



Winning Strategies for China

Key Exporting Business and Legal Issues

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Answers before Questions

- Slides available by request
 - Email Matt at mschutte@bioohio.com
- A recorded version of this webinar will be made available on BioOhio.com for BioOhio members; registrants will receive a link following the presentation.
- Q&A is reserved for the end of the entire presentation. Attendees can submit a question for consideration via the webinar “dashboard.” Those connecting by telephone also can raise their webinar “hand” (also on dashboard), whereupon the moderator will unmute you to ask your question live.



Agenda

- **Why China?**
 - Economy, Demographics and Trends
- **Does China Really Want Your Product?**
 - Segment and Product Assessment
- **Building the Foundation**
 - Product/IP Protection
 - Regulatory (SFDA)
- **Go to Market**
 - Channel Development
 - Pricing, Importation
- **Profitable Growth**
 - Infrastructure
 - Competitiveness



Why China?



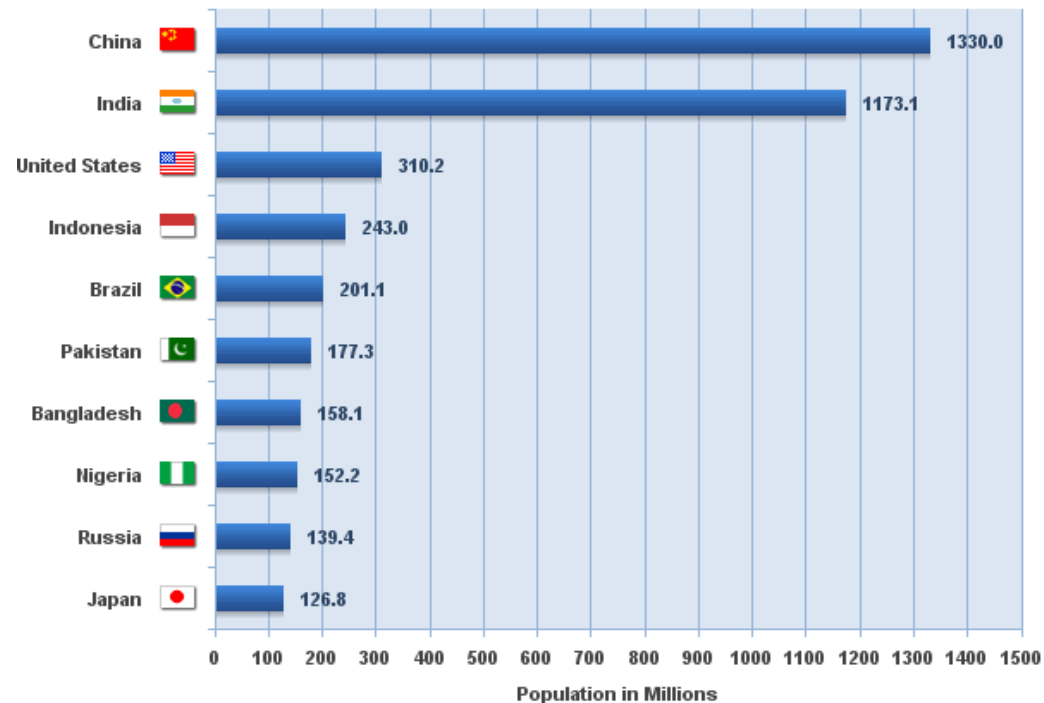
A thorough understanding of the economy, device market and product potential are all necessary to answer the question “Why China?”



Population

6.8 billion people in the World... 1.3 billion (19%) in China

Most Populated Countries in the World
Mid-Year 2010

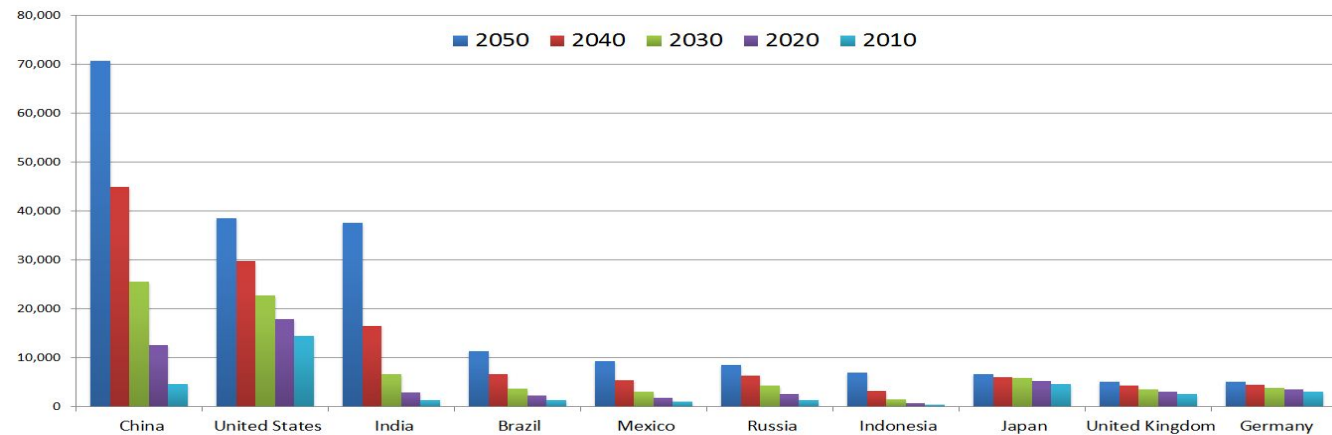


Source: U.S. Census Bureau - and - www.internetworldstats.com/stats8.htm
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Gross Domestic Product

GDP US \$ billions



- China GDP: 4.6 Billion 2010 projected to grow to 12.6 Billion in 2020, 70 Billion by 2050
- China GDP Growth Rates: 10.3% in 2010, above 2009's 9.2% expansion.
- China's Inflation rate: 4.6 percent in December 2010 from a year earlier

Source: Goldman Sachs and National Bureau of Statistics



Emerging Middle Class

Demographic shifts and a burgeoning economy has unleashed a huge wave of consumer spending in urban China. Disposable income is on the rise!

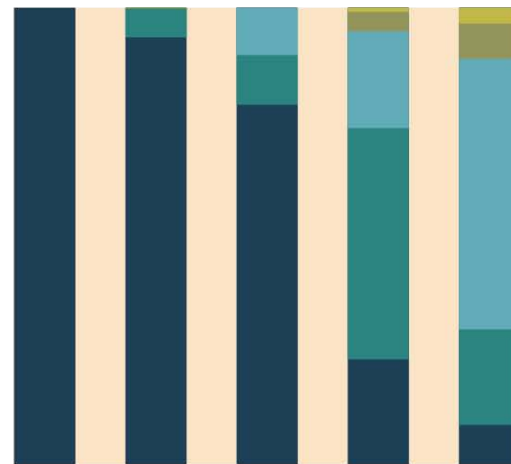
Value of China's Emerging Middle Class

Spending power is on the rise

Segments by annual income

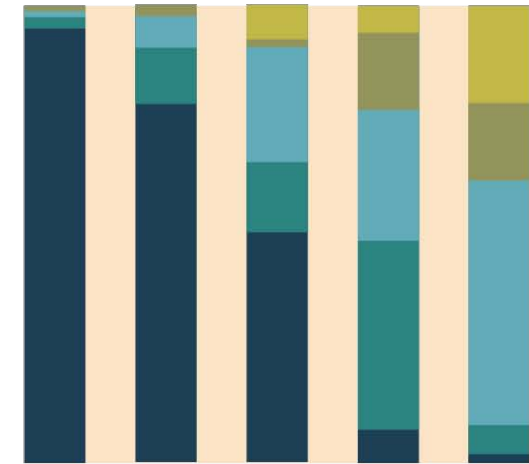
- **Global affluent** (>200,000)
- **Mass affluent** (100,000 – 200,000)
- **Upper Middle Class** (40,000 – 100,000)
- **Lower Middle Class** (25,000 – 40,000)
- **Poor** (<25,000)

Share of Chinese urban households. %



100% millions of urban households

Share of total urban disposable income. %



100% billions



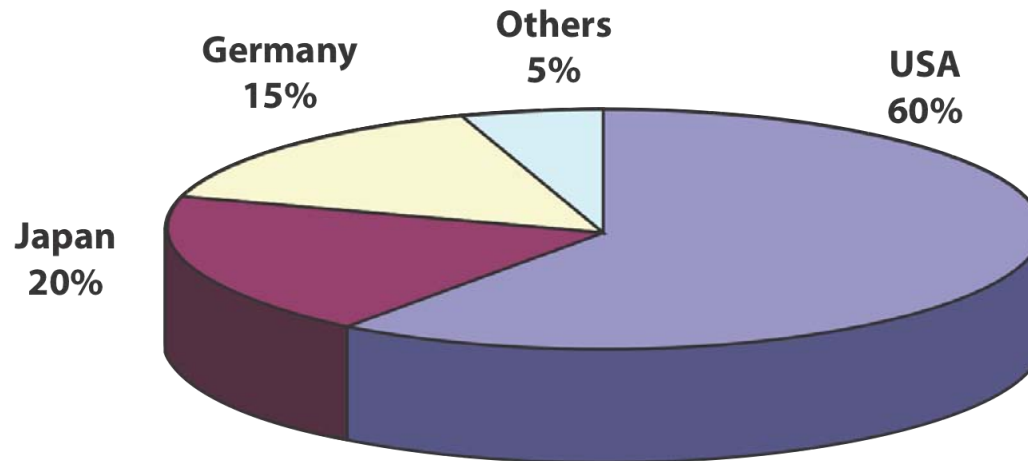
Source: McKinsey Global Institute





Medical Device Market

China Medical Device Market = \$15.2 billion
Total imports equal \$8.4 billion.



2000 thru 2010 21% compounded CAGR

Medical Device market projected to reach \$100 billion by 2020!



Why China?



The Simple Answer

- **Aging Population:** By 2020, 200 million+ will be 60+
- **Changing Lifestyles:** 1/3 world's smokers, obesity, diabetes, cancer and heart disease.
- **Healthcare Reform= \$124 Billion**
- **75% of medical products 30+ years old**
- **Increasing wealth and spending power**
- **China recently overtook Japan has the world's 2nd largest medical device market**
- **They love American products and brands**



Does anybody want your product?



China medical device market research

China Overview

- market size, demographics, trends overview
- Infrastructure, regulatory analysis

Segment Analysis

- industry drivers, competition, regulatory roadmap
- market specific channel and distribution outline

Product Assessment

- field research: hospital, doctor, distributor
- cost, volume, price analysis

Considerations

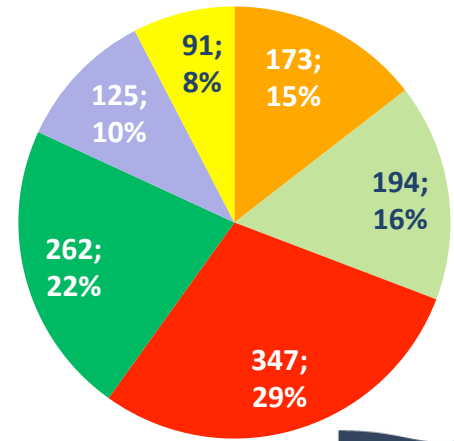
- product fit, potential, risk



Healthcare Institutions – Tier 3 Hospitals by Region



■	Northeast	173
■	North China	194
■	East China	347
■	Central South	262
■	Southwest	125
■	Northwest	91



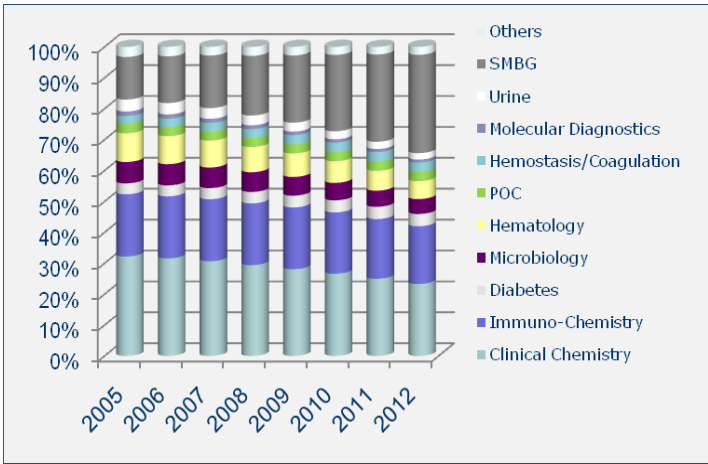
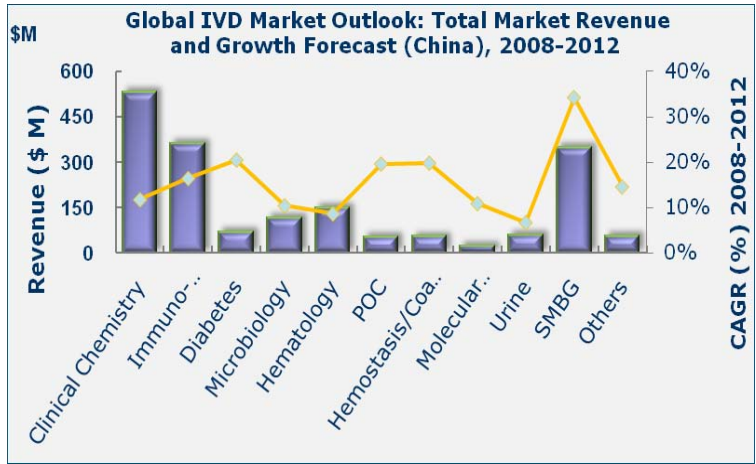
Source: Ministry of Health of China





Market Trends & Segment Forecasts

Global Market Outlook: Market Trends Ranked in Order of Impact (China), 2009-2012		1-2 Years	3-4 Years
1	Health insurance coverage is increasing, with less people paying medical expenses out-of-pocket.	High	High
2	Automation in the clinical laboratory business remains low	High	High
3	Local reagent suppliers dominate the lab market	Medium	Medium





Reimbursement Application Process

Two key steps



Note:

There are two levels of reimbursement list: (the process in following slide states in provincial level)

- ❑ National reimbursement list is updated average 5 years by medical insurance department in MHRSS*;
- ❑ Provincial reimbursement list could have about 15% adjustment based on national basic list.



Phase 1: Hospital Approved

Application for being on list of charges in hospital

Check if on the list of charges.

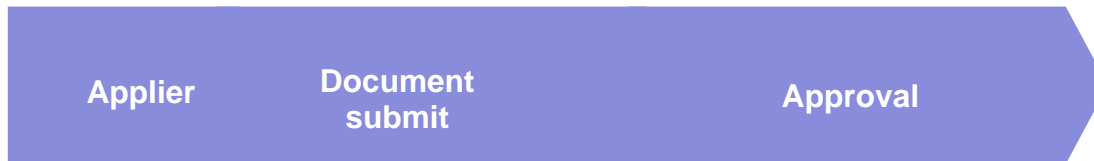
No

Yes

> Hospital can charge patients.

Hospital

> Application for being on list of charges in hospital



Healthcare institution

1. Application form;
2. Cost evaluation form;
3. Self evaluation report

1. Approver: Development & Reform Commission;
2. Approval time: It differs much from each other in different provinces. It could be one month, but also one or two years.

Yes

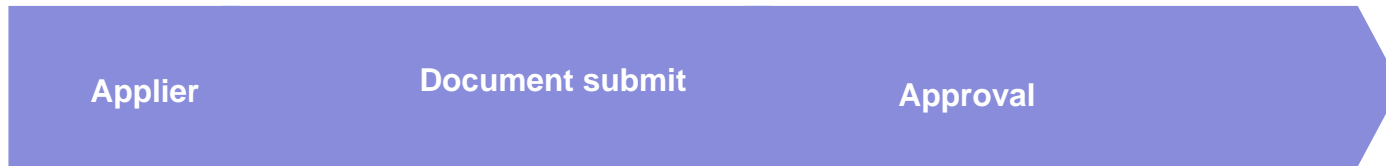
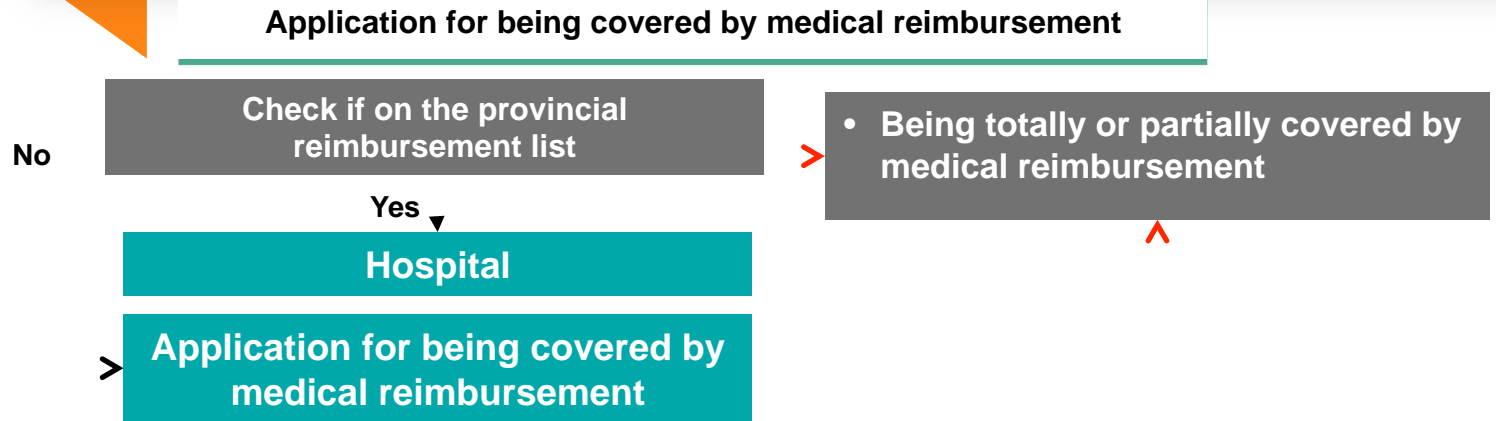
> Adding into the list

No, re-apply





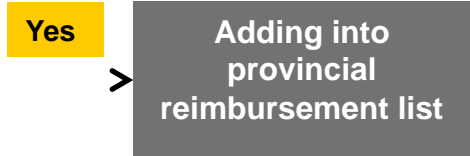
Phase 2: Medical Reimbursement



Company

1. Approval document from by health bureau;
2. License of medical equipment;
3. Approval document of charges from NDRC;
4. Materials of recent service & fees for specific test & service
5. Other related technology document & certification.

1. Approver: expert committee organized by medical insurance bureau;
2. Frequency & time:
 - Frequency: it differs from different provinces but in some provinces, once per year;
 - Time: in general, the whole process last nearly more than half a year. There is mostly an annual update for reimbursement list.





SWOT Analysis of Medical Product

Strength

- Specific XXX exam, which is to fill a vacancy of current diagnosis
- Ability to predict the remission, which is a key clinical unmet need
- Appreciated company image of manufacturer/FDA approved

Weakness

- Higher cost than its anticipated replacement.
- Product requires a clean room and professional technician, while automation is more preferred by labs.

Opportunity

- The market is huge in volume and is continuous growing
- The product has no significant competitor in XXX exam approaches

Threat

- National reimbursement list.
- Future competitors may be able to gain market share



What do I have to do to get there?



SFDA Registration and IP/Product Liability/Risk Mitigation Services

SFDA

- classification, registration, clinical trials, time and cost
- local vs. national registration

Risk Mitigation

- patents, trademarks, copyrights, trade secrets
- freedom to operate, fcpa, partner evaluation

Structure

- contracts, rep office, jv alliance, wofe

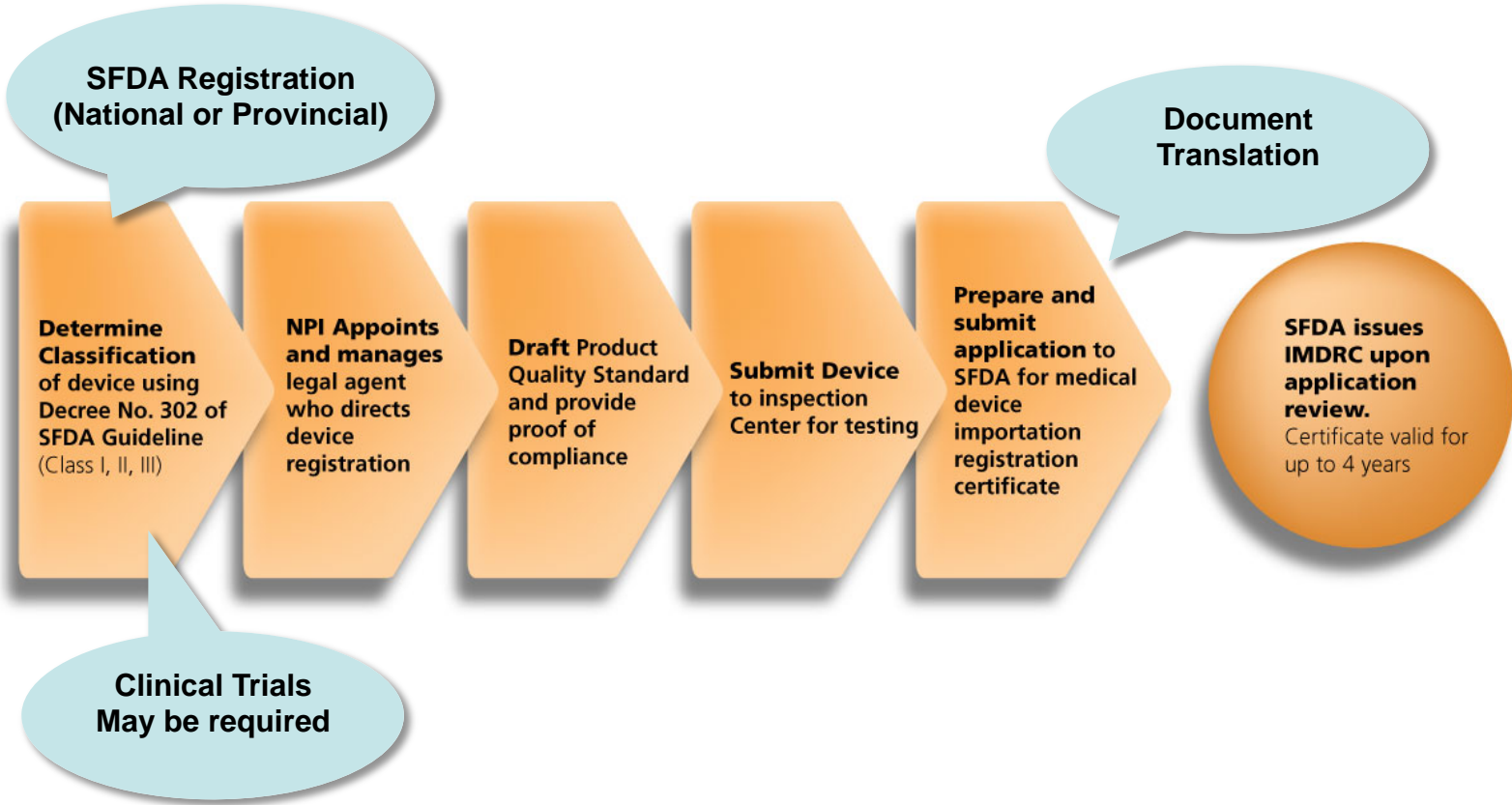


Structures, Incentives/Restrictions, Classification

- **Structure**
 - Must be specifically tailored for the specific medical device market
 - WFOE, JV (Contractual or Equity), Distributor/Agency, OEM Model
- **Incentives & Restrictions**
 - Exemption from import duties and import value-added taxes, a reduced or lower level of regulatory review, and incentives for high- and new technology (e.g., 15% v. 25% enterprise income tax rate) & special incentives in certain provinces / industrial parks
 - Certain types of medical devices (e.g., non-self destructing disposable syringes) – more regulatory review
- **Classification and Registration**
 - All medical devices, whether imported to or manufactured for sale in China, must be registered with the SFDA or its local branch, in accordance with the “Guidelines for Classification of Medical Devices” & Classification Catalogue.
 - Must separate medical devices from drugs – products combining drugs and medical devices are not allowed in China



SFDA Process Map



*Clinical Trials in China may be required for class II/III devices that do not already have regulatory approval elsewhere in the World, long term implantable devices or certain other high risk devices.



Partnering with an expert is suggested to avoid the regulatory black-hole





IP Protection Strategies

- **Registration of IP:**
 - Patent, trade mark and copyright, but not all IP rights can be registered (e.g., know-how, proprietary processes and business strategies) and IP registered outside China (e.g., in the US) does not mean it is registrable in China
 - Trademark application a must, but copyright filing – worth it?
 - Trade secrets or secrecy – concepts not well-developed in China
- **Contractual Protection**
 - Select business partners, distributors, employees and contractors carefully / prohibit or limit subcontracting
 - Limit access to certain information to a “need to know” basis
 - Keep core IP items or “black box” information in US or segregate between different vendors
 - Control over manufacturing process, including designating approved vendors for contractors to source inputs and supplying packaging and labels
 - Allow for IP and technology audits and post-termination treatment of technology
 - Prohibit Chinese parties (e.g., supplier, distributor, agent) from registering your IP rights
 - Insist upon survival of confidentiality and IP provisions in contracts post-termination
- Monitor your business partners, employees & competitors
- Enforcement in Chinese courts and remedies



FCPA & China Anti-Bribery Laws

- “Foreign official” means:
 - Any officer or employee of any department, agency or instrumentality of a foreign government or a public international organization
 - Any person acting in official capacity for or on behalf of a government or international agency or instrumentality (trade associations may be included)
 - Foreign political party or official
 - State-owned enterprise (SOE) employees
- Active enforcement by US government.
- Giving property to “state employees” to obtain unjustified benefits is prohibited.
- State employees include:
 - Government officials
 - Communist party leaders
 - SOE employees and
 - Retired state officials
- For the purposes of receiving unjustified preferential treatment or other benefits
- Chinese government will start enforcing China Anti-Bribery Law, especially in the medical device industry.



FCPA & China Anti-Bribery Laws

- “Anything of value”
- May include payment to a relative
- Authorization of illicit payment to be made by someone else (e.g., sales agent)
- Third party payments are prohibited
 - Payment to any person knowing all or a portion will be offered, given or promised to a foreign official
 - Foreign sales rep, marketing consultant, distributor, JV partner, foreign subsidiary or contractor
- Maximum penalties for willful violations:
 - Corporations: US \$25 million
 - Individuals: US \$5 million, 20 years imprisonment
- “Tangible bribes” only involving money and property
- Does not include “intangible bribes” (e.g., offering to help a functionary’s child go to school overseas, providing a job to a relative)
- BUT, the Supreme People’s Court stated that a loan or use of property, without transfer of title, constitutes an improper gift.
- Penalties: administrative sanctions, imprisonment, confiscation of property, death



How do you start to make money?



China Medical Device Distribution and Distribution Management Services

Distributor Selection

- national vs. regional, generalist vs. specialist,
- sales/agent capability, financial strength
- pricing, margins, contract, accountability

Sales and Marketing Readiness

- Chinese promotion, product marketing, training
- sales plan, performance tracking, forecast, customer visibility

Importation

- logistics, customs, duties/taxes, ftz warehousing
- traceability, inventory management



Manufacture and Distribution

- **Manufacturing**
 - Only specifically approved companies are allowed to manufacture or distribute medical devices. Registration is valid for four years, but will be invalidated if the product is not manufactured for two years.
- **Distribution**
 - Distributors must register with an SFDA branch (for Class I medical devices) or obtain a dealer license (for Class II and III medical devices), except that Licensed manufacturers may sell products to licensed dealers or hospitals without having to become licensed dealers themselves
- **OEM model or “Consignment Manufacturing”**
 - Both consigner and consignee must be medical device manufacturers, holding the appropriate licenses or registrations
 - Devices to be manufactured must be within the scope of the consignee’s license
 - Consigner will be held accountable for quality
 - Consigner must register the arrangement with the provincial-level SFDA branch.



China Market Distribution



Number of Tier 3 Hospitals by Province

Province	Tier 3	Tier 3 A	Province	Tier 3	Tier 3 A	Province	Tier 3	Tier 3 A	Province	Tier 3	Tier 3 A
Beijing	50	37	Shanghai	30	27	Hubei	60	47	Yunnan	37	9
Tianjin	36	22	Jiangsu	64	39	Hunan	42	30	Tibet	2	2
Hebei	39	31	Zhejiang	76	30	Guangdong	73	56	Shanxi	34	20
Shanxi	39	20	Anhui	30	21	Guangxi	46	33	Gansu	25	8
Inner Mongolia	30	14	Fujian	35	17	Hainan	6	6	Qinghai	7	5
Liaoning	86	46	Jiangxi	26	12	Chongqing	18	13	Ningxia	5	3
Jilin	21	20	Shandong	86	38	Sichuan	47	28	Xinjiang	20	13
Heilongjiang	20	38	Henan	35	29	Guizhou	21	8			





How do you grow once you get there?



Go-to-Market Services

L.T. Structure

- greenfield, acquisition, tax, banking, capital, local investors

Competitiveness

- localized manufacturing/packaging, product re-design
- cost productivity
- incentives, restricted industries, global positioning

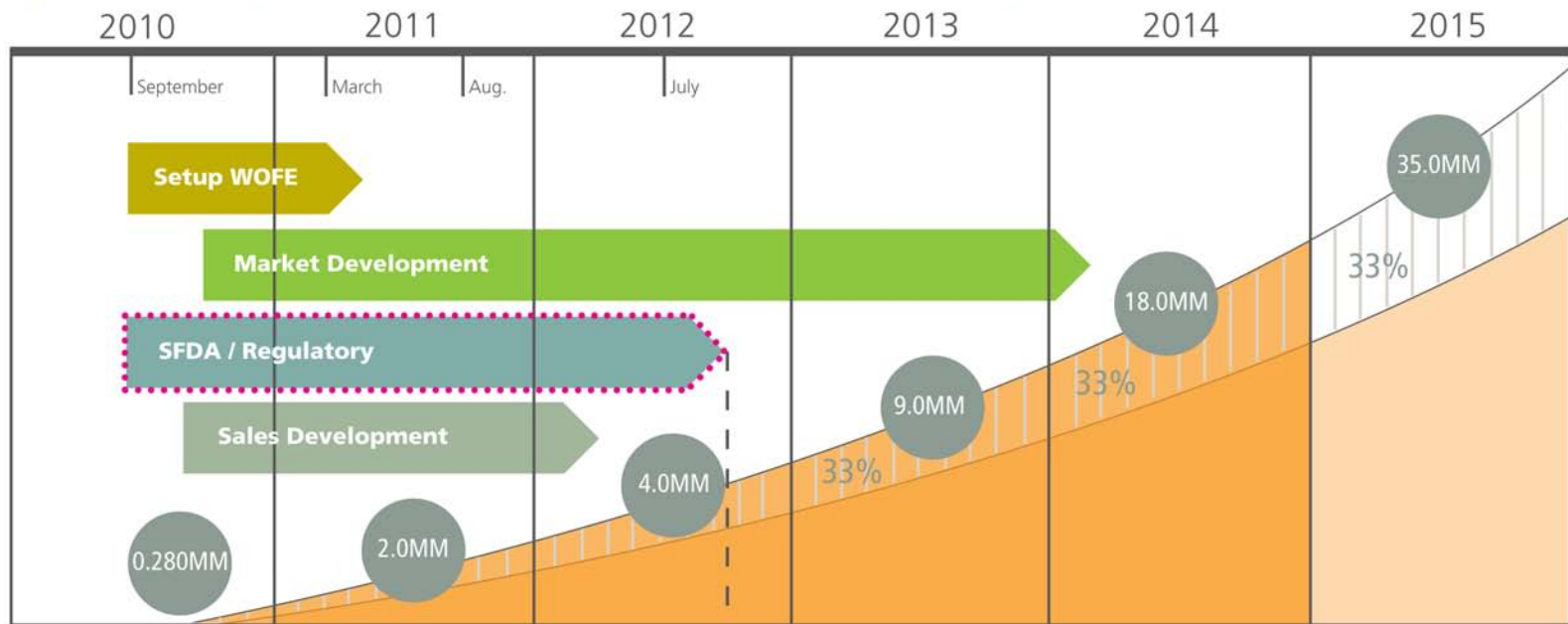
Strategy

- A long-term plan is paramount to your success in China



Strategy Map

Speed of Implementation + Multi-Channel Development = **BLOCKBUSTER**



Keys to Long Term Success

- ✓ Cultural Understanding
- ✓ Price vs. Volume
- ✓ Localization
- ✓ Investment/Repatriation





You Can Win In





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