www.medicalfair-india.com/>

Healthex: International Exhibition on Hospital, Medical and Surgical Equipment, Materials, Supplies, and Allied Services

Frequency: Annual
Next Show: September 2014
Location: Bangalore International Exhibition Center, Bangalore, India
Website: www.healthex.co.in

Indonesia

Indonesia Medical & Hospital Equipment Expo (IMEX)

Frequency: Annual
Next Show: August 27-30, 2014
Location: JIExpo, Kemayoran, Jakarta, Indonesia
Website: <http://www.indomedicaexpo.com/>

Japan

Photonics Japan: Laser, Optics and Sensing Technology

Frequency: Annual
Next Show: April 16-18, 2014
Location: Tokyo Big Sight (Tokyo International Exhibition Center), Tokyo, Japan
Website: <http://www.photonicsjapan.jp/en>

Tokyo Health Industry Show (THIS)

Frequency: Annual
Next Show: March 12-14, 2014
Location: Tokyo Big Sight (Tokyo International Exhibition Center), Tokyo, Japan
Website: <http://www.this.ne.jp/eng/>

Medtec Japan

Frequency: Annual
Next Show: April 9-11, 2014
Location: Tokyo Big Sight (Tokyo International Exhibition Center), Tokyo, Japan
Website: <http://www.medtecjapan.com/en>

Medical and Imaging Expo

Frequency: Annual
Next Show: April 23-25, 2014
Location: Pacifico Yokohama, Japan
Website: <http://www.opie.jp/en/mi/index.php>

International Home Care & Rehabilitation Exhibition (HCR)

Frequency: Annual
Next Show: October 1-3, 2014
Location: Tokyo Big Sight (Tokyo International Exhibition Center), Tokyo, Japan
Website: <http://www.hcrjapan.org/english/>

Hospex Japan: International Healthcare Engineering Exhibition

Frequency: Annual
Next Show: November 12-14, 2014
Location: Tokyo Big Sight (Tokyo International Exhibition Center), Tokyo, Japan
Website: <http://www.jma.or.jp/hospex/en/index.html>

Malaysia

Southeast Asian Healthcare & Pharma Show

Frequency: Annual
Next Show: March 4-6, 2014
Location: Kuala Lumpur Convention Centre, Kuala Lumpur, Malaysia
Website: <http://www.abce.com/>

Singapore

International Dental Exhibition and Meeting (IDEM) Singapore

Frequency: Biennial
Next Show: April 4-6, 2014
Location: SUNTEC Singapore International Convention and Exhibition Centre, Singapore
Website: <http://www.idem-singapore.com/>

Medical Fair Asia: International Exhibition on Hospital, Diagnostic, Pharmaceutical, Medical & Rehabilitation Equipment and Supplies

Frequency: Biennial
Next Show: September 9-11, 2014
Location: SUNTEC Singapore International Convention and Exhibition Centre, Singapore
Website: <http://www.medicalfair-asia.com>

South Korea

Korea International Medical & Hospital Equipment Show (KIMES)

Frequency: Annual
Next Show: March 13-16, 2014
Location: COEX Korea Exhibition Center, Seoul, Korea
Website: <http://www.kimes.kr/eng/>

International Healthcare & Medical Expo

Frequency: Annual
Next Show: April 10-13, 2014
Location: Busan Exhibition and Convention Center (BEXCO), Busan, Korea
Website: <http://iwimexpo.co.kr/english.php>

Taiwan

Sencare Expo: Taiwan International Senior Lifestyle and Health Care

Frequency: Annual
Next Show: June 19-22, 2014
Location: Taipei World Trade Center Exhibition Hall, Taipei, Taiwan
Website: <http://www.sencare.com.tw/>

Mediphar Taipei: International Show on Medical Equipment, Pharmaceuticals, and Biotech

Frequency: Annual
Next Show: June 2014
Location: Taipei World Trade Center Exhibition Hall, Taipei, Taiwan
Website: <http://www.mediphar.com.tw/>

Thailand

Medical Fair Thailand

Frequency: Biennial
Next Show: September 2015
Location: Queen Sirikit National Convention Center (QSNCC), Bangkok
Website: www.medicalfair-thailand.com

Vietnam

Medi-Pharm Expo: International Medical, Hospital, and Pharmaceutical Exhibition

Frequency: Annual
Next Show: August 21-23, 2014
Location: Tan Binh Exhibition & Convention Center, Ho Chi Minh City, Vietnam
Website: <http://www.medipharmexpo.com>

XVI. Appendix E: Government Bodies

1. Medical Device Product Registration Bodies

China

China Food and Drug Administration, Department of Medical Device Registration and
Department of Medical Device Supervision

Address: No. 26 XuanWuMen Xi Road, Building 2, Beijing, China 100053
Phone: +86 10 6831 3344
Fax: +86 10 6831 0909
Website: <http://eng.sfda.gov.cn>

Taiwan

Food and Drug Administration, Ministry of Health and Welfare

Address: No. 161-2, Kunyang St., Nangang District, Taipei City 115-61, Taiwan
Phone: +886 2 2787 8000
Fax: +866 2 2787 8099
Website: <http://www.fda.gov.tw/EN/index.aspx>

Philippines

Food and Drug Administration, Department of Health

Address: San Lazaro Compound, Tayuman, Sta. Cruz, Manila, Philippines 1003
Phone: +63 2 743 8301 Extension 23
Fax: +63 2 743 1829
Website: <http://www.fda.gov.ph/>

Thailand

Medical Device Control Division, Food and Drug Administration, Ministry of Public Health

Address: Thanon Tiwanond, Amphoe Muang, Nonthaburi 11000, Thailand
Phone: +66 2590 7244
Fax: +66 2591 8479
Website: <http://www.fda.moph.go.th/eng/medical/index.stm>

India

Central Drugs Standard Control Organization

Address: FDA Bhavan, ITO, Kotla Road, New Delhi 110002, India
Phone: +91 11 2323 6965
Fax: +91 11 2323 6973
Website: <http://www.cdsc.nic.in>

Singapore

Centre for Medical Device Regulation, Health Sciences Authority

Address: 11 Biopolis Way #11-01 Helios, Singapore 138667
Phone: +65 6213 0838
Fax: +65 6478 9028
Website: <http://www.hsa.gov.sg>

Malaysia

Medical Devices Authority, Ministry of Health

Address: Level 5, No. 26, Menara Prisma, Jalan Persiaran Perdana, Precinct 3, Putrajaya, Malaysia 62675
Phone: +60 3 8892 2400
Fax: +60 3 8892 2500
Website: <http://www.mdb.gov.my>

Vietnam

Department of Medical Equipment and Health Works, Ministry of Health

Address: 138A Giang Vo, Ba Dinh, Hanoi, Vietnam
Phone: +84 4 6273 2268
Fax: +84 4 3846 4051
Website: <http://www.moh.gov.vn>

Indonesia

Directorate General Pharmaceutical Services and Medical Device Services, Ministry of Health

Address: Jalan Percetakan Negara No. 29, Jakarta, 10560 Indonesia
Phone: +62 21 4287 3416
Website: <http://www.binfar.depkes.go.id>

2. Industrial Promotion and Economic Development Bodies

China

Ministry of Commerce

Address: No. 2 Dong Chang'an Avenue, Beijing 100731, China
Phone: +86 10 8751 9094
Fax: +86 10 8751 9093
Website: <http://www.mofcom.gov.cn>

Taiwan

Department of Investment Services, Ministry of Economic Affairs

Address: 8th Fl., 71 Guanqian Rd., Taipei 100-47, Taiwan
Phone: +886 2 2389 2111
Fax: +886 2 2382 0497
Website: <http://investtaiwan.nat.gov.tw/>

Industrial Development Bureau, Ministry of Economic Affairs

Address: No. 41-3, Hsin Yi Rd., Sec. 3, Taipei, Taiwan
Phone: +886 2 2754 1255
Fax: +886 2 2703 0160
Website: <http://www.moeaidb.gov.tw/>

Biotechnology and Pharmaceutical Industries Program Office, Ministry of Economic Affairs

Address: Room A, 17F, No. 3, YuanQu St., Nangang District, Taipei 11503, Taiwan
Phone: +886 2 2655 8133
Fax: +886 2 2655 8134
Website: <http://www.biopharm.org.tw/en>

Philippines

Department of Trade and Industry

Address: 385 Industry and Investments Bldg., Sen. Gil Puyat Ave., Makati City, Philippines 1200
Phone: +63 2 751 0384
Fax: +63 2 895 6487
Website: <http://www.dti.gov.ph>

Board of Investments

Address: 385 Industry and Investments Bldg., Sen. Gil Puyat Ave., Makati City, Philippines 1200
Phone: +63 2 890 1332
Website: <http://www.boi.gov.ph>

Thailand

Department of International Trade Promotion

Address: 22/77 Rachadapisek Road, Chatuchak, Bangkok 10900, Thailand
Phone: +66 2 512 0093
Fax: +66 2 512 2670
Website: <http://www.thaitrade.com>

Department of Business Development, Ministry of Commerce

Address: 44/100 Nonthaburi 1 Rd., Bangkrasor, Muang Nonthaburi 11000, Thailand
Phone: +66 2 547 5050
Fax: +66 2 547 4459
Website: <http://www.dbd.go.th/>

India

India Trade Promotion Organisation

Address: Pragati Bhavan, Pragati Maidan, New Delhi 110001, India
Phone: +91 11 2337 1540
Fax: +91 11 2337 1492
Website: <http://www.tradeportalofindia.com>

Pharmaceuticals Export Promotion Council (Pharmexcil)

Address: 101, Aditya Trade Centre, Ameerpet, Hyderabad 500038, India
Phone: +91 40 2373 5462, +91 40 2373 5466
Fax: +91 40 2373 5464
Website: <http://www.pharmexcil.com>

Note: Pharmexcil's mandate includes medical devices.

Singapore

Economic Development Board

Address: 250 North Bridge Road, #28-00 Raffles City Tower, Singapore 179101
Phone: +65 6832 6832
Fax: +65 6832 6565
Website: <http://www.edb.gov.sg>

Malaysia

Malaysian Investment Development Authority

Address: Block 4, Plaza Sentral, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur, Malaysia
Phone: +60 3 2267 3633
Fax: +60 3 2274 7970
Website: <http://www.mida.gov.my>

Malaysia External Trade Development Corporation, National Trade Promotion Agency

Address: Jalan Khidmat Usaha, Off Jalan Duta, 50480 Kuala Lumpur, Malaysia
Phone: +60 3 6207 7077
Fax: +60 3 6203 7037, +60 6203 7033
Website: <http://www.matrade.gov.my>

Vietnam

Vietnam Trade Promotion Agency (VIETRADE)

Address: 20 Ly Thuong Kiet St., Hanoi, Vietnam
Phone: +84 4 3934 7628
Fax: +84 4 3934 4260
Website: <http://www.vietrade.gov.vn/en/>

Ministry of Planning and Investment

Address: 6B Hoang Dieu St., Ba Dinh District, Hanoi, Vietnam
Phone: +84 4 3845 5298
Fax: +84 4 3823 4453
Website: http://www.mpi.gov.vn/portal/page/portal/mpi_en

Indonesia

National Agency for Export Development (NAFED), Ministry of Trade

Address: Jl. M.I. Ridwan Rais No. 5, 3rd/4th/13th/14th Floor, Central Jakarta 10110, Indonesia
Phone: +62 21 385 8171
Fax: +62 21 2352 8652
Website: <http://www.nafed.go.id>

Investment Coordinating Board (BKPM)

Address: Jednd. Gatot Subroto No. 44, PO Box 3186, Jakarta 12190, Indonesia
Phone: +62 21 5252 008
Fax: +62 21 5264 211
Website: <http://www.bkpm.go.id>

XVII. Appendix F: Selected Trade Associations

China

China Association for Medical Devices Industry

Address: 5th Floor, No. 20 Zhichun Road, Haidian District, Beijing 100088, China
Phone: +86 10 8228 3850
Fax: +86 10 8228 3889
Website: <http://www.camdi.cn/en>
Email: camdi@cmic.com.cn

Indonesia

Gakeslab Indonesia (Association of Indonesian Medical and Laboratory Companies)

Address: Jl. Rawamangun Muka Raya No. 1A, Jakarta 13220, Indonesia
Phone: +62 21 472 2213
Fax: +62 21 4786 4338
Email: setgakeslabindo@yahoo.co.id

Malaysia

Association of Malaysia Medical Industries

Address: Level 32 Menara Prestige, No. 1 Jalan Pinang, 50450 Kuala Lumpur, Malaysia
Phone: +60 10 4040 662
Fax: +60 3 2178 4347
Website: <http://www.ammi.com.my>
Email: secretariat@ammi.com.my

Taiwan

Taiwan Medical and Biotech Industry Association

Address: 3F-3, No. 6, Lane 609, Sec. 5, Chongsin Rd., Sanchong City, Taipei County 241, Taiwan
Phone: +886 2 2995 6099
Fax: +886 2 2995 6100
Website: <http://www.tmbia.org.tw/eng/>
Email: tmbia@tmbia.org.tw

Thailand

Thai Medical Device Technology Industry Association

Address: 11th Fl., Dr. Gerhard Link Building, 88 Krungthepkreetha Road,
Huamark, Bangkok, Bangkok 10240, Thailand

Phone: +66 2379 4279

Fax: +66 2379 4297

Website: <http://www.thaimed.co.th>

Email: thaimed@truemail.co.th, info@thaimed.co.th

XVIII. Appendix G: Selected Biomedical Development Zones in Asia

I. CHINA

China Association of Development Zones (General)

Address: 23, Kaixie Hotel, Hujiayuan, Dongzhimen Wai, Beijing, 100027 China
Phone: +86 10 6462 6232
Fax: +86 10 6462 6236
Email: zhudp@cadz.org.cn (Dongping Zhu)
Website : www.cadz.org.cn

Beijing Zhongguancun Life Science Park

Address: 29, Life Park Road, Changping District, Beijing, 102206, China
Phone: +86 10 8072 2881
Fax: +86 10 8072 7522
Email: invest@lifesciencepark.com.cn
Website : www.lifesciencepark.com.cn

Nanjing Economic & Technological Development Zone

Address: 100, Xingang Avenue, Nanjing, 210038, China
Phone: +86 25 8580 0907/ 8580 0916/ 8580 0911
Fax: +86 25 8580 0906
Email: gwh@njxg.com
Website : www.njxg.com

Shanghai International Medical Zone

- Investment Center:

Address: Room 214, Building 1, 337 Zhou Zhu Road, Pudong, Shanghai, 201318, China
Phone: +86 21 3801 9333
Fax: +86 21 3801 9309
Email: simz@simz.com.cn
Website : www.simz.gov.cn

- Customer Service Center:

Address: Room 107, Building 2, 337 Zhou Zhu Road, Pudong, Shanghai, 201318, China
Phone: +86 21 3801 9688
Fax: +86 21 3801 9093
Email: shiliuchun@simz.com.cn
Website : www.simz.gov.cn

Shanghai Zhangjiang Hi-Tech Park

Address: 69, Zhangjiang Road, Pudong New Area, Shanghai, 201203, China
Phone: +86 21 5080 1818
Fax: +86 21 5080 0686

Email: ggllb@zjpark.com
Website : www.zjpark.com

SPV Jiaxing International Biotech Park

Address: Room 606, No. 1888 West Zhongshan Road, Xiuzhou District, Jiaxing, Zhejiang, 31403, China
Phone: +86 573 8272 2222 / +86 573 8272 2100
Fax: +86 573 8272 2200
Email: info@ibp.org.cn
Website : www.ibp.org.cn

Tianjin Economic-Technological Development Area

Address: Room 1701-03, TEDA Building, 256 Jiefangnan Road, Hexi District Tianjin, 210038, China
Phone: +86 22 2320 1111/ 2320 1116/ 2320 1168
Fax: +86 22 2320 1110
Email: teda-bj@teda.net
Website : <http://en.investteda.org>

Taizhou Medical High-Tech Industrial Development Zone

Address: 105, South Jiangzhou Road, China Medical Park, Jiangsu, 225500, China
Phone: +86 523 8620 0001
Website : www.medmax.cn/

Zhongshan National Health Technology Park

Address: Torch Development Zone, Zhang, Jia Bian, Zhongshan, Guangdong 528437, China
Phone: +86 760 8828 6888
Fax: +86 760 8531 0020
Email: nhttp@nhttp.gov.cn
Website : www.nhttp.gov.cn

II. TAIWAN

Hsinchu Science Park

Address: 2, Hsin-Ann Road, Hsinchu Science Park, Hsinchu, 300, Taiwan
Phone: +886 3 577 3311
Fax: +886 3 577 6222
Website : <http://www.hspb.most.gov.tw/>

Hsinchu Biomedical Park (part of Hsinchu Science Park)

Address: 3F, No.4, Yuancyu 1st Road, Hsinchu Science Park, Hsinchu, 30079, Taiwan

Phone: +886 3 500 9700
Fax: +886 3 500 9701
Email: hbmosp@sipa.gov.tw
Website : www.hbmosp.sipa.gov.tw

Central Taiwan Science Park

Address: 40763, No 2, Jhongke Road, Situn District, Taichung City 407, Taiwan
Phone: +886 4 2565 8588
Fax: +886 4 2565 8388
Email: ctsp00@ctsp.gov.tw
Website : <http://www.ctspb.most.gov.tw/>

Southern Taiwan Science Park

Address: 22, Nanke 3rd Road, Xinshi District, Tainan City 741-47, Taiwan
Phone: +886 6 505 1001
Fax: +886 6 505 0470
Website : <http://www.stspb.most.gov.tw/>

III. THAILAND

Thailand Science Park

Address: 111, Thailand Science Park, Paholyothin Road, Klong 1, Klong Luang, Pathumthani 12120, Thailand
Phone: +66 2 564 7222
Fax: +66 2 564 7001
Email: customerrelation@sciencepark.or.th
Website : www.sciencepark.or.th

IV. INDIA

Trivitron Medical Technology Park

Corporate Headquarters

Address: #15, IV Street, Abhiramapuram, Chennai 600 018, India
Phone: +91 44 2498 5050
Fax: +91 44 2498 5757
Email: corporate@trivitron.com
Website : <http://trivitron.com/>

Lucknow Biotech Park

Address: Sec-G, Jankipuram, Kursi Road, Lucknow, 226021, India
Phone: +91 522 236 5050 / +91 522 401 2076 / +91 522 405 3000
Fax: +91 522 401 2081
Email: info@biotechpark.org.in
Website : www.biotechpark.org.in

Shapoorji Pallonji Biotech Park

Address: A-13 Ground Floor, R K Niwas Street, # 3 Indian Airlines Colony
Begumpet, Secunderabad, 500003, Andhra Pradesh, India
Phone: +91 40 2790 0893 / +91 40 2790 1428
Fax: +91 40 2790 0893
Email: dhawan@spbiotechpark.in
(Mr Suresh Dhawan – Chief Executive Officer)
Website : www.spbiotechpark.in

Ticel Biopark

Address: Taramani Road, Taramani, Chennai 600 113, India
Phone: +91 44 2254 2061 / +91 44 2254 2062
Fax: +9144 2254 2055
Email: ticel@vsnl.net
Website : www.ticelbiopark.com

Gujarat Akruiti Biotech Park

Address: Akruiti Trade Centre, 6th Floor, Marol MIDC, Andheri East, Mumbai
400093, India
Phone: +91 22 6703 7400 / +91 22 6703 7515
Fax: +91 22 2821 8230
Email: biotech@akruticity.com

V. SINGAPORE

Biopolis – Agency for Science, Technology and Research

Corporate Headquarters

Address: 1 Fusionopolis Way, #20-10 Connexis North Tower, 138632 Singapore
Phone: +65 6826 6111
Fax: +65 6777 1711
Email: contact@a-star.edu.sg
Website : www.a-star.edu.sg

Tuas Biomedical Park – JTC Corporation

Corporate Headquarters

Address: The JTC Summit, 8 Jurong Town Hall Road, 609434, Singapore
Phone: +65 6560 0056
Fax: +65 6565 5301
Website : <http://www.jtc.gov.sg/realestatesolutions/pages/tuas-biomedical-park.aspx>

VI. MALAYSIA

Penang Science Park – Penang Development Corporation

Address: 1, Pesiaran Mahsuri, Bandar Bayan Baru, 11909 Bayan Lepas, Penang, Malaysia
Phone: +604 634 0111
Fax: +604 643 2405
Email: enquiry@pdc.gov.my
Website : www.pdc.gov.my

Technology Park Malaysia – Penang Development Corporation

Address: Level 5, Enterprise 4, Technology Park Malaysia, 57000 Bukit Jalil, Kuala Lumpur, Malaysia
Phone: +603 8998 2020
Fax: +603 8998 2110
Email: webmaster@tpm.com.my / noor_arliza@tpm.com.my (Business Development & Corporate Services)
Website : www.tpm.com.my

Bio-X-Cell Biotech Park, Nusajaya - UEM Land Holdings Berhad

Address: UEM Land Sdn Bhd, Nusajaya Centre, No 8, Ledang Heights, Nusajaya 81560, Johor, Malaysia
Phone: +607 277 3700 / +607 277 3762
Fax: +607 277 3699
Email: info@silcnusajaya.com
Website : www.silcnusajaya.com

VII. VIETNAM

Saigon Hi-Tech Park

Address: D1, Saigon Hi-Tech Park, Tan Phu Ward, District 9, Ho Chi Minh City, Vietnam.
Phone: +84 8 736 0293
Fax: +84 8 736 0292
Email: info@shtpvn.org
Website : www.shtp.hochiminhcity.gov.vn

Hoa Lac Hi-Tech Park

Address: Hoa Lac Hi-Tech Management Board, Km 29, Láng - Hoà Lạc Highway, Hanoi, Vietnam
Phone: +84 4 6326 9295
Fax: +84 4 6326 9290
Email: infor@hhttp.gov.vn
Website : www.hhttp.gov.vn

XIX. Appendix H: Spreadsheet Templates

- a. Cartons per container (one SKU)
- b. Cartons per container (multiple SKUs)
- c. Calculating freight costs

Included on CD-ROM with this report are templates in Microsoft Excel that will help facilitate your transportation and shipping decisions when dealing with multiple SKUs being shipped in one container.

These spreadsheets allow you to create your own configurations to determine the optimal number of units/cartons of each SKU to fill a container. After you input the number of cartons of the first SKU, the template will calculate how much space remains in the container to load other SKUs. In addition, it will also calculate freight costs for both air and ocean shipments for the various configurations.

Pacific Bridge Medical

7315 Wisconsin Avenue, Suite 609E

Bethesda, MD 20814

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(301) 469-3409

Email: contact@pacificbridgemedical.com

www.pacificbridgemedical.com

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