



2015 China Medical Device Update

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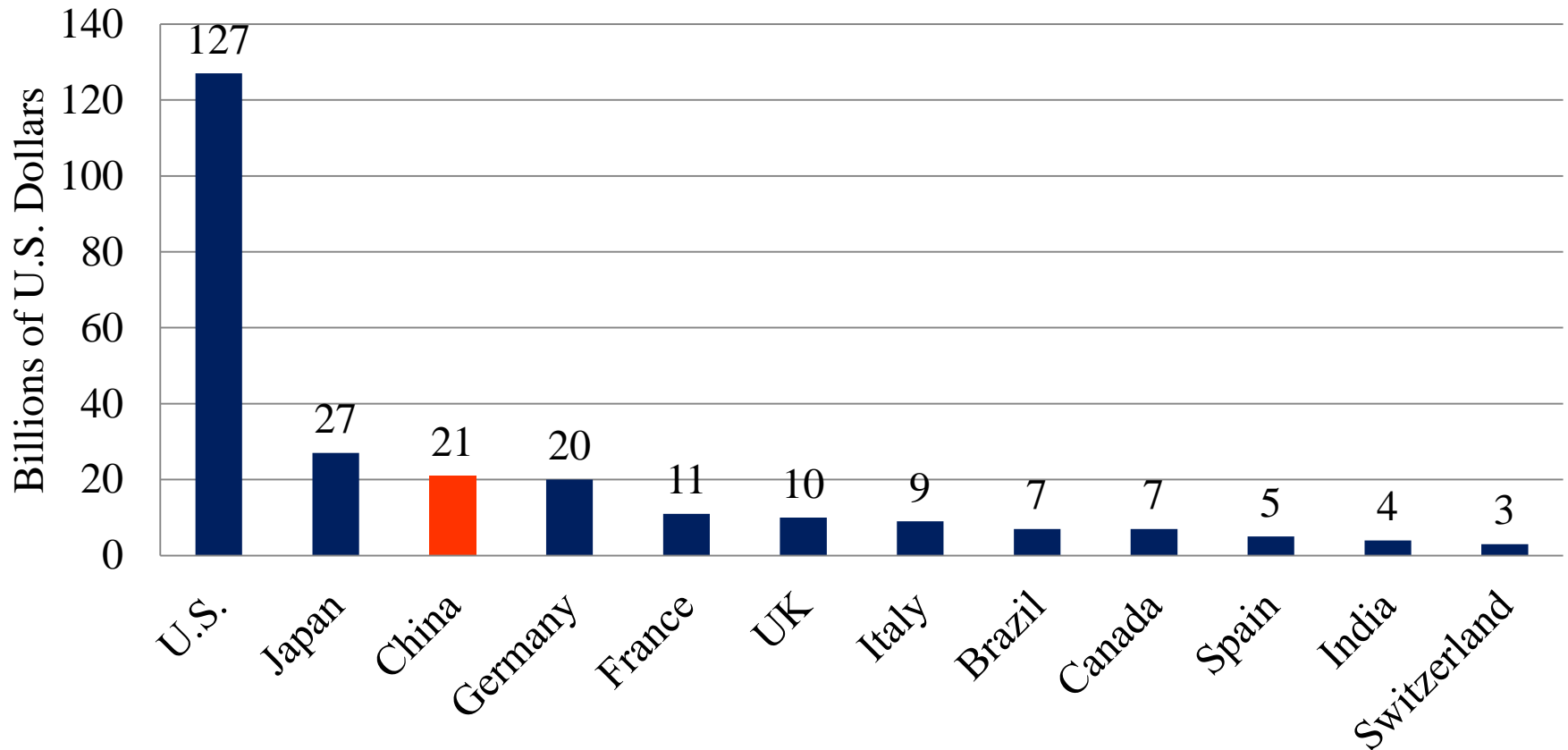
- **PACIFIC BRIDGE MEDICAL (PBM)** is a leading Asia medical consulting firm dedicated to assisting international medical companies succeed in Asia.
 - We have helped hundreds of medical device companies with regulatory affairs and business development in Asia since our founding in 1988.
 - We have offices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



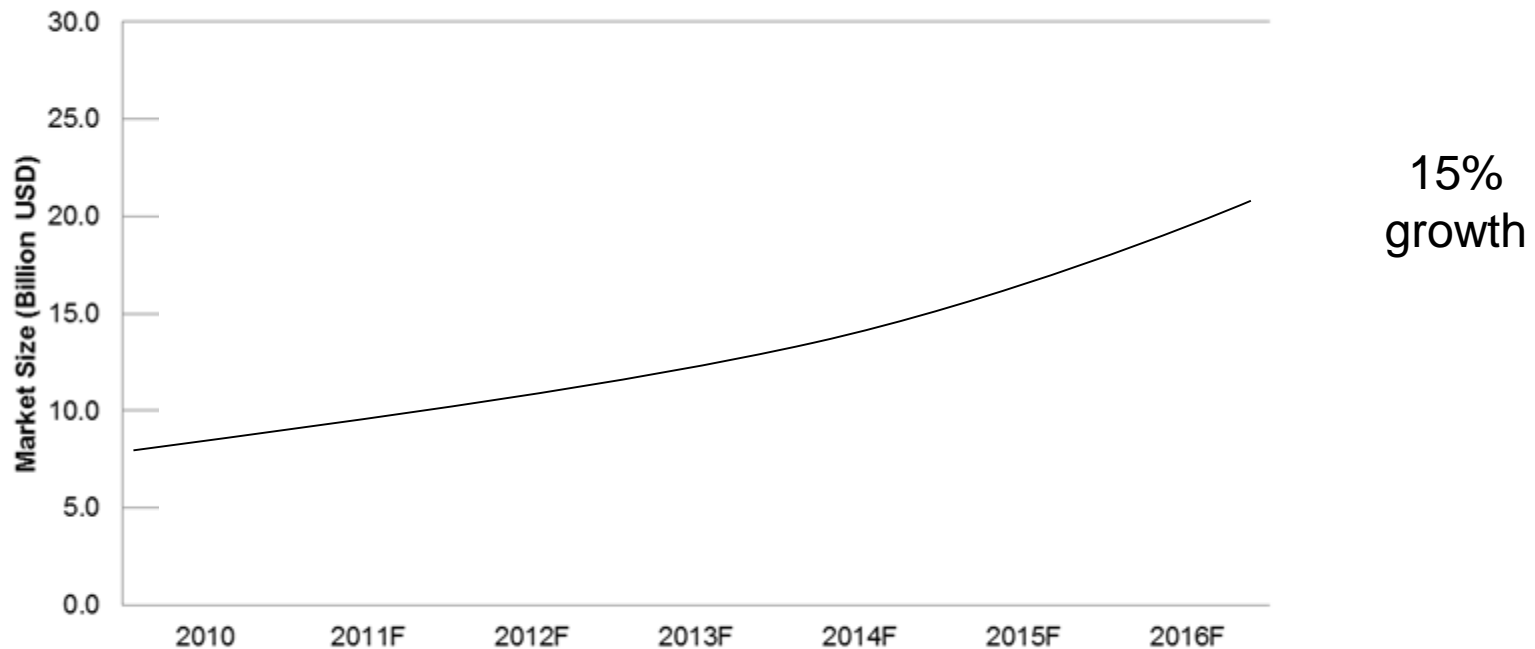
China's Medical Device Market (2015)

Medical device markets, by country



Chinese Medical Device Market Growth

China Medical Device Market Size Forecasts



Is There a Market for Your Device in China?

- ❑ Research has to be well thought out
- ❑ Secondary research – not normally that accurate; government statistics not reliable
- ❑ Primary research is the best way to go
- ❑ Researcher should have worked for foreign device companies before
- ❑ Big research companies send out 20 year olds, may not have enough experience to get answers you need; maybe a few quality interviews will do.
- ❑ Determine if there is a market before product registration

China Distributor Search

- Have you done lots of due diligence before selecting?
 - Meeting groups at trade shows will almost never work
- Are you building long term relationships of trust?
- Are you giving your distributor proper support? Training?
- Is the distributor attending the right trade shows?
- Do the distributor's people at an exhibitor booth really know your products?
- What do hospital purchasing managers think about your distributor?



China Distributor Search

- Lots of small players; some good regional players
- Are the small distributor companies going to survive?
- Conflict of interest – 3 sales teams
- Do bigger national Chinese distributors really have branch offices?
- Do distributors really do what they say they are doing?
Double check! Don't be “blind” to the market!

Chinese Medical Device Registration

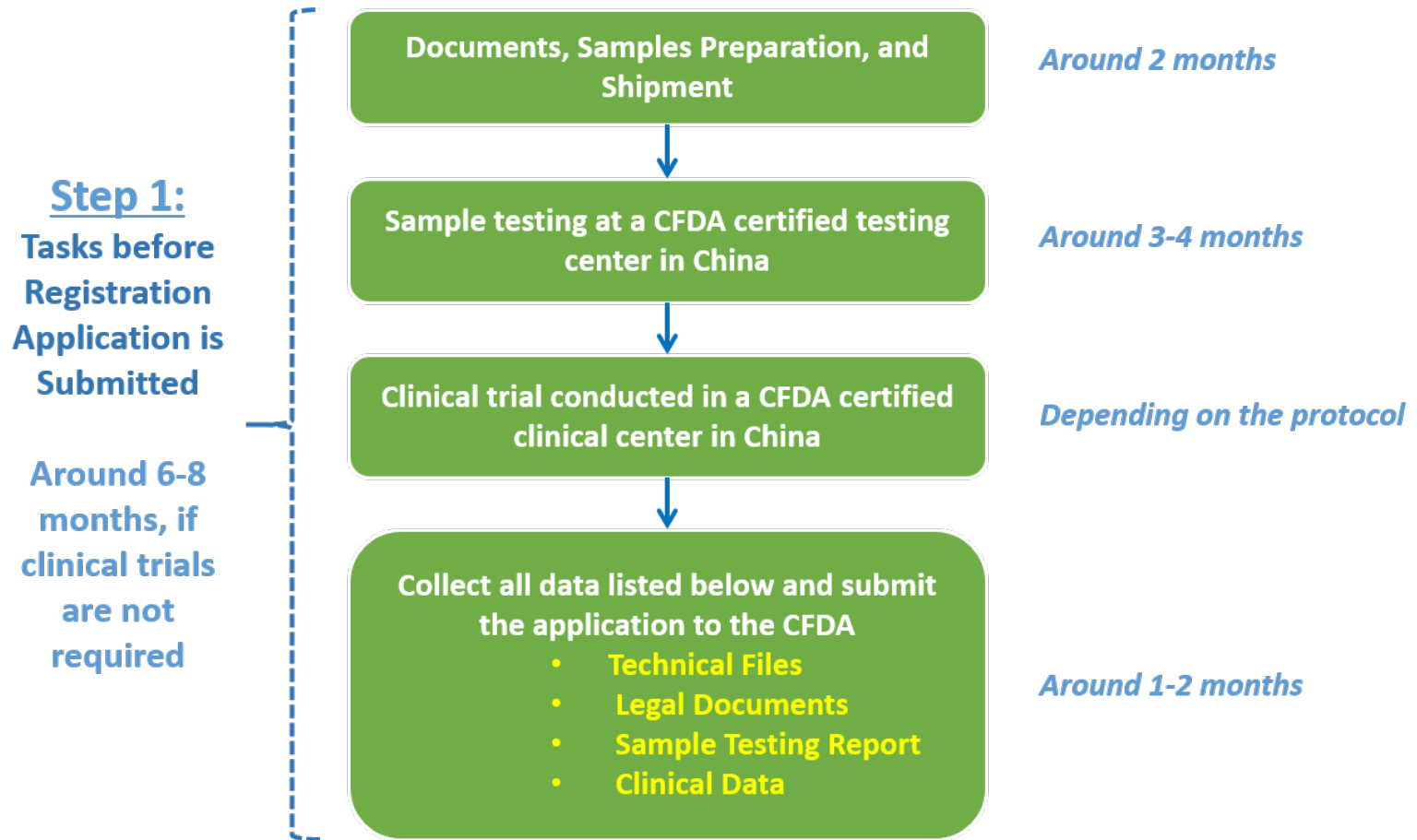
- Getting a lot tougher and longer for approvals
- New standards released
- Testing delays (only 10 centers)
- More supplementary reviews requested
- Class 2 and 3 medical devices need more local clinical trials /
New exempt list too
- Approval in county of origin still required
- IVDs approval in county of origin or where manufacturing site is located



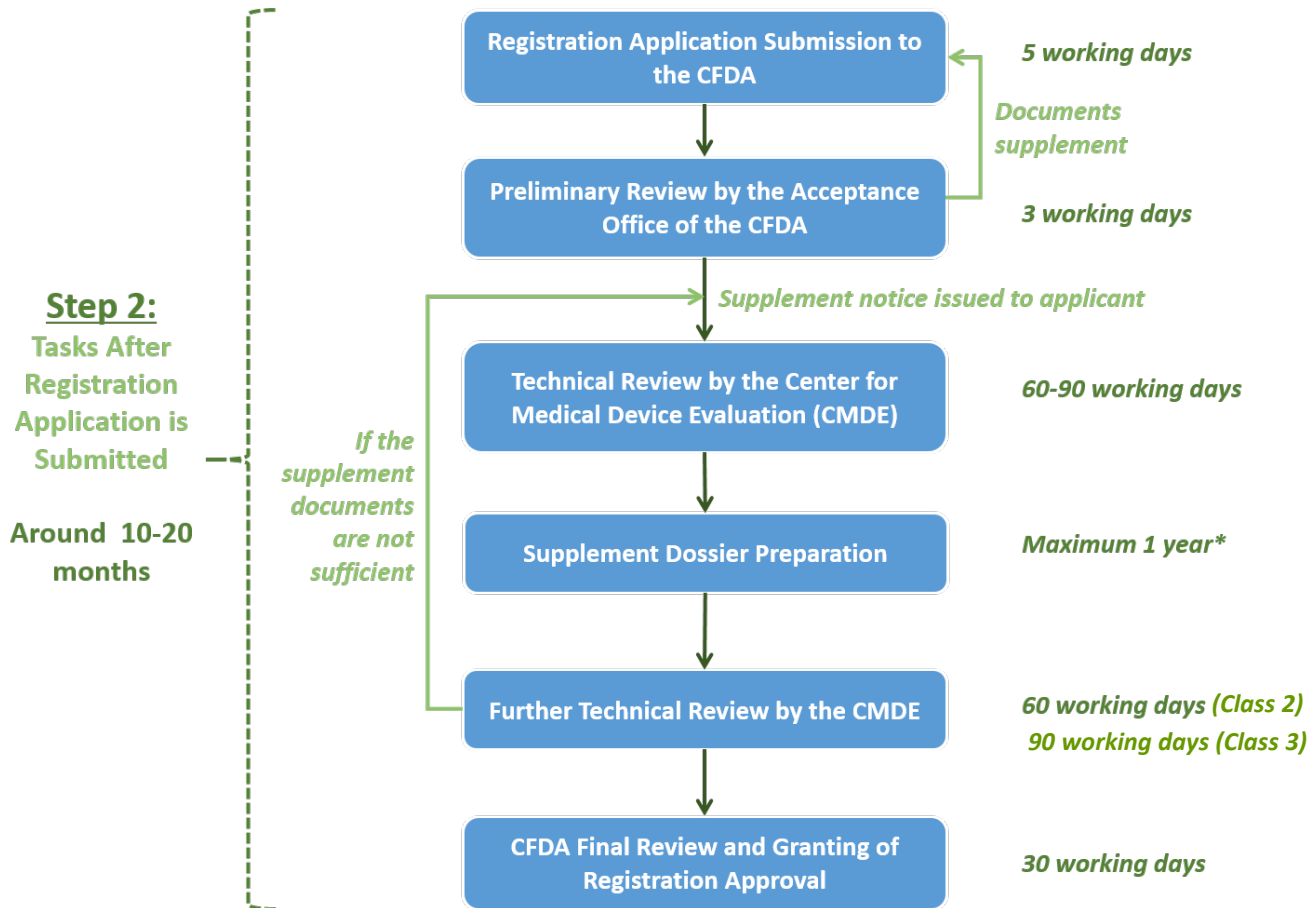
Chinese Medical Device New Regulations

- 2000 Regulations only 6 chapter and 48 articles
Now 2014 Regulations 8 chapters and 80 articles
- Class 1 – Notification, not registration, but more documentation needed than previous class 1 registration
- 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 II and III Devices



Registration Timeframe for Imported Class II and III Devices



Registration Timeframes

- 3 years ago:
 - Class II and Class III products 18-24 months to register, foreign data accepted
- Today
 - Class II and III products 24-48 months to register, and likely local, costly clinical trials required
 - Local trials can range between \$150k-750k depending on product type, and takes about 1 year

China Pricing and Reimbursement

- Pricing
 - Oftentimes national price list, but now more and more determined by provincial pricing bureau.
- Reimbursement
 - Mostly for procedures with basic domestically made products. Want a foreign stent, pay out of pocket.
 - Adjunct devices normally not reimbursed.



Chinese Competitors: Look Out!

- Local Chinese medical devices compete with foreign-made products (Lepu, MicroPort, etc.)
- Chinese government is financially incentivizing local device companies to make innovative products
 - Chinese hospitals are encouraged to buy China-made devices
- Locally made innovative product -- fast track registration
- Chinese locally-made products compete globally with Western products in Brazil, Indonesia
- Chinese companies will acquire more Western device companies in the future
 - MicroPort purchased Wright Medical's OrthoRecon business for almost \$300 million; this is just the beginning

Chinese Drug Eluting Stent Market

- 5 years ago, foreign imported products accounted for 75% of the DES market in China – Medtronic, Abbott, Boston Scientific and JNJ were the major players. Local Chinese manufacturers accounted for just 25% of the market.
- 5 years later, 75% of the DES market is controlled by local Chinese DES manufacturing companies. Just 25% of the market is controlled by foreign medical device manufacturers.

“B” Line of Products

- ❑ Western triple AAA products may not work in China
- ❑ Western medical device companies are increasing sales to China with basic models and lower prices compared to their top of the line Western products
- ❑ Many more local Chinese medical device manufacturers are now making more sophisticated products with better quality components, as demand increases in China, the region, and globally



“B” Line of Products

- Local Chinese companies who currently make a relatively cheap and basic model of a 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 Chinese locally-made products get better.
- Local players competing with a foreign device company’s “B” lines now, and “AAA” lines in the future.

Chinese Device Companies Seeking FDA Approval (Not just staying in China)

1. **Hua Medicine (Shanghai, China)**

- Developing a new treatment for diabetes
- Drug Sinogliatin 4th generation licensed from Roche
- Doing Phase II trials in China; also filing an IND in U.S. soon

2. **Lepu Medical (Beijing, China)**

- 1.3 billion sales
- Main Class 3 products: stents, PTCA balloons, prosthetic heart valves

3. **Mindray Medical International Ltd. (Shenzhen, China)**

- 1.2 billion sales (20% sales increase in Western Europe last year)
- Advanced IVD and medical imaging systems

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



Technology Transfer

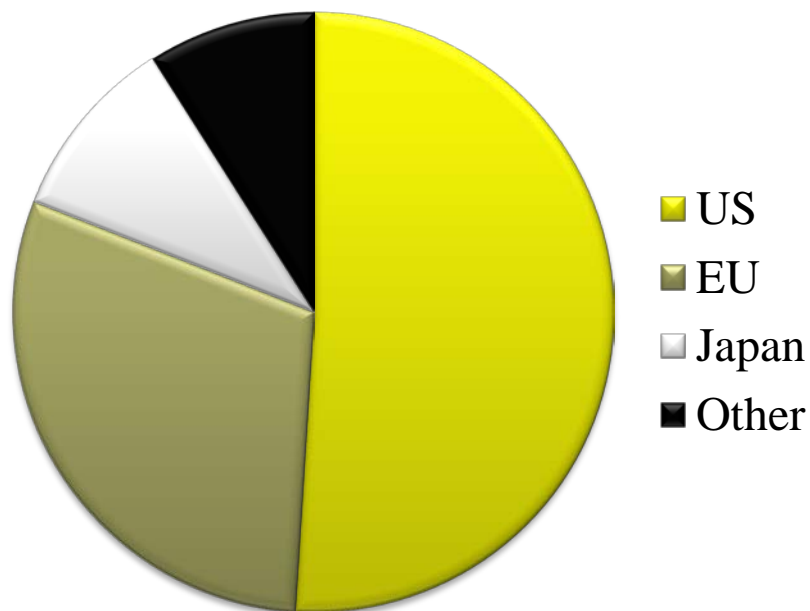
- For small to mid-sized Western device companies, registration may be too expensive and time consuming now; who has time to wait?
- Find a large Chinese device company that wants your technology for China marketplace
- Large Chinese company invests in your company in exchange for tech transfer and China distribution rights. Some large China device companies will “honor” licensing contracts

Intellectual Property

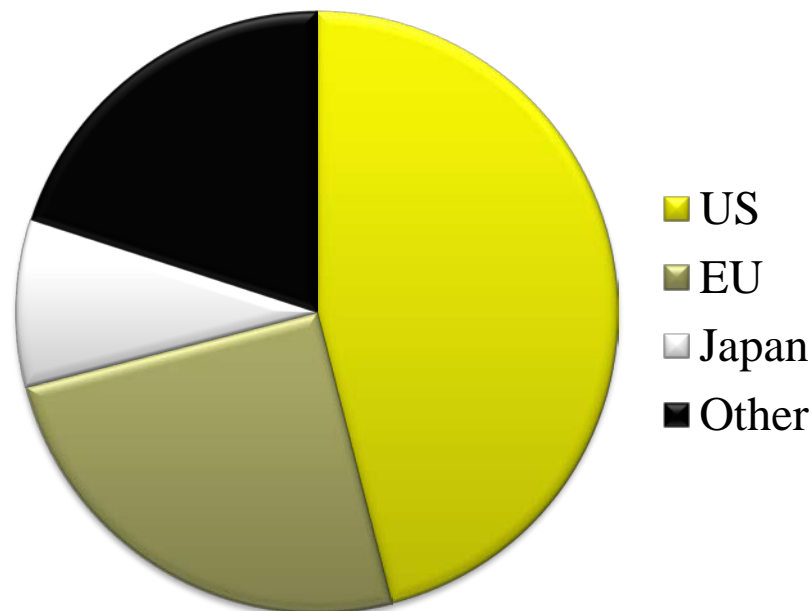
- China— better, but hard for small to mid-sized companies to win in court, very expensive
- Copying is rampant throughout China
 - They are taught that this is okay, so do not be naïve
- Best way to succeed is to continually develop new technologies

Medical Device Manufacturing Moving to Asia/China (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

Manufacturing and Sourcing

- ❑ China costs have skyrocketed, but quality has also improved
- ❑ It may be cheaper for commodity devices and components to be made in Vietnam and India (NOT China)
- ❑ Due diligence, close and continuous follow-up, monitoring, and QA will be key

Scenes from Chinese Factories



Scenes from Chinese Factories



Business in China Done Through Relationships, Not Lawsuits

- ❑ Relationships in the West are oftentimes different than relationships in China
- ❑ Is the Western medical device company global or really U.S. centric with a branch office in China?
- ❑ Understanding Chinese business practices are different than those in the West
- ❑ Chinese New Year holiday cards are a good way of maintaining relationships
- ❑ How do you write your emails?
- ❑ Multiple meetings with your Chinese counterparts is required, not optional





Thank you for your consideration!

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