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Medical Device Strategies for Success in China, Japan, and India

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Overview of Asia



Asia Economic Statistics

	GDP (PPP)	Per capita GDP (PPP)	Real GDP Growth Rate
China	\$8.789 trillion	\$6,600	8.7%
Hong Kong	\$301 billion	\$42,700	-3%
India	\$3.56 trillion	\$3,100	6.5%
Indonesia	\$969 billion	\$4,000	4.5%
Japan	\$4.137 trillion	\$32,600	-5.3%
Korea	\$1.356 trillion	\$28,000	0.2%
Malaysia	\$381 billion	\$14,800	-2.2%
Philippines	\$327 billion	\$3,300	0.9%
Singapore	\$235.7 billion	\$50,300	-2.1%
Taiwan	\$717.7 billion	\$29,800	-2.5%
Thailand	\$538.6 billion	\$8,100	-2.8%
Vietnam	\$256 billion	\$2,900	5.8%

Source: CIA World Factbook.

Asia Demographic Statistics

	Population	Population Growth Rate	Life Expectancy at Birth
China	1,330,141,295	0.494%	74.51
Hong Kong	7,089,705	0.476%	81.96
India	1,173,108,018	1.376%	66.46
Indonesia	242,968,342	1.097%	71.05
Japan	126,804,433	-0.242%	82.17
Korea	48,636,068	0.258%	78.81
Malaysia	26,160,256	1.704%	73.55
Philippines	99,900,177	1.931%	71.38
Singapore	4,701,069	0.863%	82.06
Taiwan	22,974,347	0.227%	77.96
Thailand	66,404,688	0.601%	73.36
Vietnam	89,571,130	1.096%	71.94

Source: CIA World Factbook.

Asia Health Statistics

	Health expenditure per capita	Health expenditure as % of GDP	Physicians per 1,000 people	Hospital beds per 1,000 people
China	\$342	4.7%	1.4	2.2
India	\$109	5.0%	0.6	0.7
Indonesia	\$87	2.2%	0.1	0.6
Japan	\$2,514	8.1%	2.2	13.8
Korea	\$1,487	6.5%	1.9	7.8
Malaysia	\$500	4.4%	0.7	1.9
Philippines	\$223	3.9%	1.2	1.3
Singapore	\$1,228	3.5%	1.5	3.2
Thailand	\$346	3.7%	0.4	2.2
Taiwan	\$743	6.1%	2.2	4.2
Vietnam	\$264	7.1%	0.6	2.7

Source: World Health Organization

Asia Medical Device Markets

Country	Market Size (US\$)
China	\$8.8 billion
Hong Kong	\$600 million
Indonesia	\$430 million
India	\$2.7 billion
Japan	\$25 billion
Malaysia	\$700 million
Philippines	\$90 million
Singapore	\$500 million
Korea	\$3.6 billion
Taiwan	\$1.6 billion
Thailand	\$600 million
Vietnam	\$290 million

Asia Pharmaceutical Markets

Country	Market Size (US\$)
China	\$ 37 billion
Hong Kong	\$ 1.5 billion
India	\$ 11 billion
Indonesia	\$ 350 million
Japan	\$ 60 billion
Malaysia	\$ 450 million
Philippines	\$ 300 million
Singapore	\$ 500 million
Korea	\$ 10.3 billion
Taiwan	\$ 4.5 billion
Thailand	\$ 1.5 billion

Market Research

- Is there a demand for your product? If it sells here in the U.S., that does not mean it will sell in Asia.
 - How do you do market research?
 - Real primary research is the way to go.
- Hong Kong research firm interviews ten people and multiplies by ten for 100 interviews.
- Don't register products if there's no market.

Market Research (cont'd)

- Learn more about your competitors:
 - How and who do they distribute to.
 - Do they manufacture or source locally in an Asian country?
- Understand the market fully and investigate your customers/market.
- Determine who would really “push” your product.
- Potential pitfalls?

Finding the Right Distributor

- Use the same criteria as you would for a distributor search in the rest of the world.
- Relationships and trust are key.
 - Not lawsuits
 - Need introductions -- how do you do this?
- Check references very carefully.
- Regulatory people must be more involved with distributor search to analyze distributor regulatory department.

China Distributor Search

- Previously, distributors in China were state-owned companies:
 - Slow and methodical.
 - No marketing – just here are the products.
- Today, emergence of private companies that are usually not well-funded. Many still lack expertise in selling Western products.

China Distributor Search (cont'd)

- There are very few large-scale private national medical product distributors in China; thus it is necessary to put together several private regional groups.
- Recent WTO regulations have opened China's medical markets to foreign companies, but foreigners have been slow to move in.
- Some foreign companies have been successful in the China market.

Japan Distributor Search

- Finding a Japanese distributor takes longer than in other Asian countries.
- Relationships with the Japanese may take several years to develop.
 - Move slowly
 - Build trust

India Distributor Search

- ❑ Fragmented distributor network with few national distributors.
- ❑ Most likely need more than one distributor to cover the country.
- ❑ More issues with infrastructure compared to China/Japan, so careful research key.
- ❑ Many distributors unable to handle regulatory issues such as device registration.
- ❑ Choose distributors who deal in other imported products.

Distributor Agreements

- Have registration in your name or distributor's name?
Depends on situation.
- For China if you do NOT have an office there, can register in your own name but distributor will hold physical license.
- For China, India and Japan, can have your branch office/subsidiary hold registrations in your name.
- Key regulatory clauses?
- Always keep copies of your Asian offices' or Asian distributor's key documents such as registration certificates and key correspondences at your company's headquarters

Options For Foreign Companies

- Representative office
- Branch office
- Subsidiary KK corporation (Japan specific)
- Wholly Foreign Owned Enterprise (China)
/Wholly Owned Subsidiary (India)

Representative/Liaison Office

- Simplest form of business structure
 - Usually one person with assistant
 - Established in preparation for future expansion into branch or subsidiary
- Functions:
 - Advertising
 - Market research
 - Monitor activities of distributors/agents handling parent company's products
 - Cannot sell or conduct any “real business”
 - cannot generate any profits

Branch Office

- ❑ Requires some form of registration process.
- ❑ Usually must appoint an official representative responsible for local operations.
- ❑ Branch offices can earn income and remit to parent company.
- ❑ Can often export and import goods, act as a buying or selling agent, carry out research work, etc.

Subsidiary Corporation

Kabushiki Kaisha (KK)

- A KK is similar to US public corporation, though not always listed on the stock market.
 - Often wholly owned
- Advantages:
 - Easier to arrange local financing, lease office space, attract local employees
 - Prestige
 - Indicates long-term commitment
 - Limited liability
- Requirements
 - Three directors; at least one must reside in Japan.
- A new alternative to KK came out in May 2006 called “Godo Kaisha” (GK), but this form is not as established and very few companies are GK.

Advantages and Disadvantages

- Representative/Liaison office, Branch office, WOFE?
- Depends on market opportunities.
- Depends on budget.
- Depends on long-term goals or purpose of entering Asian market.

Hiring for Your Own Office

- Returnees
 - Bilingual, bicultural individuals who have lived, studied, and/or worked in the U.S. or Western countries and wish to return to their home countries for good job opportunities.
- Expatriates
- Locals

Advantages and Disadvantages

- Returnees
 - Familiar with the “West.”
 - Often highly skilled and fluent.
 - Have knowledge of country.
 - However, may conflict with local staff over status issues and could have difficulty relating to country.
- Expatriates
 - Desirable for companies just starting out and for executive positions.
 - However, may require high compensation packages and possible difficulty relating to workforce.
- Locals
 - Lower salary requirements, knowledge of local customs, connections.
 - However, may be unfamiliar with Western business practices, need more job training, inability to communicate well in English.

Set-up of Overall Asian Operation

- ❑ Japan business and non-Japan business.
- ❑ Japan business reporting to Singapore/Hong Kong, generally not good.
- ❑ Japan and other Asian office should report directly to US.
- ❑ Don't have Japan operations manage other offices in Asia.
- ❑ Indian managers running your Asian business may be tricky.

Regulatory Personnel in Asian Offices

- Where do you put regulatory people in your Asian operations?
- How many regulatory people do you put in your Asian office?
- Company conferences/outings to foster trust between US and Asian regulatory people.
- Have Asian regulatory people work in US for 6 months to a year; and US people live/work in Asia.
- Cross-cultural training for both sides.
- Many regulatory issues are really people issues and lack of trust.

Joint Venture Structures in China

- Chinese-foreign equity joint venture (EJV)
- Chinese-foreign cooperative joint venture (CJV)
- Previously, joint ventures were 50/50 (foreign/Chinese) but now 80/20 or 90/10.

Joint Venture in China (cont'd)

- Chinese-foreign equity joint venture EJV
 - Limited liability company with Chinese legal person status.
 - Parties invest together, manage together and share risks, losses and benefits in proportion to their contribution to registered capital.
- Chinese-foreign cooperative joint venture CJV
 - Parties determine manner of operation and management, obligations, risk and profit sharing, etc through contract at beginning of venture.

Joint Ventures in Japan

- Japanese government outlook on JVs
 - Situation improving for foreign companies in Japan.
- Must be approved by Ministry of Finance
- JV staff
- Head office support
- Foreign manager
- Potential problems
 - Establishing mutual confidence
 - Communication
 - Winning overall support

Joint Ventures in India

- ❑ No separate laws for joint ventures in India; often treated the same as domestic companies.
- ❑ Government approval required to set up joint venture.
- ❑ A limited company is formed in India and the partners have % shareholding as agreed. Foreign majority shareholding is allowed.



R&D Trends

- Major multinational companies conducting R&D in China and India.
- Also allows for establishment of relationship with Chinese or Indian physicians and government officials, helpful in registration and product launch.

R&D Advantages and Disadvantages

- Lower salaries in China and India compared to counterparts in US, Europe.
 - However, these researchers may require additional training.
- Lower costs to build R&D centers in China and India.
- Spread out research so no one knows how the pieces fit together.

Growing Market for Clinical Trials in Asia

- Cost for conducting clinical trials is often lower in China and India (NOT Japan).
- Patient recruitment, one of the more time-consuming and costly aspects of clinical trials, can be much easier in China and India.
 - Large population of people
 - Genetically diverse
 - “Virginal” patients (many have had very little medical care at all)

Conducting Clinical Trials

- ❑ Large global CROs with Asian branch may not be appropriate for study; local CROs may be much better.
- ❑ Key to have a local independent regulatory person or one of your employees move abroad to help oversee trials.

Conducting Clinical Trials (cont'd)

- China: significantly lower costs to conduct clinical trials, with large, diverse population.
- Japan: very high quality, very conservative medical community.
- India: rapidly growing area with large English speaking population, many foreign-educated doctors, and a large, diverse population.

Trends and Benefits to Sourcing from Asia

- ❑ Lower costs, lower overhead, lower salaries.
- ❑ Improving quality and technology.
- ❑ More FDA approved facilities going up or being improved to meet standards.
- ❑ Presence of free trade, special economic zones with tax breaks, lower tariffs, lower duties.

Sourcing: Key Steps/Issues

- ❑ Know the difference between a trading company and a manufacturer.
- ❑ Look for quality certifications -- ISO, FDA, EU -- GMP standard production, US/EU customers.
- ❑ Keep in mind additional costs for shipping/freight, customized packaging, minimum quantity orders, currency changes, and legal jurisdiction.

Sourcing: Regulatory Issues

- Have local consultant / regulatory person do due diligence and quality assurance.
- Do a factory visit to make sure company is trustworthy and makes quality product.
- Face-to-face meetings are key in building trust and relationship.
- Clear, concise contracts -- try to avoid legalese.
- Staged payments.

Sourcing: Key Clauses

- ❑ Price and quantity.
- ❑ Product and quality specifications.
- ❑ Defective goods.
- ❑ Payment terms.
- ❑ Confidential information.
- ❑ Choice of law.
- ❑ Dispute clauses.

Japan Key Business Issues

- ❑ Long term outlook; continually build relationships.
- ❑ Meeting someone three times does not mean a relationship.
- ❑ Need deep pockets to support effort.
- ❑ US and European companies need to spend more time with Japanese employees or partners to build trust.
- ❑ Commitment to quality (many medical companies in West cannot meet Japanese standards).

Japan Main Regulatory Bodies

- Ministry of Health, Labor, and Welfare (MHLW)
 - <http://www.mhlw.go.jp/english/index.html>
 - Overseas all health programs in Japan, including drugs, medical devices, and food.
- Pharmaceuticals and Medical Devices Agency (PMDA)
 - <http://www.pmda.go.jp/index-e.html>
 - Established in April 2004, overseas regulatory affairs for drugs and medical devices.
- The Central Social Insurance Medical Council (Chuikyo)
 - Responsible for medical service fees, such as setting points and reimbursement prices for medical devices and drugs.

Japan Key Regulatory Issues

- Japan has been steadily working on improving the pace of registration to address complaints of lag and delay. Process still slow.
- Market Authorization Holder makes foreign companies supply so much data; small medical companies now wondering if it's worth it.
- New “Harmonization by Doing” (HBD) Program between US and Japan.
- Fast-track approval for some products

Best Ways to Deal with MHLW/PMDA in Japan

- ❑ Caucasians showing up at MHLW offices in Japan will NOT help your cause, may actually hurt you.
- ❑ Utilize the new available consultation sessions, but make sure to have the appropriate staff on hand attending the session.

China Key Business Issues

- ❑ Determine who owns company you are considering working with.
- ❑ Determine if Chinese company really understands Western business values.
- ❑ Find a company that's not just looking to make a quick buck.
- ❑ Make sure legal documents done according to Chinese law NOT US law.

China Main Regulatory Bodies

- State Food and Drug Administration (SFDA)
 - <http://www.sfda.gov.cn/cmsweb/webportal/W43879537/index.html>
 - Equivalent to the US FDA.
 - Establishes laws and regulations on product registration and quality surveillance for pharmaceuticals, medical devices, and health foods.
- General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ)
 - <http://www.aqsiq.gov.cn/>
 - Conducts mandatory safety registration, certification, and inspection for certain devices (3C mark).

China Key Regulatory Issues

- ❑ China has been working on improving the quality and safety of medical products.
- ❑ Increased transparency for medical device applications.
- ❑ Inspections on imported medical devices.
- ❑ Prohibitive rules for SFDA personnel.

Best Ways to Deal with SFDA of China

- Make sure all documents are cleared/pre-reviewed, especially for Chinese specifications before official submittal.
- All documents **MUST** be translated into Chinese.
- One can track basic submission and approval status on the SFDA website, local regulatory agency is best in ensuring registration goes smoothly.

India Key Business Issues

- In some respects, more Western oriented (English language) than China and Japan, but need to know that there are cultural differences.
- Increased liberalization of Indian economy.

India Main Regulatory Bodies

- Central Drug Standards Control Organization (CDSCO)
 - <http://cdsco.nic.in/>
 - Responsible for drug registration and approvals, including those medical devices classified as drugs.
- Drug Controller General India (DCGI)
 - Key official under the CDSCO.

India Key Regulatory Issues

- Many medical devices are classified as drugs. Therefore, registration can be complicated as many of the forms are the same as those used with drugs.
- India has proposed a medical device regulatory framework. Bill on medical devices still unclear.
- India has also passed new regulations on global clinical trials to allow for speedier approval and increase quality standards.

Best Ways to Deal with CDSCO in India

- ❑ Correspondence with CDSCO not recommended before applying formally.
- ❑ Make only *informal* discussion with CDSCO if you have not submitted dossier.

Intellectual Property

- ❑ Obtain patents when you can.
- ❑ In registering your product, make sure to camouflage key IP (switch arrows, leave out a key ingredient, etc).
- ❑ India and China are biggest areas of concern for IP, but problems in Korea, etc.
- ❑ World Trade Organization's agreement on Trade Related Aspects of Intellectual Property Rights to establish and protect IP in member countries.

Japan: A Different Way of Thinking

- Relationships
 - Company to company
 - Person to person (how business relationships develop); oftentimes over dinners and drinks.
 - Most successful Japanese companies keep records of client information (birthdays, anniversaries, etc.) and send cards.
- "Group" vs. "Individual"
- Holiday cards – a must.



Japan: Holding a Meeting

- Planning/agenda
- Seating Arrangements
- Attitude and Direct Communication
- Interpreters
- Negotiating

Japan: Decision-making

- Japanese companies make decisions by consensus; decisions are rarely made by a single individual.
- Takes much longer for a decision to be made than in US companies.
- Advantages:
 - Breeds loyalty, good relations.
 - Once a decision is made, it is usually a good one and is easier to implement.

Japan: Little Things That Mean A Lot

- Bowing
 - Traditional Japanese greeting to each other, though handshake is more common with Westerners.
- Shoes
 - Should be removed in some restaurants and most homes.
- Gifts
 - Gift should be wrapped and presented with both hands.



China: Personal Connections (Guanxi)

- Everybody knows someone and personal connections and payback key to doing business.
- China is still Wild West (communism to capitalism), many laws are not enforced.

What To Do When The Chinese Visit

- ❑ Be extremely hospitable.
- ❑ Give the “red carpet” treatment.
- ❑ Chinese expect to be picked up at the airport by a company executive.
- ❑ Pay for meals and sometimes hotels if they visit us in West.

The Chinese Mentality

- Chinese society emphasizes family, humility, and courtesy.
- Concept of “face:”
 - Chinese are very concerned about the status of a particular individual within a company.
 - Losing “face” – when someone is insulted or criticized in front of others; gaining face.



China: Little Things That Mean A Lot

- Banqueting:
 - Eating together is very important to the Chinese.
 - Can be an excellent way to network and build relationships.
 - Seating arrangements are important, but less so than in Japan; less formal in China.
- Chinese people in China, Taiwan, Hong Kong and South East Asia are different.

Understanding People in India

- Hierarchy (caste system) plays a large role in Indian society.
- Negotiations:
 - Can be very confrontational.
- Handshakes are appropriate between men, but men should only accept handshakes from women if the woman initiates first.
- Gifts generally exchanged after meetings.
- Keep in mind that some Indians do not take alcohol or meat for religious, traditional or personal reasons.

Positive East Asian Perceptions of Americans

- Systematic
- Data driven
- Free
- Creative
- Humorous
- Speak up
- Task-oriented
- Fair
- Individualistic
- Open-minded
- Follow the rules
- Kind
- Generous
- Confident
- Energetic
- Team players
- Egalitarian
- Independent

Negative East Asian Perceptions of Americans

- Demanding
- Bullying
- Arrogant
- Aggressive
- No action, talk only
- World police
- Prejudiced
- Self-righteous
- Selfish
- Overly laid-back
- Legalistic
- Argumentative
- Domineering
- Culturally Ignorant
- Know it all
- Selective listening
- Overcharging
- Inflexible
- Insincere
- Overconfident

Summary of Cultural Issues in Asia

- ❑ For each Asian country you must know the local traditions and unique cultural factors.
- ❑ Not all Asian countries share the same Asian attitudes, values and mindset.
- ❑ Try and get to know about these countries' histories, culture, religion, the types of people there, etc.
- ❑ Our government has alienated many governments and people overseas over the last 5 years; don't be an ugly American. Treat Asians like you want to be treated – mutual respect.
- ❑ How do you write your emails to Asians?



Thank you for your consideration!

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