




How Medical Companies can be Successful in China

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“To be part of the Asian dynamism, Westerners do not need to become Asians in culture, in values, or in habits...but it is necessary for Westerners to understand Asians, to feel at ease with Asians and to make Asians feel at ease with them.”

- Lee Kuan Yew, Former Prime Minister of Singapore

Introduction to China



Map of China



People's Republic of China (PRC):
Administrative Divisions & Territorial Disputes



- Province
- Autonomous Region
- Municipality
- Special Administrative Region
- claimed by India, administered by PRC
- claimed by PRC, administered by India

Population (2008)



- ❑ Over 1.3 billion people
- ❑ Life Expectancy: 73 years
- ❑ Labor Force: **801** million
- ❑ National Language:
Mandarin Chinese (based on
Beijing dialect)

Chinese Government Structure

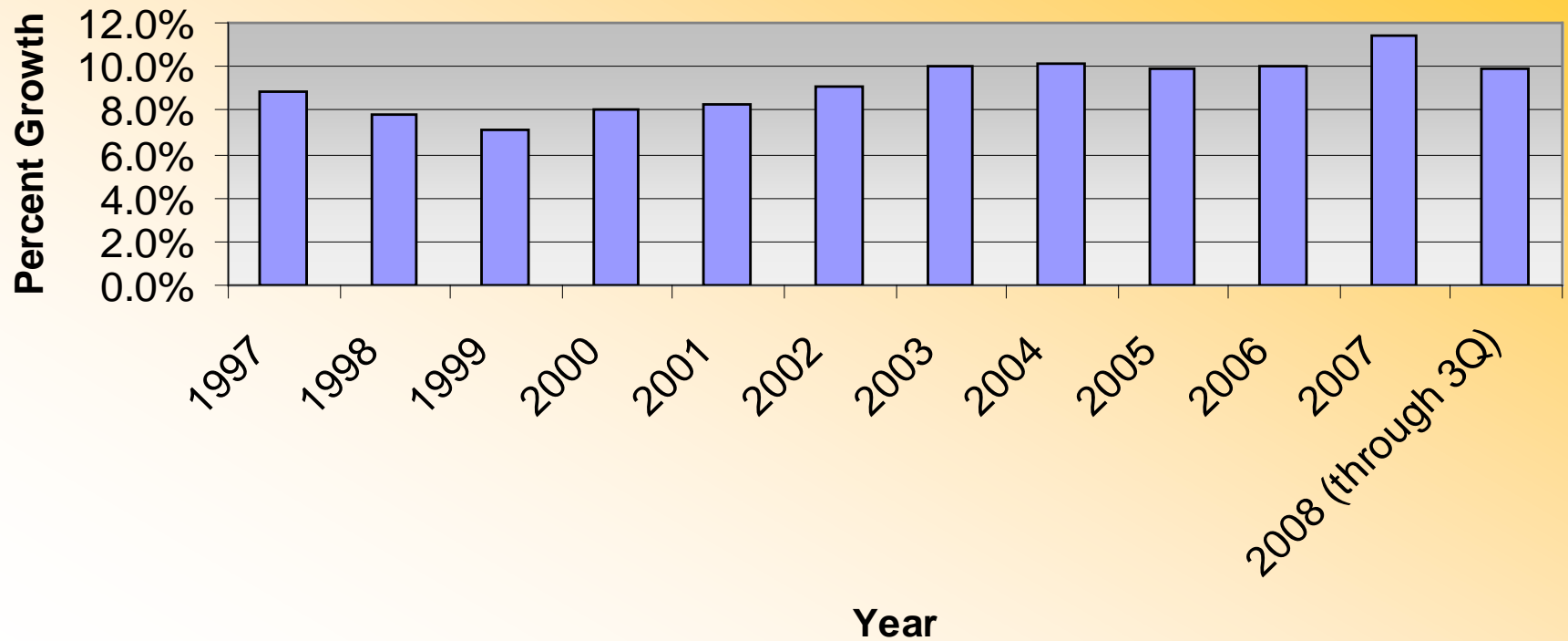
- Authoritarian Communist regime since 1949.
- Government consists of three bodies:
 - **Communist Party**
 - **People's Liberation Army (PLA)**
 - **The State:**
 - **National People's Congress:**
 - **President (Hu Jintao)**
 - **State Council:**
- The Constitution of the People's Republic
 - First promulgated in 1954.
 - Current = 4th Promulgation (1982)



Economy

- Chinese Currency (RMB):
 - Current Exchange Rate: 1 USD = 6.8 RMB.
 - 3 years ago 1 USD = 8.5 RMB
 - Revalued by 2.1% in July 2005:
- Foreign Exchange Reserves:
 - \$1.9 trillion (2008).
 - Highest foreign reserves in the world.

China's Average Annual Percentage Growth Rate



China Medical Regulatory Authorities

State Food & Drug Administration (SFDA)

- Founded in 1998.
- Equivalent to the U.S. FDA.
- Responsible for medical devices, drugs, and healthcare services.
- Headquarters is located in Beijing, with offices in each province also.

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

Center for Drug Evaluation (CDE)

Best Ways to Deal with the Chinese Government

- ❑ Make sure all documents are cleared/pre-reviewed, especially for Chinese specifications before official submittal.
- ❑ Have local affiliates involved with face-to-face meetings and make sure HQ knows exactly what is going on.
- ❑ All documents for product registration **MUST** be translated into Chinese.

China Key Business Issues

- ❑ 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.

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 China.
 - 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.
- There are very few large-scale private national medical product distributors in China; thus it is necessary to put together several private regional groups.

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, can have your branch office/subsidiary hold registrations in your name.
- Key regulatory clauses?
- Always keep copies of your China offices' or China distributor's key documents such as registration certificates and key correspondences at your company's headquarters.



Setting Up Your Own Office in China

- Representative office
- Branch office
- Wholly Owned Foreign Enterprise

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

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.

Wholly Owned Foreign Enterprise

- Enterprises established in China in which all funds are provided by foreign investors
- Most WOFEs are greenfield operations
- More foreign companies looking to set up WOFE's than JV's today

Disadvantages and Advantages

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

Joint Ventures

A Brief History

- 1979: Deng Xiaoping; Open Door Policy – first foreign firms began to invest in China.
- 1998: New foreign investment rules.
 - Today, WOFEs (Wholly Owned Foreign Enterprises) are becoming increasingly common in many industries.
- Today, 30% of all manufactured goods in China are produced by foreign JVs and WOFEs.

Joint Ventures

Summary of JV Law of the People's Republic of China

- First made law in 1979; revised in 1990 and 2001.
- 15 Articles (full text available at government site: www.china.org.cn)
- Main points:
 - Foreign company must contribute at least 25% of capital.
 - If debt + equity = \$10 million to \$30 million: 40% of foreign party's investment must be equity.
 - If debt + equity = \$30 million+: 33% of foreign party's investment must be equity.
 - Government is restricted from nationalizing JVs in most cases.
 - Once established, JV is considered a Chinese legal entity: Can hire staff and build facilities with limited government intervention.

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

The Good News

“If we were doing it now from scratch, we would still take local partners. The Coke business is a local business. We need a local partner, they smooth the way to getting things done with the local government. They get rid of some of the red tape.”

-Paul Etchells, President, Coca Cola China

- Many big companies have been successful with JVs in China
- AOL / Legend Online
 - In 2001 AOL established a 49/51 JV with Legend Online
 - \$200 million investment
 - Win/win
- Amstrad / Haier
 - Haier had a strong manufacturing and distribution network already in place.
 - Haier also had the necessary licenses.
 - Ultimately, this saved Amstrad time and money entering the China market.

Joint Ventures

The Bad News

“As a rule of thumb, if you have enough knowledge locally, if you have the distribution or can develop distribution, if you have adequate resources, then do it on your own.”

-Kenneth Yu, Managing Director, 3M China

- Survey of members of the American Chamber of Commerce in Beijing and Shanghai:
 - 1999 = 78% had JV operations
 - 2005 = 27% had JV operations
- Common problems encountered with Joint Ventures:
 - Bureaucracy (unclear laws and regulations)
 - Corrupt business practice
 - Piracy (local partner copies and sells product on its own)
 - Lack of infrastructure
 - Misalignment of goals

Joint Ventures

Some Considerations

- Who owns the local company/factory?
- What are the motivations of the Chinese partner?
 - Chinese saying: “Same bed, different dreams.”
- Adapt to Chinese business practices, but do not compromise corporate values and ethical standards
- “Padding the price” is common in China
- Conflict of interest is not fully understood
- Consider using Westernized Chinese (who are more familiar with a Western sense of right and wrong) to do audit, contracts, etc.

Mergers and Acquisitions in China

- Net Asset Value plus premium – only true measure.
- Auditor can determine NAV.
- Do not rely on EBIT or PE ratios – unreliable.
- Due diligence – liabilities, patents, etc.
- Need legal documents according to the laws of China.
- Learn the Regulations
 - Rules change quickly in China; stay on top of the latest regulations.
- Future: more Chinese medical companies will buy US companies.



R&D Trends

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

R&D Advantages and Disadvantages

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

Growing Market for Clinical Trials in China

- Cost for conducting clinical trials is often lower
- Patient recruitment, one of the more time-consuming and costly aspects of clinical trials, can be much easier
 - Large population of people
 - Genetically diverse
 - “Virginal” patients (many have had very little medical care at all)

Conducting Clinical Trials

- Large global CROs with China 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.

CROs in China

- China Clinical Trials Centre based in Beijing, China
- Tigermed Consulting based in Shanghai, China
- Excel Pharmastudies based in Beijing, China
- We are selling a report on CROs in Asia, please see our website for more details.



Sourcing from China

- Chinese manufacturers are becoming increasingly sophisticated.
- Prices remain much lower than most other countries.

Trends and Benefits to Sourcing from China

- ❑ 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.

Contract Manufacturing Opportunities

- Chinese manufacturers are becoming increasingly sophisticated
- Product quality has increased dramatically
- Prices remain much lower than most other countries

Contract Manufacturing Opportunities

- Steps to successful contract manufacturing:

1. Identify product manufacturers

2. Initial Planning and Communication

- Emails and phone calls
- Plan for time difference
- Begin building relationship



Contract Manufacturing Opportunities

□ Steps to successful contract manufacturing:

3. Know the Difference: Factories vs. Trading Companies

4. Due Diligence Before the Site Visit

Contract Manufacturing Opportunities

- Steps to successful contract manufacturing:

- 5. Visit the factory

- Face to face communication is necessary
- Evaluate quality of key personnel

- 6. Examine regulatory requirements

- FDA requirements
- QSR requirements

Contract Manufacturing Opportunities

□ Steps to successful contract manufacturing:

7. Negotiate a contract

- Be concise
- Include dispute clause
- Include shipping terms

8. Establish quality assurance system

- Hire Chinese quality control company
- Use in-house quality control team

Issues in Manufacturing

- Who owns the factory
- Who owns the company -- what their % ownership is
- Determine if Chinese company really understands Western business values.
- Who owns the mold/designs when things go bad
- 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.



Key Clauses

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







New Regulations for Quality Control

- *Provisions for Implementation of the Special Regulations of the State Council on Intensifying Safety Control of Food and Other Products*
- *Requirements on the Compilation and Revision of Medical Device Industrial Standards*
- *Eight Prohibitive Rules for Personnel Involved in Food and Drug Supervision*
- The SFDA's National Sampling and Testing of Medical Device Quality has increased in scope.
- Chinese government is investing the equivalent of over one billion dollars to improve the food and drug regulatory infrastructure, especially its underequipped testing centers.

New Plans For Quality Control

- *Interim Requirements for Further Intensifying and Standardizing the Registration of Medical Devices*
- New industry standards for medical devices
- Strengthening risk management for medical devices
 - *Provisions on the Adverse Events Monitoring and Re-evaluation of Medical Devices (Draft)*
 - *Provisions on Medical Device Recalls (Draft)*
 - *YY/T0316 Application of Risk Management to Medical Devices; equivalent to ISO 14971 (2007 version)*

2008 Contract Labor Law

- Important changes:
 - Required written contracts for all full-time employees
 - Increased regulations for hiring temporary workers, making this practice more costly
 - Limits on overtime and new overtime pay requirements
 - “Unlimited” labor contract requirement with guaranteed compensation for workers who have been employed at the same enterprise for 10 or more years.
- Implications
- Enforcement

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).
- World Trade Organization's agreement on Trade Related Aspects of Intellectual Property Rights to establish and protect IP in member countries.

Intellectual Property Rights

“You cut off one counterfeiter and two spring up in his place. Sometimes they may close their factory, give the equipment to their brothers-in-law, and open a new facility in the village down the road.”

- Norman Givant, Office Managing Partner, China Practice Group,
Freshfields Bruckhaus Deringer

- IPR infringement has a long history in China – still a huge problem!
- After joining the WTO, China established basic copyright, trademark, and patent laws.
- Enforcement is the biggest issue – despite progressive laws, piracy is rampant throughout China.

Dealing with IPR Infringement

Reducing the Risk

- Work with the government
 - Be cooperative, not confrontational
 - Develop relationships with local officials in charge of enforcement.
 - Example: Microsoft China

- Lobby for change
 - Still difficult in China, but some recent successes for foreign companies.
 - L'Oreal China: formed a lobby group with other skincare and cosmetic companies.
 - Research and Development-based Pharmaceutical Association in China (RDPAC): 40 member companies.

Dealing with IPR Infringement

Reducing the Risk

- In-house Spending
- Develop prevention strategies
- Incorporate protection into contracts
 - Beijing and Shanghai: new labor regulations allow for 3-year non-compete and six-month resignation notice clauses in contracts for certain positions.

Intellectual Property Rights

The Good News

- Domestic demand for IPR protection is growing.
- Stronger enforcement and sophistication of business culture are likely to follow.

Dealing with Chinese Competitors

“The Chinese have a vision of what they want to be – they want to be a technologically leading country, and they are going in that way.”

-Dr. Ernst Behrens, Siemens China

- ❑ Innovation
- ❑ Do not overspend on engineering

Dealing with Chinese Competitors

“These are the new Chinese companies – with advanced products and global competitiveness.”

-Dominique de Boisseson, CEO Alcatel

- Be Realistic – you can't always win
 - Some markets in China are extremely tough to compete in:

- Merge and Acquire
 - Often less risk involved than traditional JV partnerships.
 - Simultaneously gain benefits and eliminate competition.

Effective Communication

China Office → US Headquarters

“China is a priority at Microsoft. Everybody understands that this is a country we cannot lose.”

-Jun Tang, President, Microsoft China

- Make China a priority

- Find a GM/President with solid international/China experience
 - Must have the ability to work effectively with both the local Chinese workforce and corporate office.

Effective Communication

China Office → US Headquarters

“In our case, we are lucky because the president himself makes an effort to know and understand China.”

-Paolo Gasparini, Managing Director, L’Oreal China

□ Cross-cultural education

- Make sure people at headquarters understand China.
- Arrange VIP trips to China
- Send Chinese staff to work at headquarters

Effective Communication

China Office → US Headquarters

“There are a lot of difficulties getting fast information about China. It is very important for headquarters representatives to be close to the market. They have to know exactly what is going on in China.”

-Dr. Elmar Stachels, China CEO, Bayer.

□ Shift Decision-making to China

- Saves time and money in the decision making process.
- Examples:
 - There are now more than 100 regional headquarters of MNCs in Shanghai.
 - More than 600 MNCs have established major R&D Centers in China.

U.S. vs. Chinese Cultural Tendencies

US

- ❑ Egalitarianism
- ❑ Role-oriented
- ❑ Individualistic
- ❑ Result/Task
- ❑ Confront problems
- ❑ Family-oriented/time
- ❑ Maximize short-term profits
- ❑ Make changes quickly

China

- ❑ Authoritarianism
- ❑ Status-oriented
- ❑ Group-oriented
- ❑ Results/relationship
- ❑ Avoid conflicts
- ❑ Family-oriented/money
- ❑ Establish long-term foundations
- ❑ Move when ready

Positive Chinese Perceptions of Americans

- Systematic
- Data driven
- Free
- Creative
- Humorous
- Speak up
- Task-oriented
- Fair
- Individualistic
- Open-minded
- Rules-oriented
- Kind and civil
- Generous
- Confident
- Energetic
- Good at Teamwork
- Egalitarian
- Independent

Negative Chinese Perceptions of Americans

- Demanding
- Bullying
- Arrogant
- Aggressive
- No action, talk only
- World police
- Prejudiced
- Self-righteous
- Legalistic
- Argumentative
- Domineering
- Culturally ignorant
- Know it all
- Selective listening
- Overcharging
- Inflexible

Conducting Effective Business

Negotiating

- Don't be an "ugly American."
- Americans value straightforward dialogue; Chinese are masters of the oblique.
- At least one member of your team should have in depth technical knowledge of every aspect of your business.
- Chinese may appear indifferent to the success or failure of the meeting at the negotiating table and then make excessive demands later.

Little Things That Mean a Lot

Gifts

- The Chinese love to give gifts, and it would be extremely rude to refuse a gift, even if it seems excessive. Also make sure to pick out plenty of gifts before traveling to China
- If one gift is given, it should be presented to the head of the Chinese group.

Boss-Employee Relationships

Relating to a Foreign Boss

“Chinese employees like to have a good relationship with the boss. You need to make sure you are not only a boss, but also a friend and a teacher.”

-Dominique de Boisseson, Alcatel China

- An awkward beginning
 - At first, local employees may be overly respectful or distant towards foreign managers.

- The “curiosity stage”
 - Questions that may seem rude in Western culture are acceptable and even typical in Chinese culture

- Acceptance into the family – a landmark step in increasing staff loyalty

Boss-Employee Relationships

Guanxi

- *Guanxi* = Personal Connections
- *Guanxi* in the Management Context
- *Guanxi and Retention*

关系

Boss-Employee Relationships

Saving Face

- Concept of “Face”
 - The Chinese are particularly sensitive to preserving trust and authority. In business relationships, it is essential to do nothing to openly offend or unnecessarily criticize a Chinese business partner, especially in front of his colleagues.

- “Face” and Management – how to avoid turnover
 - Don’t pit employees against one another



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