

# Asian Medical Device Regulations

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# China

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# China Medical Device Market

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- The Chinese medical device market is growing rapidly (currently around \$2.5 billion)
- China holds much untapped market potential
- U.S. is leading exporter of medical devices to China (more than 1/3 of all imports)
- Exporting to China is becoming easier, and tariffs are being reduced (to 3.9% by January 1, 2005)



# China Medical Device Market

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- There are still many difficulties in exporting medical devices to china
  - Local procurement policies
  - Test requirements
  - Protection of intellectual property
  - Rules on types of business activity which foreign firms may conduct
  - Product registration



# China Medical Device Regulatory Agencies

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Two main agencies in China regulate imported medical devices:

1. State Food & Drug Administration (SFDA)
  - Chinese equivalent of the U.S. FDA
  - All imported medical devices must obtain registration certificate from SFDA
2. General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
  - Conducts mandatory safety registration, certification, and inspection for certain devices



# China Medical Device Regulation Update #1

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- SFDA issued new registration regulations on August 9, 2004
- No major changes in new version, but application and dossier review process simplified
- More detailed requirements for clinical trials added



# China Medical Device Regulation Update #1

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- Previous registration process:
  - 1) Apply to SFDA for specification validation
  - 2) After specification is reviewed and approved (1-1.5 months), company sends samples to testing center
  - 3) After testing, company files dossier with approved specifications and official testing report to SFDA
  - 4) SFDA reviews technical documents and issues import license



# China Medical Device Regulation Update #1

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- New Registration Process (effective August 9, 2004):
  - 1) Company drafts specifications, submits samples for testing
  - 2) Testing center conducts tests based on company's submitted specifications
  - 3) After testing, company submits whole dossier to SFDA
  - 4) SFDA sends dossier to Medical Device Evaluation Center
  - 5) MDEC reviews specifications, dossier, government certificate, and clinical report
  - 6) MDEC sends conclusion to SFDA
  - 7) SFDA awards import license if no supplement dossier requested

# China Medical Device Regulation Update #1 : Previous Registration Process

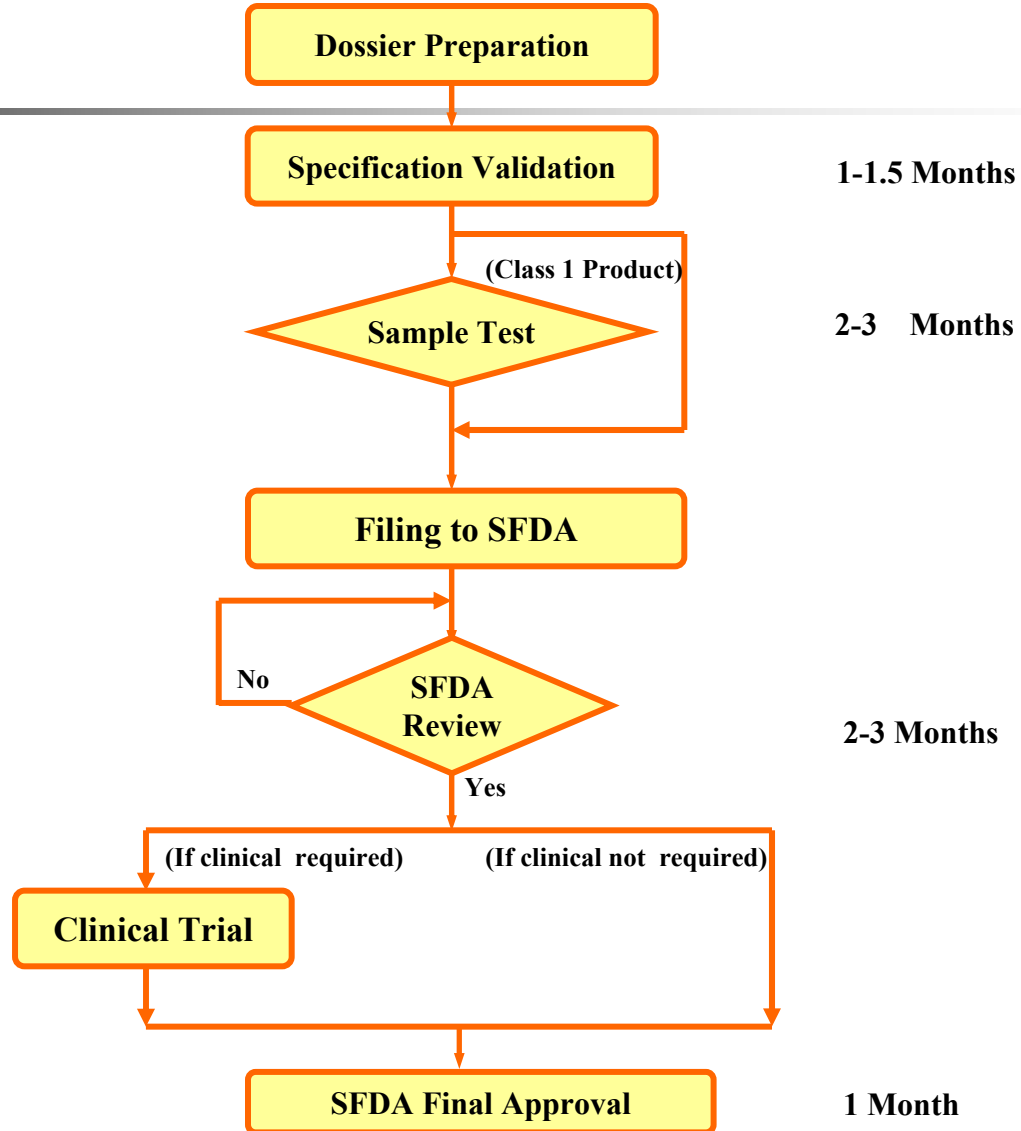
Normal:

**Class 1:** 4-6 months

**Class 2&3:** 6-8 months  
(without clinical)

**Class 2&3:** 9-14months  
(with clinical)

60 Cases, usually 3-6 months



1-1.5 Months

2-3 Months

2-3 Months

1 Month

# China Medical Device Regulation Update #1 : New Registration Process

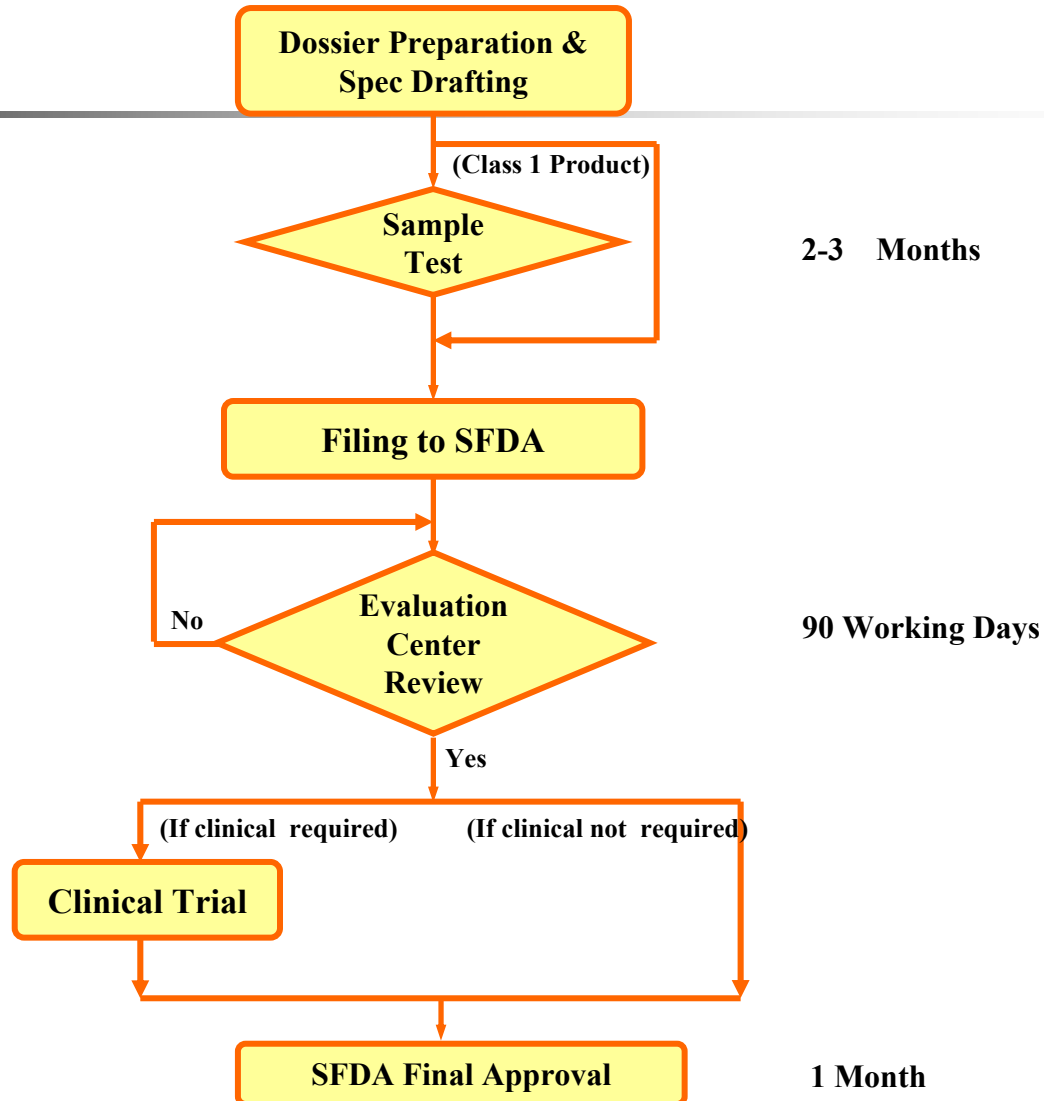
Normal:

**Class 1:** 5-6 months

**Class 2&3:** 7-8 months  
(without clinical)

**Class 2&3:** 12-14months  
(with clinical)

100 Cases, 2-3 SFDA  
appointed clinical center





# China Medical Device Regulation Update #1

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- Potential problems with new registration process:
  - IF MDEC requests supplement dossier, company must complete supplement and re-submit to SFDA within 60 working days
  - Since specification validation not required before testing, testing done on *company's* specifications
  - MDEC may request company to revise specifications and re-test, which requires extra time and money

# China Medical Device

## Regulation Update #1

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- New registration process more transparent
- More pressure on company when drafting specifications – they must be drafted correctly the first time; revising specifications after testing has been done adds time and money
- Total review time shorter if no supplement notice issued, longer if notice is issued



# China Medical Device Regulation Update #1

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- Previous regulations did not have specific requirements for clinical trials, just on what kind of devices required trials in China
- Under new regulations, all clinical trials for medical devices must follow Good Clinical Practices (GCP)
- Clinical center/hospital selected for trial must be on SFDA approved list
- Medical Device Clinical Trial Regulation issued by SFDA earlier this year, became effective in April 2004
- Regulation gives detailed requirements for clinical protocol, clinical hospitals, and clinical reports

# China Medical Device Regulation Update #2



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- SFDA issued new regulation on inserts, labeling, and packaging for medical devices on July 8, 2004 – China's first such regulation
- Detailed instructions for information to include on insert, label, and package (previous regulations did not provide specific requirements)
- All medical devices imported into China must have Chinese inserts, labeling, and packaging
- Insert must be reviewed and approved by SFDA during registration
- After approval, content of insert cannot be changed
- Any insert changes must be submitted to SFDA for approval



# China Medical Device Regulation Update #3

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- SFDA announced second draft of new diagnostic device registration regulation on July 29, 2004
- Regulation only concerns diagnostic products in medical device category (not those in drug category)
- Registration requirements similar to those for medical devices
- At least 3 batches of products required for sample testing
- New draft does not mention whether clinical trials are required



# China Medical Device Classification

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- As in U.S., device classification is basis for determining regulatory requirements
- Classification is split into three categories:
  - Class I – low risk, regulated by provincial governments
  - Class II – modest risk, regulated by provincial governments
  - Class III – high risk, regulated by the SFDA



# China Medical Device Registration: Required Documentation

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A total of 11 documents must be collected and submitted to the SFDA in both Chinese and English

1. *SFDA registration form* (can be downloaded from [www.cmdi.gov.cn](http://www.cmdi.gov.cn))
2. *Legal Production Qualification* (eg., U.S. FDA registration)
3. *Business license for the Chinese agent registering the product* (The agent must be located in China, have a valid license, and have a letter of commission from the manufacturer)



# China Medical Device Registration: Required Documentation

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4. *Marketing approval from government of country of origin* (Certificate to Foreign Government as well as 510(k), pre-market approval (PMA) application for U.S.-made devices issued by FDA or Free Sale Certificate)
5. *Product Standards* (ISO, CE, AAMI, etc.)
6. *Operation Manual* (Product instructions)
7. *Test report issued by SFDA-certified test center* (only required for Class II and III Products that have not received ISO9000 certification)
8. *Clinical trial report* (only required for certain types of devices; manufacturer may submit clinical trial data that was submitted in the country of origin)



# China Medical Device Registration: Required Documentation

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9. *Quality guarantee letter* (certifying that the product being registered and sold in China is identical to the product approved in the country of origin)
10. *After-sales authorization* (this includes an authorization letter from the manufacturer, a promise letter from the after-sales agent, and an after-sales agent qualification document)
11. *Self-guarantee declaration* (to vouch for truthfulness of submitted documents)

Note: Some of these regulations are fairly complicated; a more detailed description can be found on the SFDA website ([www.sfda.gov.cn](http://www.sfda.gov.cn))



# China Medical Device

## Registration: Procedural Issues

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- 2 original copies of the application must be submitted in both Chinese and English
- SFDA will issue acknowledgment letter of acceptance for the review
- SFDA will issue approval or denial letter within 90 working days (in practice, this is not always true – some U.S. companies have waited up to a year)



# China Medical Device Registration: Changing Registration Information

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- To change manufacturing location or add new manufacturing location, a *new product registration* must be submitted
- To change basic information (manufacturer's name, product name, after-sales service provider, name of manufacturing location, product line extension, etc.), an *amendment to the product registration* can be submitted



# China Medical Device Registration: Renewing Registration

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- Product registration is valid for 4 years
- Renewals must be requested 6 months before registration expires (forms can be downloaded from [www.cmdi.gov.com](http://www.cmdi.gov.com))
- The renewal process is similar to the initial registration
- A copy of the current registration must be submitted
- Product quality follow-up reports must be submitted
- The registration cannot be transferred
- Foreign manufacturers will not be directly granted registration to import medical devices unless they have a JV in China



# China Medical Device Registration: CCC Mark

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The China Compulsory Certificate (CCC mark) is administrated by the China Quality Certification Center. It is required for 7 categories of medical devices:

- Medical Diagnostic X-Ray Equipment
- Haemodialysis Equipment
- Hollow Fiber Dialysers
- Extra-corporeal Blood Circuit for Blood Purification Equipment
- Electrocardiographs
- Implantable Cardiac Pacemakers
- Artificial Heart-Lung Machine.



# China Medical Device Registration: CCC Mark

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- Products requiring the CCC mark that are not properly marked may be held at the border by Chinese Customs and subject to other penalties.
- Manufacturers can apply for the CCC mark directly to an Authorized Certification Body (ACB) or through a Chinese agent



# China Medical Device Registration: Authentication

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- Documents produced in the U.S. must be authenticated before submitting to the Chinese Embassy (or Consulate-General)
- Documents must be:
  - Signed before a notary public
  - Certified by the clerk of Court of the County where document is commissioned (if applicable)
  - Certified by the Secretary of the State where document is executed
  - Certified by the relevant Consulate-General (for applicants in the consular jurisdiction of the Embassy, documents must be certified by the U.S. Department of State Authentication Office, then by the Embassy)



# China Medical Device Registration: Authentication

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After all certifications are obtained, applicant must apply to location with jurisdiction over applicant's place of business by:

- Completing application (can be downloaded from <http://www.china-embassy.org/visa/english/G1.pdf> )
- Providing authenticated documents and one copy to the Chinese Embassy or Consulate-General's office

Note: applications must be mailed or submitted in person. Many documents must be signed or stamped by multiple parties; refer to the SFDA website for more detailed instructions.



# China Medical Device Registration: Authentication

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## Authentication Fees:

- \$40 per document
- \$5 for mail service
- \$30 for 1 day processing (regular processing time is 4 days)
- \$20 for 2-3 day processing
- Must be paid by money order, cashier's check, company check or cash (no personal checks)