

Frequently Asked Questions

- Is there a way to track submissions electronically for China?
 - Yes, though the SFDA announced in November, 2006 that their website was recently revamped for improved functionality.
- Have there been any new regulations/trends for IP protection?
 - For China, IP protection is based on three laws called the *Patent Law*, the *Trademark Law*, and the *Copyright Law*.

Frequently Asked Questions (cont'd)

- Are there any websites you would recommend when doing manufacturer searches for outsourcing/OEM?
 - Alibaba (www.alibaba.com) is probably the main one out there, as it provides company information, photos and contact info. There's also medibix.com and ec21.com.

- Are there regulations available in English?
 - Check the SFDA website at www.sfda.cn.gov.cn/eng/

- Can the Product Registration license be in our name if we are a foreign medical device company?
 - Yes.

Sourcing from Asia





Trends and Benefits to Sourcing from Asia

- ❑ Lower costs, lower overhead, lower salaries.
- ❑ Improving quality and technology.
- ❑ Presence of free trade, special economic zones with tax breaks, lower tariffs, lower duties.

Key Steps/Issues

- Know the difference between a trading company and a manufacturer.
- Look for quality certifications -- ISO, FDA, EU -- GMP standard production, US/EU customers.
- Keep in mind additional costs for shipping/freight, customized packaging, minimum quantity orders, currency changes, and legal jurisdiction.

Regulatory Issues

- Have local consultant / regulatory person do due diligence and quality assurance.
- Do a factory visit to make sure company is trustworthy and makes quality product.
- Staged payments.