



Opportunities in the Asian Medical Device Markets

Presented by: Ames Gross
President of Pacific Bridge Medical
www.pacificbridgemedical.com

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About Pacific Bridge Medical

- **PACIFIC BRIDGE MEDICAL (PBM)** is a leading Asia medical consulting firm dedicated to assisting international medical companies in Asia.
 - We have helped hundreds of medical device companies with business development and regulatory affairs in Asia since our founding in 1988.
 - We have offices in Shanghai, Tokyo, Singapore, and Hong Kong, and affiliate partners in other Asian markets.
 - <http://www.pacificbridgemedical.com>

Overview of Asia



Demographics (2013)

Country	Population (millions)	GDP (PPP)	Per Capita Income (PPP)
China	1,349	\$12.38 trillion	\$9,100
ASEAN	577	\$3.349 trillion	\$6,300
India	1,220	\$4.784 trillion	\$3,900
Japan	127	\$5.984 trillion	\$36,200

Asian Ethnic Diversity

- ❑ **Japan and Korea:** very homogenous; small minority populations
- ❑ **China:** 92% Han, Over 50 National Minority Groups for other 8%
- ❑ **Singapore:** 77% Chinese, 14% Malay, 8% Indian
- ❑ **Malaysia:** 50% Malay, 24% Chinese, 7% Indian
- ❑ **Indonesia:** 40% Javanese, over 300 ethnic groups for other 60%
- ❑ **Thailand:** Majority Thai, 14% Chinese
- ❑ **Philippines:** Very diverse population in terms of language, religion and ancestry
 - Tagalog 28%, Cebuano 13%, Ilocano 9%, Bisaya/Binisaya 8%, Hiligaynon Illonggo 8%
- ❑ **Vietnam:** over 50 ethnic groups
 - Almost 90% Vietnamese
 - Chinese (Hoa) around 1%
- ❑ **India:** 3 major groups
 - 72% Indo-Aryan, 25% Dravidian, 3% Mongoloid and other

Global Medical Device Market Trends

- Growing slowly in the West – US/EU
- Western device companies facing increasing cost pressures
- Growing quickly in developing countries with high double digit growth – especially in Asia
- More emphasis on cost-effective devices with fewer bells and whistles for developing countries
- BRIC really means China
- Developing world experiencing more Western diseases as they eat more McDonald's and Kentucky Fried Chicken
- Cardiology, orthopedics and cancer segments growing
- Developing world needs more devices to manage more Western diseases

Asian Medical Device Markets

Country	Market Size (US\$)
China	\$13 billion
Hong Kong	\$850 million
India	\$3.5 billion
Indonesia	\$780 million
Japan	\$27 billion
Malaysia	\$1 billion
Philippines	\$300 million
Singapore	\$530 million
Korea	\$3.9 billion
Taiwan	\$2.5 billion
Thailand	\$850 million
Vietnam	\$630 million

Is There a Market for Your Device in Asia?

- ❑ Research has to be well thought out
- ❑ Secondary research – not normally that accurate; government statistics not always reliable
- ❑ Primary research is the best way to go
- ❑ Researcher should have worked for foreign device companies before
- ❑ Research company should have strong analytical skills, understand overall strategy and overseas trends
- ❑ Big research companies send out 20 year olds, may not have enough experience to get answers you need
- ❑ Hong Kong company multiplied 10 doctor comments by 10, now 100 interviews; $\frac{1}{10}$ the work for 100% of fees
- ❑ Determine if there is a market before product registration – IVD case

Case Study: Which Asian Country Should We Start With

- ❑ Small U.S. medical device company has a new respiratory therapy device
- ❑ They tell me they want to register their FDA approved device in China and India
- ❑ Why do they want to register in China and India? – Because there are big respiratory problems in these 2 large markets
- ❑ Okay, but I probe deeper

Case Study: Which Asian Country Should We Start With

- Can the new therapeutic respiratory device be reverse engineered? – Yes
 - These markets are copy cat markets
- Do they have a patent? – No
 - Small companies can never win patent issues in China and India
- Do they have a patent in Japan? – Yes
 - Maybe they should focus in Japan where the technology will be protected, even though there are less incidents of respiratory disease there
- How much will it cost to find the right distributor and register in Japan?
- Started with China/India – but Japan may be best Asian country for them

Asia Distributor Search

- Have you done lots of due diligence before selecting?
 - Meeting groups at trade shows once will not work
- Are you building long term relationships of trust?
- Are you giving them proper support?
- Is the distributor attending the right trade shows?
- Do the distributor people at an exhibitor booth really know your product?
- Are you constantly training them and making sure they do the right thing?
- How can you make sure they are doing the right thing if you do not speak Japanese, Korean, or Chinese?

Japan Distributor Search

- ❑ Takes time to find the right distributor – trust issue
- ❑ Moving registrations can be difficult and costly
- ❑ MAH / DMAH
- ❑ Continual follow-up a MUST to keep the relationship and business moving forward
- ❑ Just because there is a market in the West does not mean there is a market in Japan

China Distributor Search

- ❑ Lots of small players
- ❑ Are the small distributor companies going to survive?
- ❑ Conflict of interest – 3 sales teams
- ❑ Do bigger Chinese distributors really have branch offices?
- ❑ Do distributors really do what they say they are doing? Double check!

Regulatory Issues

- ❑ If the device company (subsidiary, distributor, etc.) does not have capable regulatory people in Asia, there may be approval delays at the China CFDA, Indian CDSCO and ASEAN Ministries of Health, etc.
- ❑ Is it possible to get résumés of the device companies' regulatory people in Asia before you work with them?
- ❑ Do the distributors you want to sign up have good regulatory people?
- ❑ Bad regulatory people can kill good business opportunities
- ❑ Regulatory approvals, delays, lost sales

Regulatory Issues

- ❑ Huge shortage of qualified RA/QA people in Asia
- ❑ Check your regulatory team's work to determine if they are good
- ❑ Western executives may complain that registrations are too slow, but in actuality the regulatory team is excellent
- ❑ Give excellent regulatory people reasons to stay, otherwise they can be easily poached

Regulatory Issues

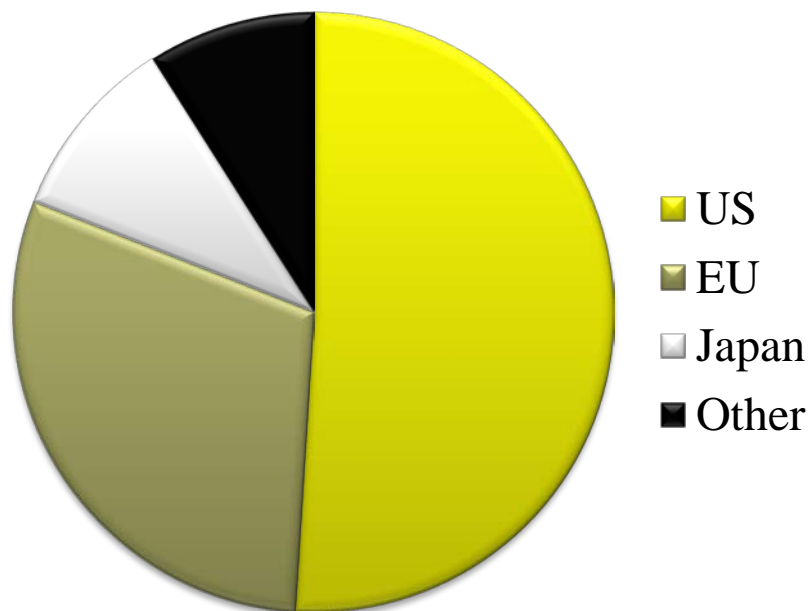
- ❑ Japanese are very conservative, it is normal for them to ask for more paperwork than necessary, personal liability issues
- ❑ Chinese and Indians are more professional than before, but bribery still occurs in some cases
- ❑ Does the Asian country not want to approve your product until local companies can copy the product?
- ❑ Do not give out trade secrets in documents submitted, camouflage everything

Regulatory Issues

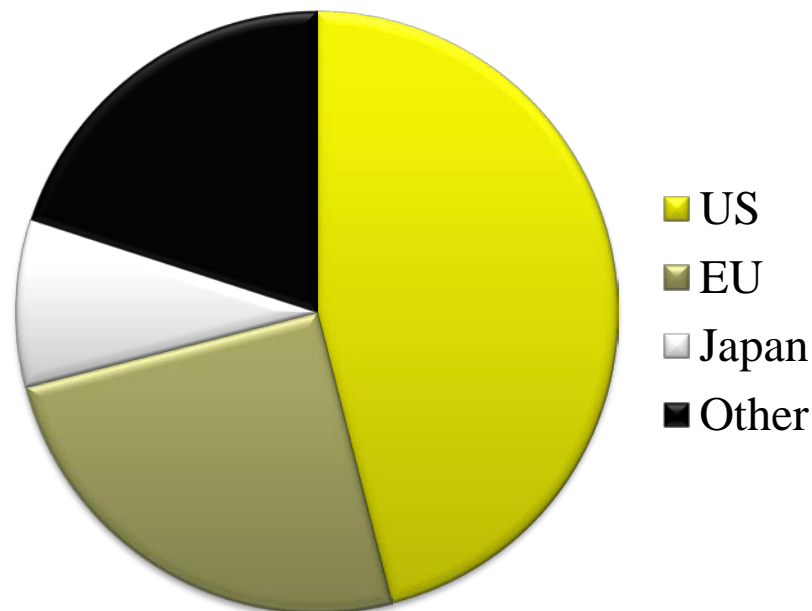
- ❑ Japan – all Class II and some Class III products will be approved by notified body (not PMDA)
- ❑ Malaysia – now device registrations are required
- ❑ India – about 30 classes of products need registration now, but a new bill may increase the number of classes
- ❑ Korea – device registration is becoming a lot tougher
- ❑ If you have CE Mark (but no FDA approval), you may be able to register in some Asian countries

Medical Device Manufacturing Moving to Asia (to reduce costs and get closer to growing markets)

2005



2015



**Sources: Frost and Sullivan, Department of Commerce, and other PBM sources*

***Asia is 90% of Other*

“B” Line of Products

- Western medical device companies are increasing sales to Asia with basic models and lower prices compared to their top of the line Western products
- Many more local Asian medical device manufacturers are now making more sophisticated products with better quality components, as demand increases in the region and globally

“B” Line of Products

- Local Chinese and Indian companies who currently make a very cheap and basic model of device are *improving quality* and still have low prices vis à vis imported Western devices.
- More rigorous GMP, FDA and local manufacturing regulations and standards will help the quality of local products get better.
- Local players will compete with a foreign device company’s “B” lines



Manufacturing and Sourcing

- ❑ China costs have skyrocketed
- ❑ It can oftentimes be cheaper for commodity devices and components to be made in Vietnam and India
- ❑ Due diligence, close and continuous follow-up, monitoring, and QA will be key

Scenes from Chinese Factories



Scenes from Chinese Factories



Acquisitions/Joint Ventures

- Acquisition – do lots of due diligence and do not overpay
 - Staged payments, with incentives to keep management interested
- Joint ventures – do lots of due diligence
 - More companies call us for break-up help than setting up joint ventures these days
- Make sure you know what you are buying

Intellectual Property

- China and India – better, but hard for small to mid-sized companies to win in court, very expensive
- Copying is rampant in most Asian countries
 - They are taught that this is okay, so do not be naïve
- Japan still honors patents, but Japanese can try and go around your patent
- Hong Kong and Singapore have good IP protection
- Best way to succeed is to continually develop new technologies

Is the Medical Device Company Serious about Growing its Asian Business?

- Which medical device companies are setting up local manufacturing in China, India or Malaysia to lower their costs of production? Which are tailoring more products to local consumers?
- Right now, Asia (not including Japan) primarily produces Class I and II medical device products. Some Chinese manufacturers can make decent quality Class III medical device products. More Class III products will be made in Asia.
- Local device companies and foreign device companies: Who will win?

Key Asian Trends: Is the Medical Device Company's Asian Organization Set Up Right?

- When in Rome, act like Romans; the same applies to Asia
- Hire natives to run each Asian country's business: In Korea, hire Koreans. In Japan, hire Japanese.
- Why should Western expats run Asian businesses? How well would a Chinese run a Chinese company's business in the US, if they didn't speak English?

Business Cultural Issues

- ❑ Mr. Wang, was your father at Pearl Harbor?
- ❑ It is difficult to call you Tetsuya, can I call you Ted?
- ❑ I am going to Japan next week, can you set up meetings for me?
- ❑ In Chinese companies, the boss calls the shots – In Japanese companies, consensus
- ❑ Local Chinese and Indians are generally different than Chinese and Indians who grew up in the West

Business in Asia Done Through Relationships, Not Lawsuits

- ❑ Relationships in West are oftentimes different than relationships in Asia
- ❑ Is the Western medical device company global or really U.S. centric with branch offices in Asia?
- ❑ Understanding Asian business practices are different than those in the West
- ❑ How do you send emails to Asian counterparts?
- ❑ Holiday cards are a good way of maintaining relationships

Doing Business in India

“I do understand that many of you may have [a] difficult time in doing business in India... I think, you need to stay the course. You need to be there. We are a work in progress, because we are a developing country. We still need to improve our systems and we will continue to move in that direction. I can assure you that as time goes by, doing business in India will not be as messy as you think it is today.”

-- Arvind Mayaram, Indian Ministry of Finance

Nizamia Hospital (public) - Hyderabad



Saifee Hospital (private) - Mumbai





Thank you for your consideration!

Pacific Bridge Medical

www.pacificbridgemedical.com

contact@pacificbridgemedical.com

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