

Asian Medical Device Regulations

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Map of Asia



Source: CIA



Demographics (2003)

Country	Population	Population Growth (2004 est.)	GDP (PPP)	Per Capita Income (PPP)	Life Expectancy (Years)
China	1,298,847,624	0.57%	\$6.449 trillion	\$5,000	71.96
Hong Kong	6,855,125	0.65%	\$212.2 billion	\$28,700	81.39
Philippines	86,241,697	1.88%	\$390.7 billion	\$4,600	69.60
Indonesia	238,452,952	1.49%	\$758.1 billion	\$3,200	69.26
Japan	127,333,002	0.08%	\$3.567 trillion	\$28,000	81.04
Malaysia	23,522,482	1.83%	\$207.2 billion	\$9,000	71.95
Singapore	4,353,893	1.71%	\$109.1 billion	\$23,700	81.53
South Korea	48,598,175	0.62%	\$855.3 billion	\$17,700	75.58
Taiwan	22,749,838	0.64%	\$528.6 billion	\$23,400	77.06
Thailand	64,865,523	0.91%	\$475.7 billion	\$7,400	71.41

Source: CIA World Fact Book 2004



Healthcare Statistics (2003)

Country	Number of Hospitals	Doctors per 1000 Person	Per Capita Spending on Healthcare (US\$)
China	330,348	1.69	30
Hong Kong	103	1.4	N/A
Philippines	1,652	N/A	33
Indonesia	1,089	0.14	19
Japan	169,556	1.91	2,908
Malaysia	360	0.7	101
Singapore	28	1.39	4,107
South Korea	21,686	1.35	584
Taiwan	18,265	7.42	677
Thailand	1,392	0.32	71

Source: Compiled from various sources by PBI



Size of Asian Medical Device Markets (2003)

Country	Market Size (US \$)
China	US \$2.5 billion
Hong Kong	US \$500 million
Philippines	US \$75 million
Indonesia	US \$150 million
Japan	US \$24 billion
Malaysia	US \$300 million
Singapore	US \$410 million
South Korea	US \$1.4 billion
Taiwan	US \$900 million
Thailand	US \$500 million

Source: Compiled from various sources by PBI



Asian Medical Device Markets

- Over 30% of new expenditures on healthcare worldwide is attributable to Asia
- Spending there is expected to increase an additional 45% by 2005
- Spending is driven by:
 - Aging population
 - Increasing life expectancy
 - Increasing incidence of major diseases
 - Increasing health consciousness
 - Higher disposable income

Asian Medical Device Regulation Updates





Japan Medical Device Regulation: Update

- Pharmaceutical Affairs Law (PAL) establishes original vendor or Marketing Authorization Holder (MAH) entity that is solely responsible for marketing and distributing medical products
- Marketing and distributing are completely separated from manufacturing



Japan Medical Device Regulation: Update

- MAH can:
 - Sell medical devices without manufacturing license
 - Transact OEM sales
 - Purchase medical device notes from manufacturer
 - Sell and/or lease medical devices to businesses
 - Import medical devices
 - Store medical devices for future sale
- MAH cannot manufacture medical products
- MAH must assume all responsibility for medical products it markets in Japan



Japanese Medical Device Regulation: Update

- Ministry of Health, Labor and Welfare (MHLW) has adopted new consultation system
- In past, visits to MHLW for advice were free and non-binding
- Comments made during visits did not carry weight in future sessions



Japanese Pharmaceutical Trends: New MHLW Consultation System

- New system includes three options:
 - *Preliminary Consultation*: applicants offered 30 minutes of free, initial feedback
 - *Regular Consultation*: 30 minute consultation provides assistance with application without prior review of documents, costs US\$350
 - *Detailed Consultation*: 2 hour maximum consultation (with applicant, manufacturer's representatives, experts (if desired), and MHLW), costs \$16,000. MHLW gives non-binding prediction of what will happen during regulatory process. List of questions must be submitted on the Monday 3 weeks before consultation. MHLW reviews documents before meeting.



Hong Kong Medical Device Regulation: Update

- Hong Kong's Department of Health (DH) and the Electrical and Mechanical Services Department (EMSD) issued "Regulation of Medical Devices in Hong Kong"
- Proposed medical device regulations similar to those recommended by Global Harmonization Task Force
- Currently no specific legislation for importation of medical devices
- Majority of Hong Kong's medical devices are imported from US, EU, Japan, and China



Hong Kong Medical Device Regulation: Update

- On June 1, 2004, Hong Kong's Department of Health launched Center for Health Protection (CHP)
- CHP meant to help Hong Kong handle health threats and outbreaks of diseases
- Central communicable disease information system to be created, will provide healthcare professionals with reports on latest communicable diseases and infections of concern in Hong Kong



Singapore Medical Device Regulation: Update

- Singapore's Health Sciences Authority (HSA) and China's State Food and Drug Administration (SFDA) signed a Memorandum of Understanding (MOU) formalizing their agreement to strengthen cooperation
- Information and expertise will be exchanged between HAS and SFDA on medical devices and other medical products
- Committee of Coordination and Liaison to be formed, will facilitate bilateral exchanges



India Medical Device Regulation: Update

- India considering new medical device regulatory body
- India currently does not have regulatory body to oversee medical devices and equipment
- Proposal includes establishment of system based on US FDA and European model called Indian Medical Devices Regulatory Authority (IMDRA)
- No timetable yet for implementation, but recognized need
- India's medical devices market has grown 25% in past several years, is valued at \$1.25 billion

Vietnam Medical Device Regulation: Update



- Ministry of Culture & Information and Ministry of Health jointly issued updated guidelines on health and medical products advertising
- Advertising for medical check-ups and treatment may not overstate qualifications of health professionals involved. Only procedures and practices approved by Ministry of Health can be advertised
- Advertising not allowed for pharmaceutical products and medical devices prohibited in Vietnam



Taiwan



Taiwan Medical Device Market

- One of Asia's most advanced medical equipment markets – and Asia's 4th biggest market (around \$900 million)
- Growing domestic industry, which is becoming more sophisticated but remains fragmented and is largely export-oriented
- Taiwanese market dominated by imports (around 80%), particularly by U.S. (>30%) and Japanese companies



Taiwan Medical Device Regulatory Agencies

The R.O.C. Executive Yuan's Department of Health (DOH)

<http://www.doh.gov.tw/dohenglish/>

- Taiwanese equivalent of the U.S. FDA
- All imported medical devices must obtain registration certificate from the DOH's Bureau of Pharmaceutical Affairs (BPA)
- DOH performs on-site inspection for local manufacturers and reviews Quality System Documentation (QSD) provided by foreign manufacturers



Taiwan Medical Device Regulation Update #1

- DOH made announcement December 31, 2003 concerning mad cow disease
- DOH will not accept drug or medical device registration cases and/or will not approve applications for which bovine derivatives from BSE (mad cow disease) listed countries by OIE or Taiwan were used in process or in finished products



Taiwan Medical Device Regulation Update #2

- Grace period for IVD (In Vitro Diagnostics) Reclassification and Registration ended February 9, 2004
- Product registration documents required for product renewal or for new products
- All IVDs on market should be properly licensed by June 20, 2005



Taiwan Medical Device Regulation Update #3

- DOH published draft of revised reclassification and registration requirements for medical devices in April 2004
- Some previously exempt Class I products must be registered (previously all Class I products were exempt from product registration)
- Class I products requiring registration will only need “simple” documents, but this will still increase workload significantly



Taiwan Medical Device Regulation Update #3

- Several medical devices were re-classified (new sub-categories to the three classes of devices were added)
- The regulation will be formally announced in late 2004 after the DOH receives feedback from the medical industry



Taiwan Medical Device Regulation Update #4

- DOH published draft announcement on Post Marketing Surveillance (PMS) regulation of new drugs and designated medical devices in June 2004
- Announcement has undergone industry review
- When it becomes effective, medical devices designated by DOH will be subject to PMS regulation for 3 years after license is granted

Taiwan Medical Device Regulation Update #5



- DOH published draft announcement on the Exchange of Letter (EOL) with the Quality Auditing Third Parties of the EU in July 2004
- Draft recognizes 6 parties within the EU: TÜV PS, TÜV Rhineland, mdc, NSAI, BSI, and G-Med
- Draft became effective at end of August 2004
- Plants in EU countries which are certified by one of these 6 parties will have simplified QSD registration requirements (like US plants that have been FDA inspected)

Taiwan Medical Device Regulation



- New classification system for medical devices will come into effect in June 2005
- Number of cases submitted to the Department of Health (DOH) for import licenses has increased tremendously, resulting in prolonged review time
- Quality System Documentation (QSD) requirement is one of the industry's most complicated challenges

Taiwan Medical Device Classification



- Taiwan divides medical devices into 3 classes:
- Class I Products only require QSD registration with DOH (this will change in late 2004 when some Class I Products will require product registration)
- Class II and III Products require QSD registration and product registration
- Some Class III Products also require a clinical trial proposal or published clinical trial reports



Taiwan Medical Device Registration: Procedural Issues

- All foreign manufacturers without local offices must select a Taiwanese trading company as an agent to import medical devices
- Medical device registration requires the submission of at least 6 different documents (some types of medical devices require additional documents)
- QSD requirements must be met before products can be registered



Taiwan Medical Device Regulations: QSD Requirements

- Requirements are different for U.S. and non-U.S. factories (requirements will also be lowered for EU factories inspected by approved third party auditors)
- If a company plans to export products manufactured both inside and outside the U.S., it must submit QSD for all of the plants



Taiwan Medical Device Regulations: QSD Registration for U.S. plants

- *Free Sale Certificate* (FSC) issued by FDA (must cover all products manufactured in the plant)
- *Establishment Inspection Report* (EIR) issued by FDA
- *ISO13485* or *EN46001*
- *General information*
 - *Factory name and address*
 - *Brief history*
 - *Organizational chart*
 - *Registered capital*
 - *Plant description* (size, location, product manufacturing activities, etc.)



Taiwan Medical Device Regulations: QSD Registration for U.S. plants

- *Product list* (name and code of all products manufactured at plant; any toxic or hazardous substances handled; whether drugs for humans or animals, radiopharmaceuticals, diagnostic reagents, cosmetics, or food products are also manufactured on site)
- *Layout* (drawing of plant, drawing of buildings showing each floor separately with a list of rooms and facilities, flows for personnel and materials coded by color, blueprints (if requested))
- *Manufacturing flow chart for products*
- All documentation should be collected in one file and sent to the DOH



Taiwan Medical Device Regulations: QSD Registration for *NON*-U.S. plants

- All documents required for U.S. plants
- Master index
 - List of all Standard Operating Procedure (SOP) numbers and document description
 - List of Level III SOP numbers and document description (not necessary for first submission but must be submitted if requested by DOH)
- Quality Manual (QM) of the plant
 - Contents must cover all 20 points required by QSD



Taiwan Medical Device Registration: Required Documentation

1. *Letter of authorization* (must authorize Taiwanese agent to register product)
2. *Free Sale Certificate* (demonstrating that product is freely sold in its home market)
3. *Leaflet/Catalogue* (specifying product usage – 3 copies are required)
4. *Quality control* (including testing methods and testing results)



Taiwan Medical Device Registration: Required Documentation

5. *Product specifications* (form, structure, dimensions, raw materials or ingredients, quantity, performance, purpose of use, and effects)
6. *Sample* (if device is extremely heavy or bulky, or if other special circumstances apply, sample may be replaced by pictures that identify the structure, properties, and form of the device)



Taiwan Medical Device Registration: Additional Requirements

7. *Clinical trial reports* (required for certain medical devices such as newly developed devices or approved devices with new applications)
8. *Circuits and testing records of electric insulation and duration* (required for electronic equipment)
9. *Instructions for operating security* (required for electronic equipment)



Taiwan Medical Device Registration: Additional Requirements

- 10. Operation records of automatic measurement adjustment (required for automatic temperature adjusting equipment)*
- 11. Testing record and certificate of radiation leakage (required for radioactive equipment)*



Taiwan Medical Device Registration: Registration Information

- Product licenses are valid for 5 years
- Application process can take 1-2 years
- The Taiwanese agent who registers the product is the license-holder
- After the product license is available, the product is allowed to be imported by the agent
- The license-holder may transfer the license to another agent with the consent of the manufacturer



Taiwan Medical Device Registration: Registration Information

- Manufacturer may authorize other agents to register the same product concurrently
- Manufacturers with different locations but the same company name, (e.g. branch manufacturers) must file separate applications
- DOH has implemented medical device GMP requirements since 1999. New GMP requirements based on ISO9001 and ISO13485 came into effect in February 2004.
- Manufacturers must comply with Taiwanese GMP requirements (as outlined in the QSD section)



China



China Medical Device Market

- 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

- 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

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

- 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

- 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

- 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

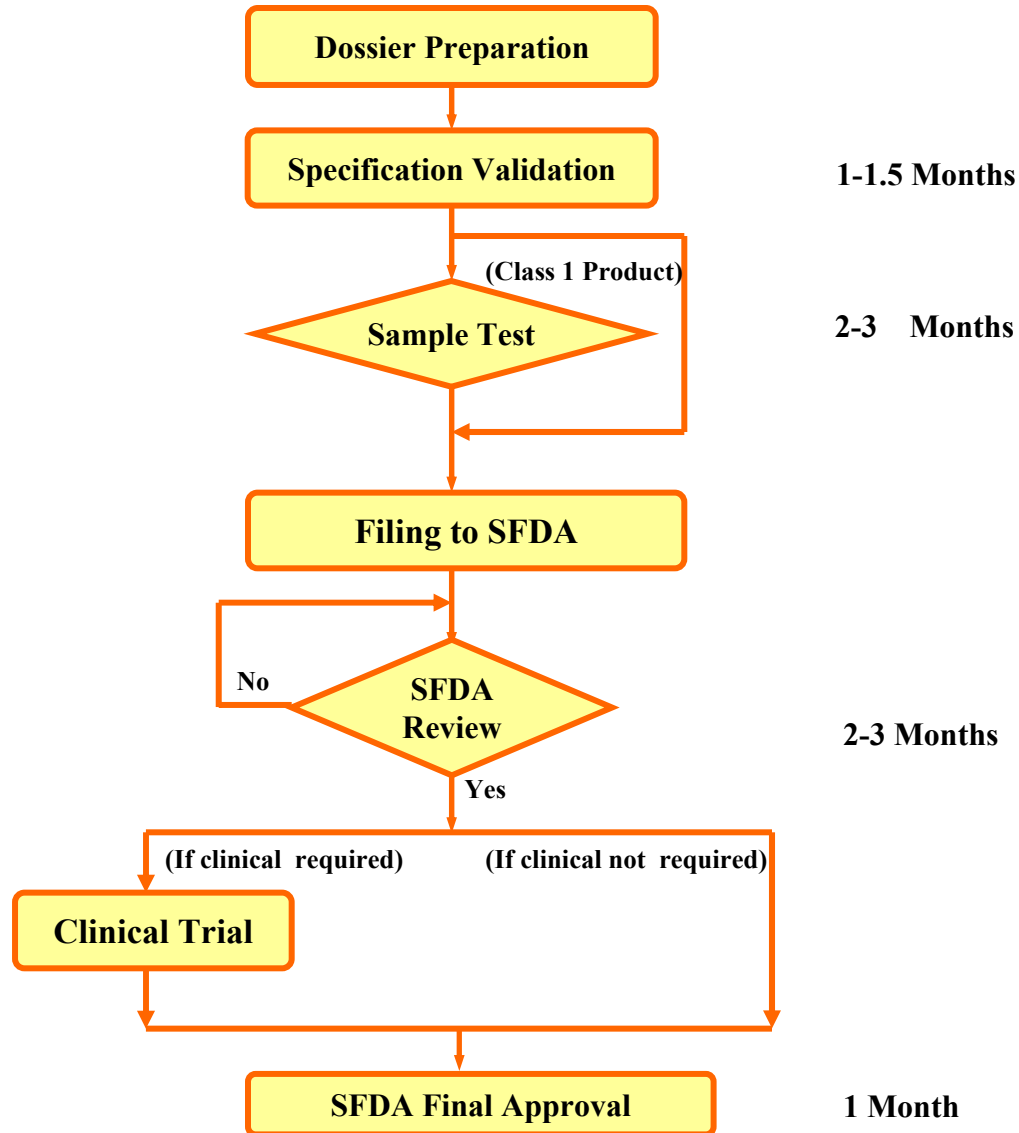
Normal:

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



China Medical Device Regulation Update #1 : New Registration Process

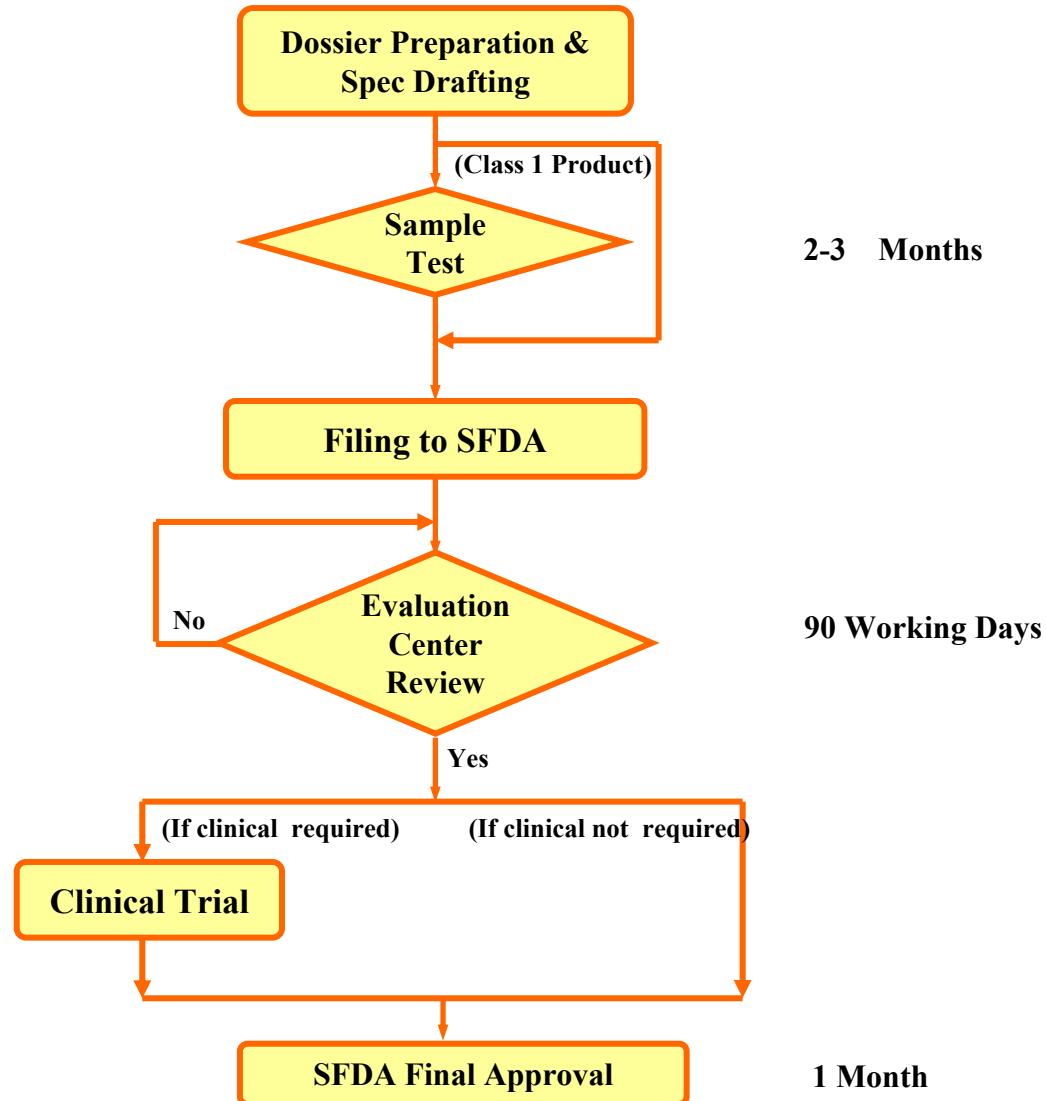
Normal:

Class 1: 5-6 months

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

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

100 Cases, 2-3 SFDA
appointed clinical center





China Medical Device Regulation Update #1

- 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

- 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

- 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



- 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

- 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

- 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

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)
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

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

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)



China Medical Device

Registration: Procedural Issues

- 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

- 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

- 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)
- 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

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

- 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

- 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

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.

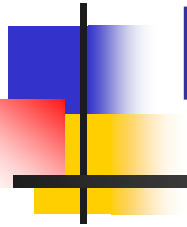


China Medical Device Registration: Authentication

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)

South Korea





Korea Medical Device Market

- 3rd largest market in Asia (\$1.4 billion in 2003)
- Imports represent 2/3 of market
- Most advanced medical technology comes from imports
- Market relies on both universal public health insurance and consumer cost sharing



Korea Medical Device Market

- Korea has strict trade regulations for medical devices
- The America Chamber of Commerce in Korea lists market access for medical devices as an “area of concern”, noting that they are “particularly vulnerable to lengthy, cumbersome and costly testing requirements”

Korea Medical Device Regulatory Agencies



Korea Food & Drug Administration (KFDA)

<http://www.kfda.go.kr/english/english.html>

- All medical devices required to obtain KFDA product license or product approval
- KFDA only issues product licenses to local firms; foreign firms must submit documentation and receive approval through a Korean importer
- Korean importers must maintain qualification certifications (“Certifications of Compliance to Quality Management System (QMS) for Imported Devices”) issued by a KFDA-authorized entity



Korea Medical Device Classification

- Similar to China, Taiwan, U.S.
- Devices divided into Class I, II, and III Products based on level of risk
- Different registration requirements for each product class



Korea Medical Device Registration

- Class I Products require premarket notification
- No product testing is required
- Korean importer must complete and submit “Pharmaceutical Affairs Act Implementing Regulations Attachment Form 15-2” (with supporting documents) to local KFDA district office in importer’s region



Korea Medical Device Registration

- Form 15-2 for Class I Products must include:
 - Local importer's company information
 - Trade name, model name and classification name of device
 - Raw materials, external appearance and internal structure
 - Manufacturing methods
 - Intended effects
 - Instructions for use, precautions for use
 - Packaging unit and labeling
 - Foreign manufacturer's company name



Korea Medical Device Registration

- Class II and III Products require premarket approval
- Importers of Class II and III Products must submit “technical dossier” to KFDA
- Must file “Pharmaceutical Affairs Act Implementing Regulations Attachment Form 17-2” entitled “Standards and Testing Method (STM) Review Application” with KFDA’s Medical Device Evaluation Department.
- Purpose of STM review is to evaluate manufacturer’s quality standards



Korea Medical Device Registration

- Form 15-2 for Class I Products must include:
 - Local importer's company information
 - Foreign manufacturer's company name, address, country
 - Trade name, model name, classification name of device
 - Raw materials, ingredient list, % breakdown by ingredient
 - External appearance, internal structure, size
 - Manufacturing methods
 - Effectiveness, purpose, instructions and precautions for use
 - Packaging unit, storage methods, validity period
 - Standards and test methods



Korea Medical Device Registration

- KFDA may also require a Safety and Efficacy Review (SER) for products with new-to-market features (usually just for Class III Products)
- SER is most rigorous review process (similar to premarket approval in U.S.)
- SER requires Pharmaceutical Affairs Act Implementing Regulations Attachment Form 16
- KFDA-authorized labs test device after STM review and/or SER completed
- Korean importers submit KFDA-approved STM and/or SER documents, foreign test reports, and products samples to lab



Korea Medical Device Registration

- Form 16 for SER must include:
 - Information on origin, discovery and background of development
 - Information on determination of structure and physicochemical and biological properties
 - Stability data - Toxicity data
 - Pharmacological action
 - Clinical study report
 - Previous use in foreign countries
 - Comparative analysis with products currently on the market
 - Functional performance
 - Electromagnetic interference
 - Electrical or mechanical safety, biological or radiation safety, etc.



Korea Medical Device Registration

- KFDA may (hypothetically) exempt imported products from local type testing or clinical trials upon submission of equivalent foreign test reports
- Obtaining exemption is very difficult and requires original, certified, and notified test data from test labs in country of origin
- U.S. labs usually only issue one set of test data originals to manufacturer
- FDA does not certify test documents
- No U.S. companies have been exempted from Korean type testing



Korea Medical Device Registration

- To apply for marketing approval for a device, Korean importer must submit 3 documents to KFDA:
 - Approved STM
 - Type test certification
 - Qualification certification for the appropriate product category
- KFDA may take up to 10 days to issue a product license for importation



Korea Medical Device Registration

- Review of applications for product licenses must be completed in a total of 55 days
- Korea has adopted 3rd party review
- KFDA-accredited 3rd parties can process product license reviews for Class II Products (except radiological devices)

Korea Medical Device Registration – Direct Expenses

Classification	Charging Organizations	Fee Ranges
<i>Review Fees</i>		
Safety and Effectiveness Review (SER) (Class I, II, III)	KFDA	Korean Won 30,000
Standard and Test Methods (STM) review (Class II, III)	KFDA	Korean Won 20,000
STM (Class II)	Third Party	Korean Won 340,000
Product Import License Issue	KFDA	Korean Won 10,000
<i>Type Test Fees</i>		
SER + STM Product	Third Party	Korean Won 8-10 million
STM Product	Third Party	Korean Won 2-3 million
Human Tissue Product	To be determined	Quote
<i>Fees for Quality Management System Certification for Imported Devices</i>		
Imported Device QS Certification (Primary)	Third Party	Korean Won 1.1 million
Imported Device QSC (Biennial Renewal)	Third Party	Korean Won 1.1 million
<i>Fees for Electronic Listing of Approved Devices for Customs Clearance</i>		
Electronic Listing of Approved Product	Third Party	Korean Won 50,000 /mo.

Korea Medical Device Registration – Time Schedule

Category	Descriptions	Usual Turnaround Times*	
<i>Product Registration</i>	Products equivalent to those devices already approved for marketing in Korea	Class I	4 weeks
		Class II, III	3-6 months
	New-to-Korea devices that are not equivalent to those devices already approved for marketing in Korea (for all classes)	6-12 months	
	Product License Transfer	4 weeks	
<i>Health Insurance Reimbursement Listing</i>	New Application	6-8 months	
	Appellate Case	6-8 months	



Conclusion

- Taiwan, China, and Korea all have complicated and evolving requirements for medical device registration
- Must understand that each Asian culture is different to be successful
- Remember that who you “know” may be just as important as the paperwork



Useful Contact Information

- Pacific Bridge, Inc.
www.pacificbridgemedical.com
- Department of Commerce
www.ita.doc.gov
- U.S. Commercial Service
www.buyusa.gov