Asia Medical Markets Overview

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Presented by Ames Gross, President

Pacific Bridge Medical

7315 Wisconsin Avenue, Suite 609E, Bethesda, MD 20814

www.pacificbridgemedical.com

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 over 500 medical 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 all the other Asian markets.
  - http://www.pacificbridgemedical.com

Overview of Asia

Demographics (2014)

Country	Population (millions)	GDP (PPP)	Per Capita Income (PPP)
China	1,356	$13.4 trillion	$9,800
ASEAN	600	$3.35 trillion	$6,300
India	1,240	$4.99 trillion	$4,000
Japan	127	$4.73 trillion	$37,100

Asia Economic Statistics (2014)

Three tiers of wealth and advancement

	GDP (PPP)	Per capita GDP (PPP)	Real GDP Growth Rate
China	$13.4 trillion	$9,800	7.7%
Hong Kong	$381.3 billion	$52,700	2.9%
India	$4.99 trillion	$4,000	3.2%
Indonesia	$1.29 trillion	$5,200	5.3%
Japan	$4.73 trillion	$37,100	2.0%
Korea	$1.7 trillion	$33,200	2.8%
Malaysia	$525 billion	$17,500	4.7%
Philippines	$454.3 billion	$4,700	6.8%
Singapore	$339.0 billion	$62,400	4.1%
Taiwan	$926.4 billion	$39,600	2.2%
Thailand	$673.0 billion	$9,900	2.9%
Vietnam	$358.9 billion	$4,000	5.3%

Source: International Monetary Fund

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, 7% Indian, 2% other**
- 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

Why Do Western Medical Companies Want to Go to Asia?

- This is where the growth is
- Over 4 billion people
- Rising middle class, with more money to spend on healthcare
- Aging populations in Japan, Korea, China
- Richer Asians demanding better drugs, devices, and healthcare services

Asian Medical Market Growth Rate Higher than Global Growth Rate

- **Cardiology**: Growth in Asia is significantly above the global average of 3%. The CAGR for cardiology surgery devices in Asia is predicted to be 15% from 2014-2020.

- **Orthopedics**: Asia will witness much faster growth than the rest of the world, which had market growth of 6% in 2014. The CAGR for orthopedic devices in Asia is predicted to be 14% from 2014-2020.

Asian Medical Device Market Trends

- Explosive demand for medical devices in the Asian markets is attracting Western and local medical device companies

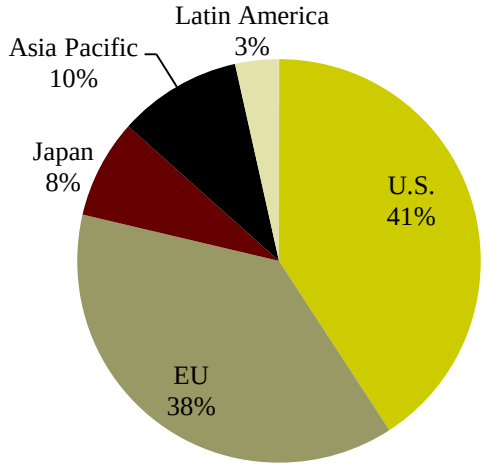
- Western medical device companies are increasing sales to Asia with basic models (B product line) and lower prices compared to their top of the line AAA Western products

- 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

Medical Device Markets

Global Medical Device Markets		
Region	Market Size (US$)	Growth
U.S.	$140 billion	3%
EU	$130 billion	2%
Japan	$27 billion	1.5%
Asia Pacific	$34 billion	20%
Latin America	$12 billion	10%

Global Medical Device Markets



Asian Medical Device Markets	
Country	Market Size (US$)
China	$20 billion
Hong Kong	$850 million
India	$3.5 billion
Indonesia	$780 million
Korea	$3.9 billion
Malaysia	$1 billion
Philippines	$300 million
Singapore	$530 million
Taiwan	$2.5 billion
Thailand	$850 million
Vietnam	$630 million

Medical Device Product Registration

- Medical device product registration is getting tougher in Asia
- Always helps if manufacturer has U.S. and EU approval already

Regulatory Issues

- Japanese are very conservative – it is normal for them to ask for more paperwork than necessary (for U.S. FDA), 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 (Too many Western executives do not care – in 3 years when they copy, I will be at another job)

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? (Can you speak with them directly to better understand their experience?)
- Do the distributors you want to sign up with have good regulatory people?
  - Bad regulatory people can kill good business opportunities
- Regulatory approvals, delays, lost sales
- International sales and marketing people need to engage RA before distributor contract is signed!

Asia Distributor Search

- Have you completed lots of due diligence before selecting?
  - Meeting groups at trade shows once will not work
- Are you building long term relationships of trust?
  - Extensive hand holding & tender loving care are required to build strong relationships
- Are you giving them proper support?
- Is the distributor attending the right trade shows? (You can check this out)
- 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? (Do no-names research, talk to hospital purchasing managers)
- How can you make sure they are doing the right thing if you do not speak Japanese, Korean, or Chinese? (Make sure translator is neutral)

Map of China

Medical Device Market

- China is the 3rd largest medical device market in the world – soon to be the 2nd largest
  - Worth approximately USD $20 billion in 2014

China Distributor Search

- Lots of small players
- Are the small distributor companies going to survive? (Can they import a container of your products?)
- Conflict of interest – 3 sales teams (selling similar products to same customers)
- Do bigger Chinese distributors really have branch offices?
- Do distributors really do what they say they are doing? Double check! (Do due diligence on a no-names basis)
- India requires regional distributors

Chinese Medical Device Registration

- Getting a lot tougher and longer for approvals
- New standards released
- Testing delays (only 10 centers)
- More supplementary reviews
- Class 2 and 3 medical device need more local clinical trials / New exempt list too
- Approval in county of origin

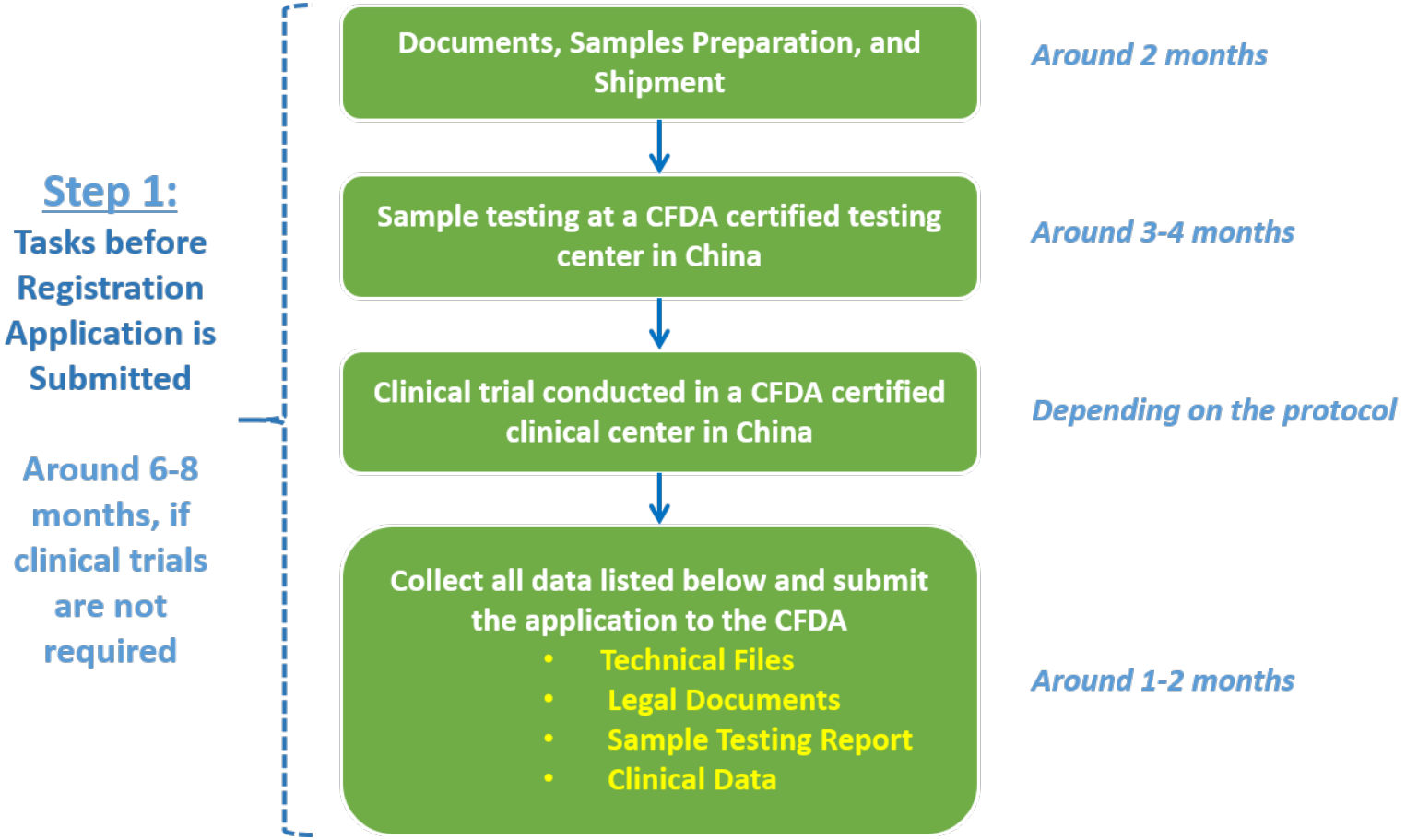
New Chinese Medical Device Regulations

- 2000 Regulations: only 6 chapters and 48 articles

  New 2014 Regulations: 8 chapters and 80 articles
- Class 1 – Notification not registration but more documentation needed
- Class 3 device clinical trials require CFDA protocol approval
- Class 2 and 3 IVDs must have local clinical trials

  1000 sample size, comparison study required (Gold Standard)
- Registrations now good for 5 years, not 4
- More information required on outside labels in Chinese

Registration Timeframe for Imported Class 2 and 3 Devices



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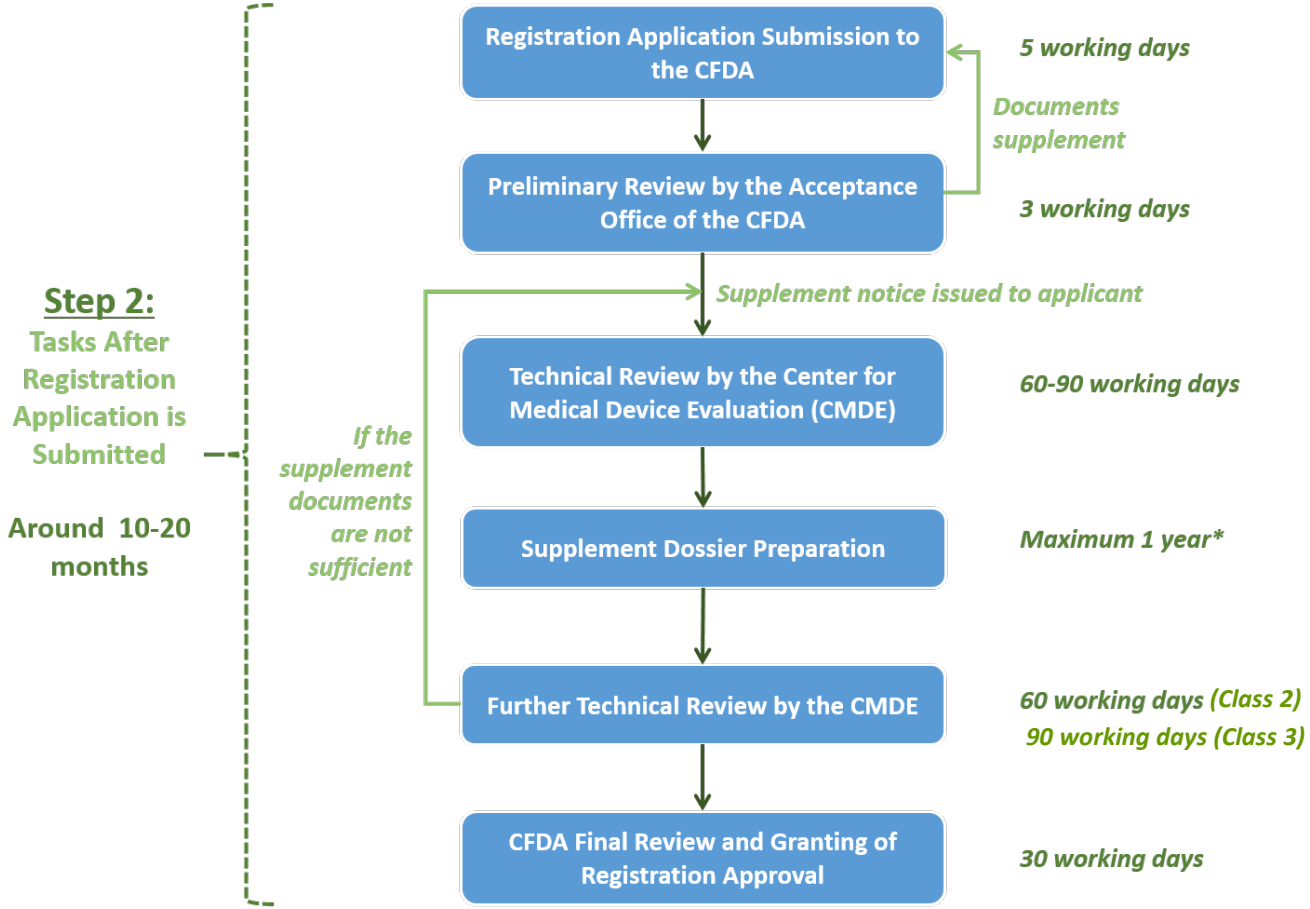

Map of Japan

Japan

- Currently, the 3rd largest economy (not 2nd)
- Population shrinking from 125 million to 90 million in 30 years
- Highly competitive medical device market; quality is key
- Regulations are still very extensive and tough
- Reimbursement is very good but slowly decreasing

Distributor/Partner Search

- Takes time to find the right distributor/partner
- Moving registrations can be difficult and costly
- DMAH
- Continual follow-up is 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

Device Classification in Japan

- The Japanese Medical Device Nomenclature (**JMDN**) is a combination of the classification rules of the GMDN and of the GHTF (GHTF/SG1-N15:2006 *Principle of Medical Devices Classification*) which uses the word "**risk**" to classify 4 classes (Class A-D).
  - The terms used in ISO 14971 and their definitions are used in the GHTF guidance document.
- The JMDN (> 4,000 codes) was created in 2004, based upon GMDN, to globalize and internationally harmonize the old "Nomenclature and Types of Medical Devices"
- Japan introduced **risk classification** (Class I-IV)
- New MDs are evaluated on their efficacy (development concept, non clinical tests, clinical studies) & safety (biological safety, absorbable materials – strength/safety)

Medical Device Classification

Category	Classification/Definition	Registration Category	Review Body
General	Class I: The risk to patients in the event of malfunction is regarded as almost negligible.	Notification	N/A
Controlled	Class II: The risk to patients in the event of malfunction is regarded as relatively low.	Certification or Approval	NB or PMDA
Specially controlled	Class III: The risk to patients in the event of malfunction is regarded as relatively high.	Approval	PMDA
	Class IV: The device is highly invasive with potential fatal risk to patients.	Approval	PMDA

Medical Device Application Form

- Medical Device Category
  - JMDN Code and Class I, II, III, or IV
  - If a single product belongs to multiple categories, select the category of the medical device with the highest risk class
- Name (General Nomenclature/Trade Name)
- Intended Use and Efficacy or Effects
  - Target patient population and disease, usage conditions, anticipated effects, etc.
- Shape, Structure, and Principle
- Raw Materials or Components
- Product Specifications
  - Specifications ensuring the quality, safety, efficacy of the device
- Operation or Usage Method
- Manufacturing Method
- Storage Method and Shelf Life
- Manufacturing Site of the Product to be Marketed
- Manufacturing Site of Raw Materials
- Remarks – Medical device classification, MAH license number of the applicant, etc.
- A checklist is available on the PMDA website in Japanese for the application dossier and all the required documents that are part of it

Japan: Medical Device Registration

1. Consultative sessions
2. Dossier: includes STED, QMS + FMA
3. QMS + FMA have new simplified regulations
4. Normally risky products (Class 3/4) need expensive local clinical trials in addition to foreign data for PMDA approval

Japan: New Medical Device Regulations

- All Class 2 and some Class 3 products only require certification, not PMDA approval
- Some Class 3 and all Class 4 products still require PMDA approval
- Cell/tissue based products: new classification separate from medical devices
  - Able to get on the market quicker via less upfront clinical trials and more post market data
- Software stand alone registration

Product Reimbursement Categories

Category	Description
A1	**(Inclusive)** Included within the technical fee. No separate reimbursement is made for the device itself. Product examples: gloves, gauze, sutures
A2	**(Designated inclusive)** Technical fee granted for use of the device or class of devices. No separate reimbursement is made for the device itself. Product examples: MRIs, CTs, and most types of capital equipment
B	**(Individual evaluation)** "Me-too" products that are similar to other products on the market. As a result, these products fit into existing technical fee and STM reimbursement categories. Product example: CoCr hip stem
C1	**(New function)** New products based on existing products/therapies. Technical fees exist for the procedure; however, the product itself is a significant improvement vs. prior technologies and is deserving of a new STM reimbursement category. Product example: hip stem using a new material not currently available in Japan
C2	**(New function and New technology)** New products that result in a new therapy or procedure. No predicate product or treatment exists. As a result, a new STM reimbursement category and technical fee must be created. Product example: sinuplasty balloon catheter (currently unavailable in Japan)
F	Products that does not match the reimbursement system in place or that are not suitable for insurance coverage

ASEAN Member States

Thailand: Medical Device Classification

- Foreign medical device companies wishing to sell their products in Thailand must first register them according to a **risk-based** classification system
  - This system is the exact opposite of that used by the US FDA, which considers Class I devices to be the lowest risk

- In Thailand, Class I devices -- called “licensed” devices -- have the highest risk classification. They are more stringently controlled than Class II and Class III devices, which are referred to as “notification” and “general” devices.

Vietnam: Medical Device Market Overview

- Vietnam is a fast-growing country with a population of about 87 million. The population is receptive to the use of advanced medical products.
- Vietnam's medical device market is expanding rapidly. The market – valued at $630 million in 2014 – is expected to grow 18 to 20% from now through 2020
- Since 2009, some healthcare coverage has been mandatory for all Vietnamese
  - Currently, 64% of Vietnam's 90 million people are covered under it.
  - By 2015, the Ministry of Health (MOH) wants to cover 75% of citizens; 90% by 2020
- The government is making significant investments in national healthcare infrastructure. In its 2013 healthcare budget, the MOH set aside funding for new facilities & upgrades to existing facilities in mountainous and disadvantaged areas.

Vietnam: Overview of Regulatory Environment and Regulations Governing Medical Devices

- Medical device regulation is developing in Vietnam
  - The new regulatory system will be largely based on the ASEAN Medical Device Directives (AMDD)
- Medical devices belonging to 50 categories need to get import licenses before importation

Map of India

India: Regulation of Medical Devices

- Generally, the Central Government plays the leading role in the regulation of medical devices, while the State Government has a supporting role
- Regulatory responsibilities of the Central Government (under the CDSCO)
  - Approval of new drugs and medical devices
  - Clinical Trials in the country
  - Drug/Medical Device standards
  - Control over the quality of imported drugs/medical devices
  - Coordinates the activities of State Drug Control Organizations
- Regulatory responsibilities of the State Governments (under State Drugs Control Organization) are more limited
  - Manufacture, sale and distribution of drugs/medical devices
- The Drug Controller General of India (DCGI) is the key official in the CDSCO
  - DCGI has formulated 12 advisory committees of expert doctors (cardiology, orthopedics, etc.); each committee has 10 doctors. The committees are more important than individuals.

Current List of *Notified* Medical Device *Families* Requiring Registration in India

As of 2010, the CDSCO replaced a list of individual devices requiring registration with a list of 14 product "families" or categories – no longer listing individual items

S.No	Name of the Device	Notification Number	Date of Notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	3-17-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	3-17-1989
3	Disposable Perfusion Sets	GSR 365 (E)	3-17-1989
4	In vitro Diagnostic Devices for HIV, HBsAG and HCV	GSR 601 (E)	8-27-2002
5	Cardiac Stents	S.O. 1468 (E)	10-6-2005
6	Drug Eluting Stents	S.O. 1468 (E)	10-6-2005
7	Catheters	S.O. 1468 (E)	10-6-2005
8	Intra Ocular lenses	S.O. 1468 (E)	10-6-2005
9	IV Cannula	S.O. 1468 (E)	10-6-2005
10	Bone Cements	S.O. 1468 (E)	10-6-2005
11	Heart Valves	S.O. 1468 (E)	10-6-2005
12	Scalp Vein Set	S.O, 1468 (E)	10-6-2005
13	Orthopedic Implants	S.O. 1468 (E)	10-6-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	10-6-2005

India Distributor Search

- Multiple distributors are necessary to cover the country
- Difficult to find the best groups, who oftentimes lie about everything
- Distributor may not have good in-house RA people, so be cautious

Business in Asia Done Through Relationships, not Lawsuits

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

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

- When in Rome, act like Romans.
- Hire natives to run each Asian country's business: In Korea, hire Koreans. In Japan, hire Japanese.
  - *One MNC – Caucasian guy in Singapore runs Asia; Japan office has Caucasian reporting to Singapore – What's wrong with this picture?*
- Why should Western expats run Asian businesses? How well would a Chinese run a Chinese company's business in the U.S. if they didn't speak English?

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www.pacificbridgemedical.com

contact@pacificbridgemedical.com

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