



2015 China Regulatory Update: Devices, IVDs, and more

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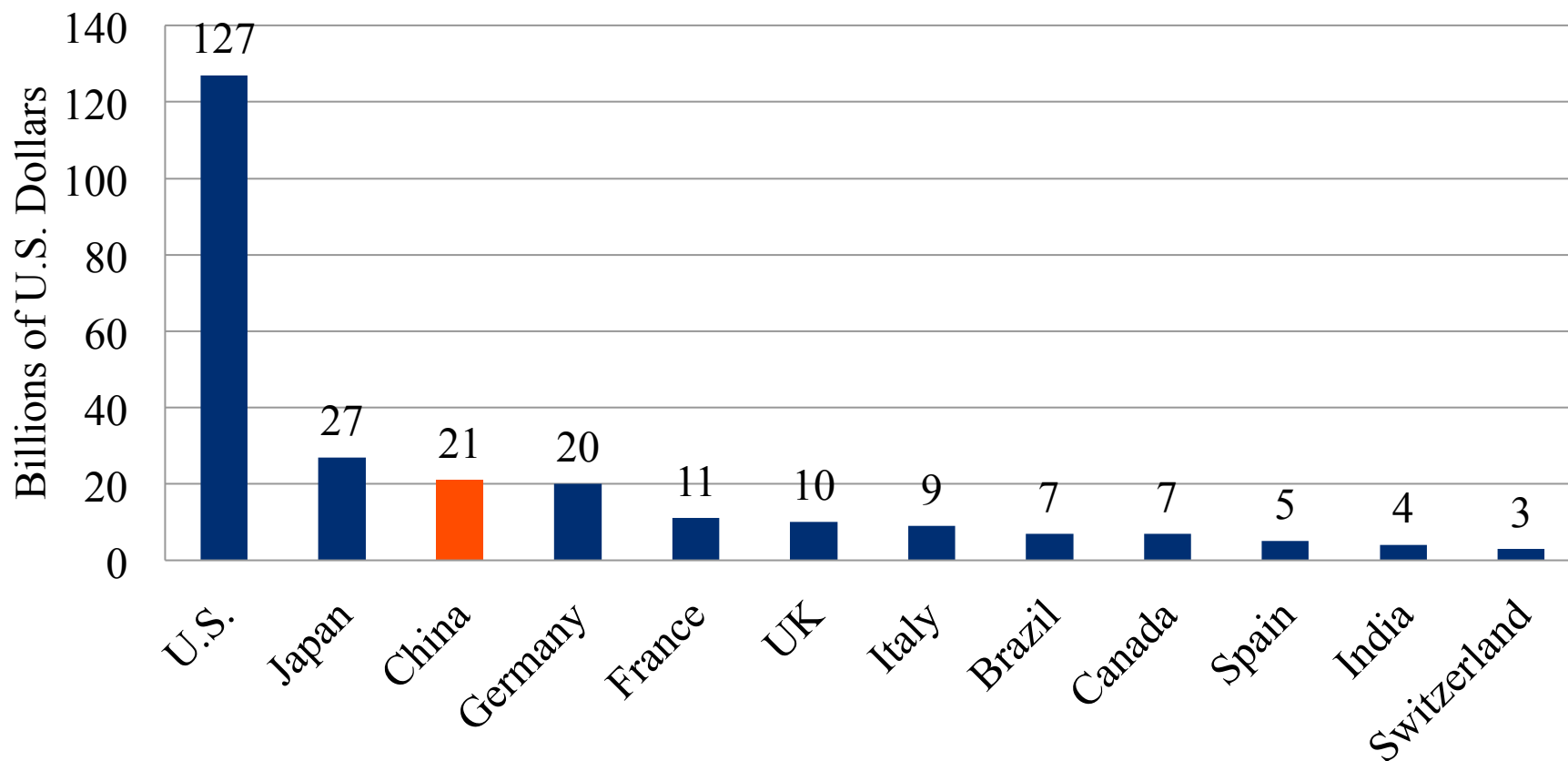
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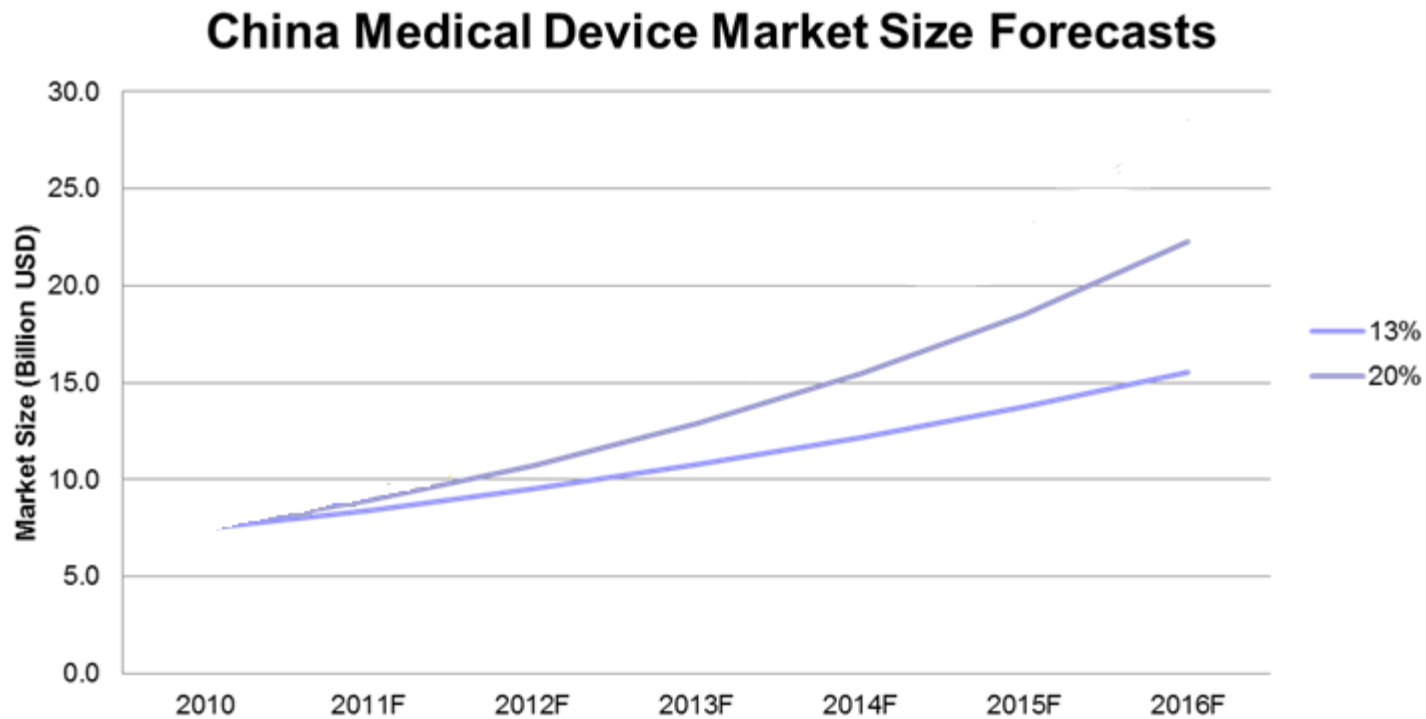
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China's Medical Device Market (2013)

Medical device markets, by country



Chinese Medical Device Market Growth



Chinese Agents

- The responsibilities of a “Legal Agent” and an “After Sales Agent” have been combined together as an “**Agent in China**” and must be a registered entity in China

- Registration Agent
 - Must be a registered entity in China

China: Medical Device Regulatory Authorities

China Food & Drug Administration (CFDA)

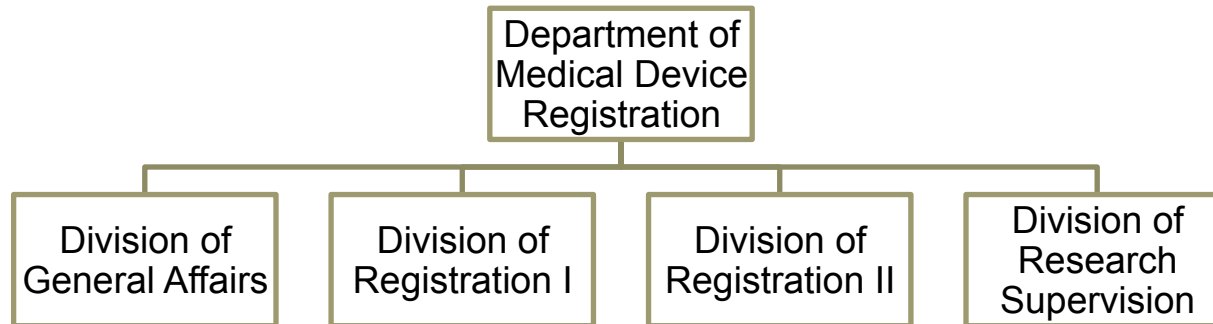
- Founded in 1998
- Equivalent to the U.S. FDA
- Responsible for medical devices, drugs, healthcare services, cosmetics, food
- Headquarters is located in Beijing, with offices in each province

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

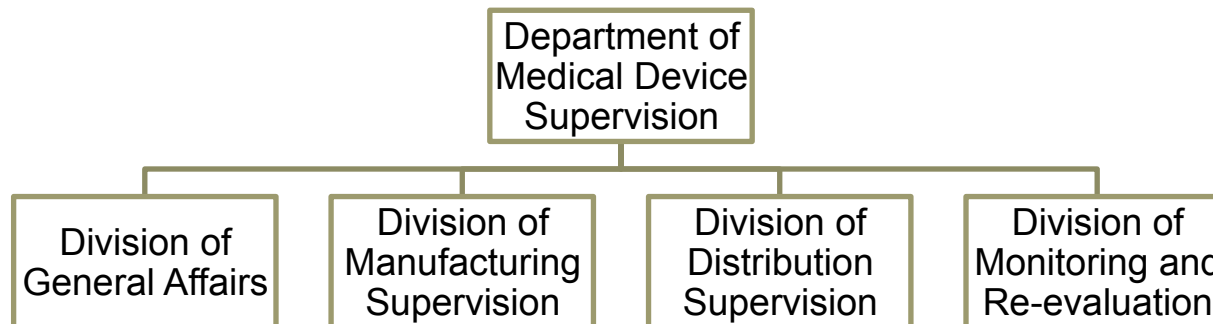
- Conducts mandatory safety registration, certification, and inspection for certain devices

CFDA Organization for Medical Devices

❑ Pre-market approval: Department of Medical Device Registration



❑ Post-market supervision: Department of Medical Device Supervision



Medical Device Regulations

(Updated 2014) / NEW

- **New laws include (Decree of State Council #650 June 1, 2014)**
 - 12 Administrative rules
 - 197 Normative documents
 - 1015 Medical Device Standards

- **New regulations released (Oct. 1, 2014)**
 - Decree of CFDA No.4 for MD Registration
 - Decree of CFDA No.5 for IVD Registration
 - Decree of CFDA No.6 for Labeling
 - Decree of CFDA No.7 for Production
 - Decree of CFDA No.8 for Distribution
 - Decree of CFDA No.15 for Classification
 - Decree of MoH No.82 for Recall
 - MD Good Manufacturing Practice
 - Classification Catalogue of MD
 - Accreditation of MD testing bodies
 - GB 187 (88 Compulsory, 99 Recommended)
 - YY 864 (376 Compulsory, 488 Recommended)

Main Regulations

(to be discussed throughout webcast) / **NEW**

- ❑ 2000 Regulatory Edition (6 chapters, 48 articles), 2014 Regulatory Edition (8 chapters, 80 articles)
- ❑ Class I products: filing instead of registration
- ❑ More local clinical trials required for product approval of Class II and III devices
- ❑ Some clinical trial exemptions for Class II and III devices
- ❑ License extension from 4 years to 5 years
- ❑ Biocompatibility data is still required for submission as part of the research data.
- ❑ Time window to submit supplementary documents increased from 60 days to 365 days.
- ❑ Generally, more details required for product approvals
- ❑ QMS audit may be required for some registrations

Medical Device Regulation and Classification

- ❑ Regulation on Supervision and Administration of Medical Devices (Order 276, 2002)
- ❑ Device Classification is the basis for determining regulatory requirements:
 - **Class I** – Those which safety and effectiveness can be ensured through routine administration
 - **Class II** – Those which further control is required to ensure their safety and effectiveness
 - **Class III**– Those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness

Medical Device Regulation and Classification

- For innovative products and combination products, getting an official CFDA classification can be very helpful
 - The classification process can take anywhere from 3 to 12 months
 - In the new 2014 regulations, CFDA provides an alternative pathway for a product whose classification is not very clear in China.
- Some Chinese classifications are different from the EU/ U.S.

Medical Device Classification

- Draft Classification Rules announced:
 1. Kits containing multiple devices will be classified per the highest device
 2. Device accessory classifications are determined by their influence on safety & the effectiveness of devices that such accessories are used for
 3. Standalone software will be in the same classification as the device it works with
 4. If the risk level of a device changes, the device may need to be re-classified (broader statement than before, which said so if the function or purpose changed)
 5. Some categories have changed – medical dressings are now classified as “functional” or “ordinary” medical dressings
 6. New category for IVDs, separate from medical devices

Example from the CFDA Medical Device Classification Catalogue

CFDA Classification Code 6825 for High Frequency Medical Devices (English translation)

编码代号 Classification Category Code	序 Subcategory	名称 Product Type	品名举例 Examples	管理类别 Class
6825 医用高频仪器设备 6825 high frequency medical devices	1	高频手术和电凝设备 high frequency devices for surgery and electric coagulation	高频电刀(high frequency electric knife)、高频扁桃体手术器(high frequency surgical equipments for tonsillectomy)、内窥镜高频手术器(endoscopic high frequency electro surgical unit)、后尿道电切开刀(posterior urethra electric resector)、高频眼科电凝器(high frequency ophthalmological electric coagulation apparatus)、高频息肉手术器(HF polypus surgical unit)、高频鼻甲电凝器(HF nosepiece electric coagulation unit)、射频控温电凝器(radio frequency temperature-controlled electric coagulation apparatus)	III
			高频腋臭治疗仪(HF treatment apparatus for underarm odour)、高频痔疮治疗仪(HF treatment apparatus for hemorrhoids)、高频电灼器(HF electric cautery)	II
	2	高频电熨设备 high frequency electric ironing devices	高频妇科电熨器(high frequency electric ironing for Gynaecology)、高频五官科电熨器(high frequency electric ironing for Ophthalmology and Otorhinolaryngology)	II
	3	微波治疗设备 microwave therapeutical devices	微波手术刀(microwave surgery scalpel)、微波肿瘤热治疗仪(microwave tumor thermotherapy apparatus)、微波前列腺治疗仪(microwave prostate therapeutic equipment)、微波治疗机(microwave therapeutic equipment)	III
	4	射频治疗设备 radio frequency therapeutical equipments	射频前列腺治疗仪(radio frequency prostate therapeutic equipment)、射频消融心脏治疗仪(heart radiofrequency ablation treatment equipment)、射频消融前列腺治疗仪(prostate radiofrequency ablation treatment equipment)、内生物/场?肿瘤热疗系统(Endogenetic field tumor hyperthermia system)、肿瘤射频热疗机(radio-frequency tumor hyperthermia treatment equipment)	III
			短波治疗机(short wave treatment apparatus)、超短波治疗机(ultrashort wave treatment apparatus)	II
5	高频电极 high frequency electrodes	电凝钳(electric coagulation pincers)、电凝镊(electric coagulation forceps)、阴极板(negative plate)、手术电极(surgery electrode)	II	

Product Technical Specifications (1) / NEW

- According to the 2014 new regulations, the previously required YZB Product Standards are replaced by “**Product Technical Specifications**”
- Similar to the previous YZB Product Standards, the Product Technical Specifications are still the **most important** part of the registration process.
 - Since it is not reviewed by the CMDE before testing, Type Testing is done on the company’s own draft

Product Technical Specifications (2) / NEW

- Just like the previous requirements for YZB Product Standards, the Product Technical Specifications should do the following:
 - List all required performance specifications and safety specifications for the finished product.
 - List testing methods for each specification.
 - Type Testing is required for all specification items listed in this file with the method described in this file.
- Different from previous YZB Product Standards, CFDA simplified the requirements for this file. Evaluation research during the product design & development stage is no longer required, therefore, biocompatibility requirements do not need to be included as specification items.



Updates – New Standards Released

- The CFDA released 120 new medical device industry standards in June 2014:
 - All are recommended standards, not mandatory standards

- These 120 new standards will come into effect on July 1, 2015.

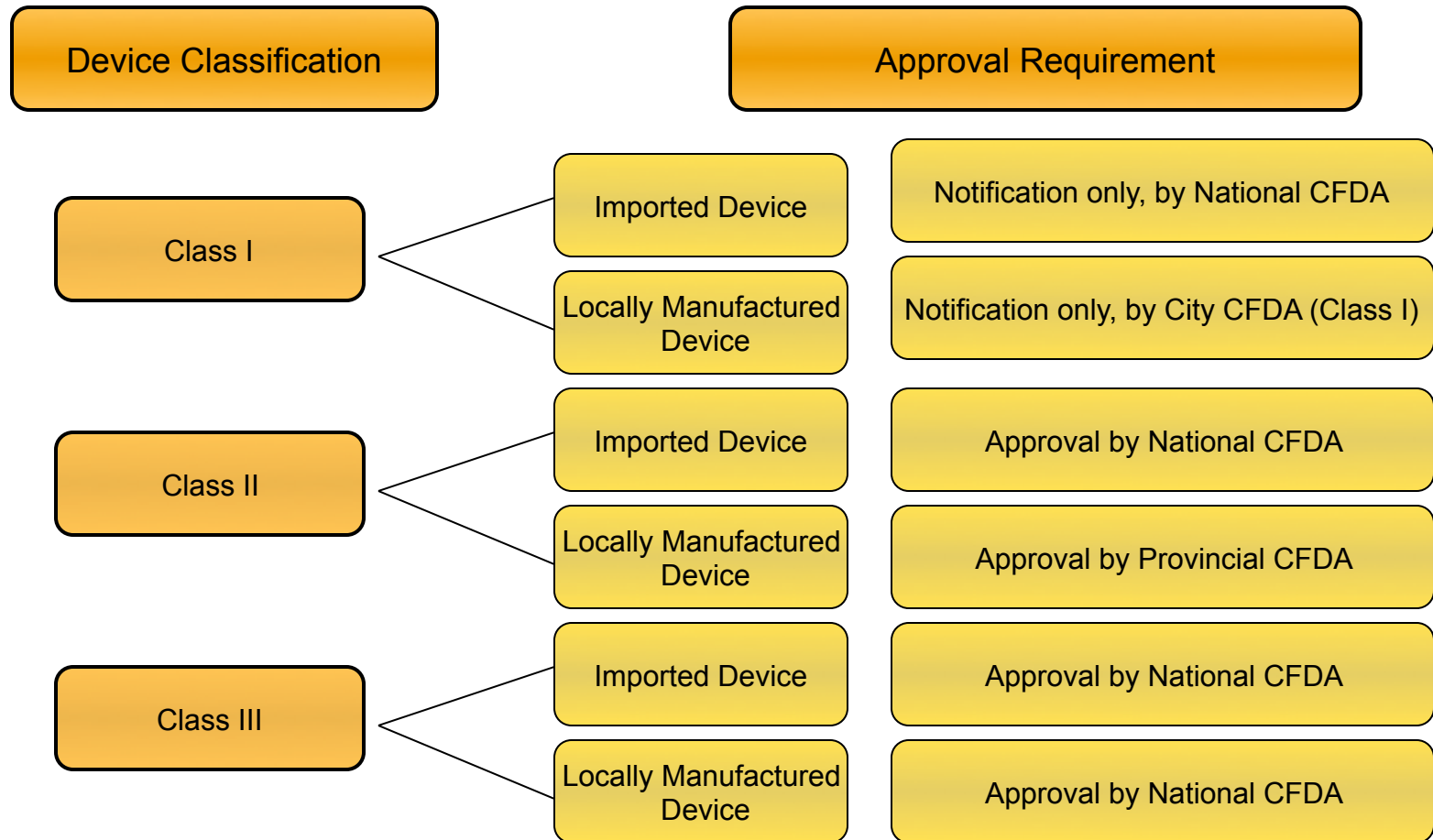
Type Testing

- Now, for Class 2 and Class 3 devices, CFDA will request samples for type testing. For Class 1 products, CFDA will accept a company's foreign report.
- Testing centers will test all specification items listed in the Product Technical Specifications (which is drafted by the company.)
- For each specification item, testing centers will utilize the testing method described in the Product Technical Specifications.
- While conducting the tests, CFDA now requests that testing centers provide comments on the company's drafted Product Technical Specifications.
 - The comments from the testing center should be submitted together with the testing report to avoid repeats and additional testing, which occurs frequently, leading to long delays in the registration process.

Testing Centers

- There are 10 national testing labs around the country that are CFDA certified:
 - National Testing Institute (Beijing)
 - Beijing Testing Institute
 - School of Dentistry, Beijing University (“Beida”)
 - Shanghai Testing Institute
 - Jinan Testing Institute
 - Shenyang Testing Institute
 - Tianjin Testing Institute
 - Wuhan Testing Institute
 - Hangzhou Testing Institute
 - Guangzhou Testing Institute
- There are also over 40 affiliated testing institutes
- Biocompatibility is no longer required in the Product Technical Specifications.

Product Approval by Classification



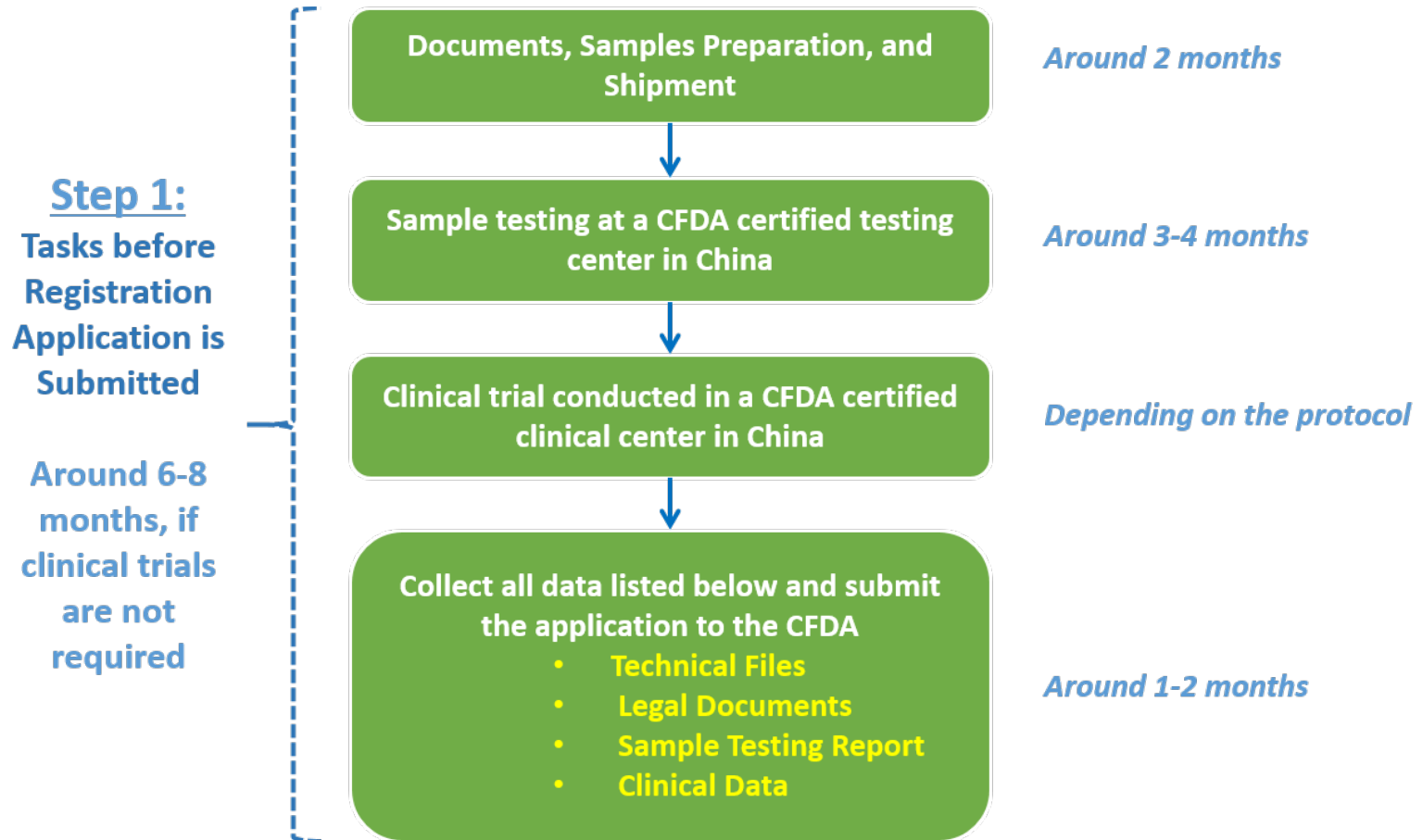
Product Registration for Class I Devices – Revised in 2014 / NEW

- Class I devices will no longer require registration, only filing a notification application with the CFDA.
- Compared to Class 2 and 3 dossier, the CFDA reviews more strictly on the format of Class 1 filing documents and the constancy of the legal documents.

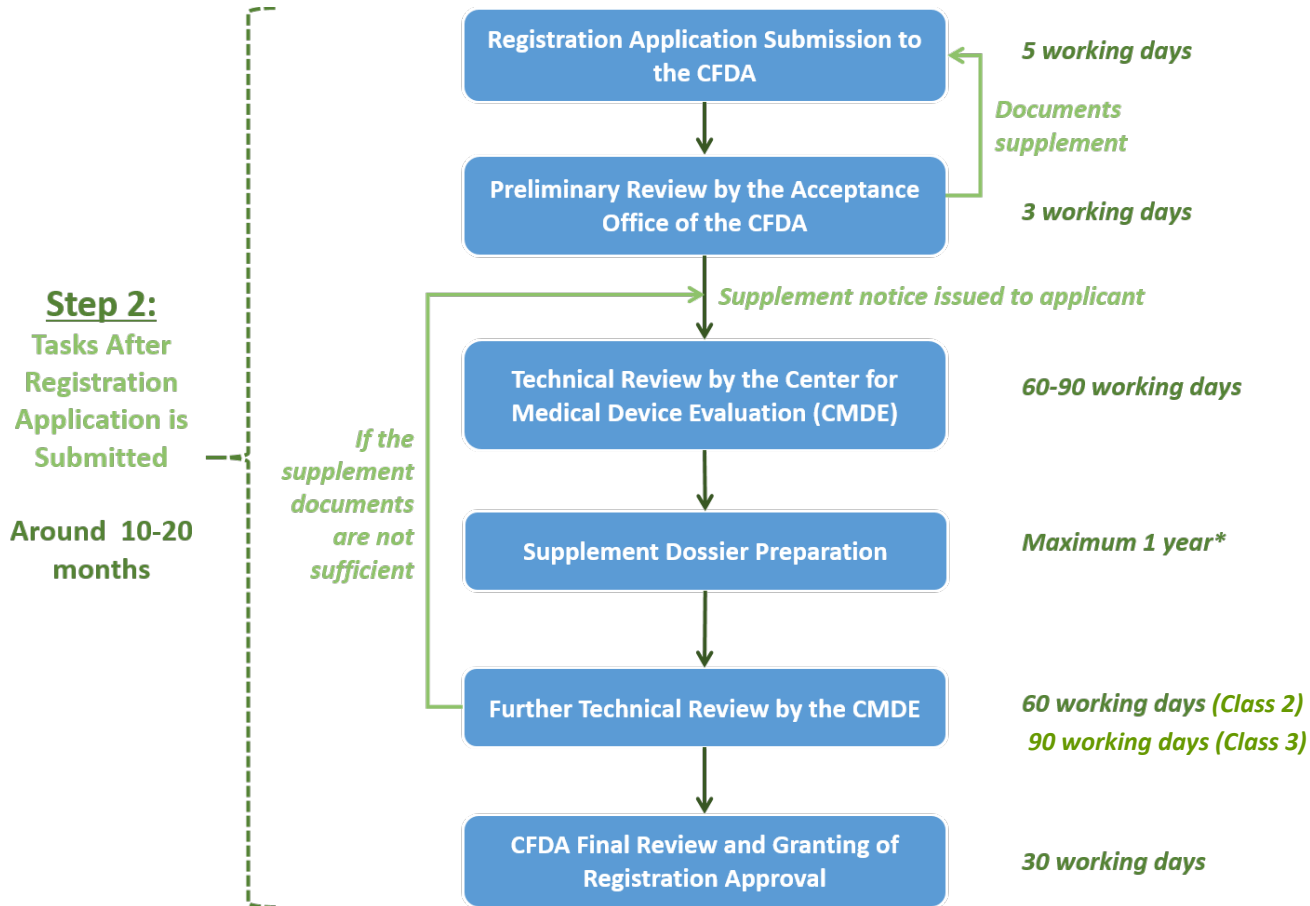
Product Registration for Class I Devices (Document Requirements) / NEW

- Please note that for all documents sent to the CFDA, the applicant should provide the Chinese translation as well. For the legal documents listed below, the applicant should submit the original or a notified copy.
- 1) Product risk analysis document
- 2) Product Technical Specification
- 3) Product Testing Report (company's self-testing report or 3rd party report)
- 4) Clinical Evaluation Report
- 5) Key Manufacturing Information (process, flowchart, material, etc.)
- 6) Design/artwork of IFU and product label for the minimum selling unit
- 7) Legal Documents
 - Legal qualification of the foreign manufacturer (i.e. ISO 13485)
 - Market authorization approval at the country of origin (i.e. CFG+510k or CE)
 - Authorization letter to the agent in China.
- 8) Self-declaration letters
 - Letter to declare that the documents submitted meets CFDA's regulation for Class I Medical device notification
 - Letter to declare that the product conform to the Class I Medical Device classification catalog
 - Letter to declare the product conforms to the National and/or Industry standards (GB/YY) in China, and provide the list of these conformed standards.
 - Letter to declare that all submitted documents are true

Registration Timeframe for Imported Class II and III Devices



Registration Timeframe for Imported Class II and III Devices



Registration Requirements for Dossier

- A total of 12 document items must be collected and submitted to the CFDA
- Three parts to these 12 items:
 - Legal Documents (9)
 - Technical Documents (2)
 - Testing report issued by CFDA certified testing center

Product Registration for Imported Class II Medical Devices (Document Requirements)

申报资料一级标题 Dossier item	申报资料二级标题 Dossier sub-item
1. 申请表 (Application Form)	
2. 证明性文件 (Legal Documents)	
3. 医疗器械安全有效基本要求清单 (Main Safety and Efficacy Specifications list)	
4. 综述资料 (Summary Data)	4.1 概述 (Overview) 4.2 产品描述 (Product Description) 4.3 型号规格 (Product Model) 4.4 包装说明 (Description of the Package) 4.5 适用范围和禁忌症 (Intended Use and Contraindications) 4.6 参考的同类产品或前代产品的情况 (如有) (Predicated device, if have) 4.7 其他需说明的内容 (Other information need to be described)
5. 研究资料 (Research Data)	5.1 产品性能研究 (Product Performance Evaluation data) 5.2 生物相容性评价研究 (Biocompatibility Evaluation data) 5.3 生物安全性研究 (Biosafety Research Data) 5.4 灭菌和消毒工艺研究 (Sterilization and disinfection process validation data) 5.5 有效期和包装研究 (Self shelf and package evaluation data) 5.6 动物研究 (Animal Research data) 5.7 软件研究 (Software validation data) 5.8 其他 (Other data if necessary)

Product Registration for Imported Class II Medical Devices (Document Requirements)

申报资料一级标题 Dossier item	申报资料二级标题 Dossier sub-item
6. 生产制造信息 (Manufacturing information)	6.1 无源产品/有源产品生产过程信息描述 (Manufacturing process description for active/inactive device) 6.2 生产场地 (Manufacturing site description)
7. 临床评价资料 (Clinical Evaluation Data)	
8. 产品风险分析资料 (Product Risk Analysis Data)	
9. 产品技术要求 (Product Technical Specification)	
10. 产品注册检验报告 (Registration Testing Report)	10.1 注册检验报告 (Testing report issued by CFDA certified lab) 10.2 预评价意见 (The preliminary evaluation comment from the testing lab)
11. 说明书和标签样稿 (artwork for IFU and product label)	11.1 说明书 (IFU) 11.2 最小销售单元的标签样稿 (the artwork of the product label for the minimum selling unit)
12. 符合性声明 (Self-declaration documents)	

Supplementary Review Process / NEW

- ❑ After technical review by the CFDA, they will likely request further information. A supplement notice will be issued after the initial technical review.
- ❑ Based on the supplementary notice, additional testing may also be required.
- ❑ As of 2014, the time granted to the company for supplementary documents preparation has been extended from 60 to 365 days.

Clinical Trials (more required) / NEW

- For Class II and III medical devices, more local clinical trials will be required for product approval
- There is a device list for exemption:
 1. Exemptions will apply if the manufacturing process is mature and the working mechanisms are clear
 2. The safety and efficacy can be proved by non-clinical evaluations
 3. The safety and efficacy can be approved via clinical trials or data from similar products
- Manufacturers that are applying for registration of one of these now-exempted medical devices would be able to submit a written application to the CFDA to receive an exemption from undertaking clinical trials in China

Class II and Class III devices exempt from local clinical trials / NEW

- CFDA Notice 2014 No.12, announced a batch of Class II devices in which clinical trials are exempt.
 - A total of 488 categories of Class II products are included
- CFDA Notice 2014 No.13, announced a batch of Class III devices in which clinical trials are exempt.
 - A total of 79 categories of Class III products are included

Clinical Trials in China / NEW

- Before conducting a Class II or III device clinical trial, the clinical trial protocol must be approved by the Ethical Committee of the clinical site.
- CFDA Notice 2014 No.14, announced a batch of Class III devices which requires CFDA approval of local clinical trials before kicking off the study.

GCP (Good Clinical Practice)

- All clinical trials for medical devices must follow China's Good Clinical Practices

- The CFDA published a *draft* revised *Regulation on Medical Device Clinical Trial Requirements*

- The revised Chinese GCP will be in accordance with international GCP standards
 - Strengthening management of technical aspects of clinical trials

 - Establishing quick and effective mechanism to coordinate trials with medical device registration

Labeling Requirements for Medical Devices / NEW

- ❑ Chinese *must* be used as part of the outside packaging and for the text of labels
- ❑ Below are some examples of information required by CFDA on a label. Other Chinese government agencies may require additional information.
 - ❑ Product Name, model ID or number
 - ❑ Manufacturer's name and contact information
 - ❑ Product Registration Serial No.
 - ❑ Product Standard Serial No.
 - ❑ Intended Use
 - ❑ Contraindication, precaution and warnings
 - ❑ Required marks, symbols
 - ❑ Installation and user instruction
 - ❑ Maintenance, cleaning and storage conditions
 - ❑ Shelf life (if applicable)

Labeling Regulations for Imported Medical Devices in 2014 / NEW

- ❑ Current labeling and IFU can be used until the registration certificate is no longer valid
- ❑ The above will apply if the registration dossier was submitted or product approval was granted prior to October 1, 2014
- ❑ For dossiers submitted after October 1, 2014, the labels need to include the date of manufacture and expiration or the related shelf life

Device Re-Registration Requirements / NEW

- Product registration is now valid for 5 years, not 4 years
- Renewal application must be submitted 6 months before import license expires.
 - If the product remains unchanged, CFDA should grant renewal approval before the expiry date.
 - However, if the product has changed since its initial registration or last registration amendment, the company should prepare additional technical files according to the requirements under relevant registration amendment categories.

Update – Registration Amendment Requirements / NEW

- According to CFDA Decree No.4, from Oct. 1, 2014, if any change has occurred after registration approval, a Registration Amendment application is required. If the amendment is approved, the license expiry date of the initial product registration remains the same.
- If changes are categorized as a “Notification Amendment,” the CFDA will conduct a quick review and issue amendment approval documents within 10 business days.
- If changes are categorized as a “Permission Amendment,” the CFDA will conduct technical review regarding the changed technical files. The review timeline is the same as a new registration.



Country of Origin

- If a product is made in the U.S. but does not have FDA approval, it cannot be registered in China
- Many U.S. companies get a CE mark and do some manufacturing in Europe; product approved in country of origin



Updates – Issues with Raw Materials

- Over the past year, the CFDA has been asking for more information regarding the raw materials used in medical devices
- Working with your supplier is crucial for registering your product in China successfully

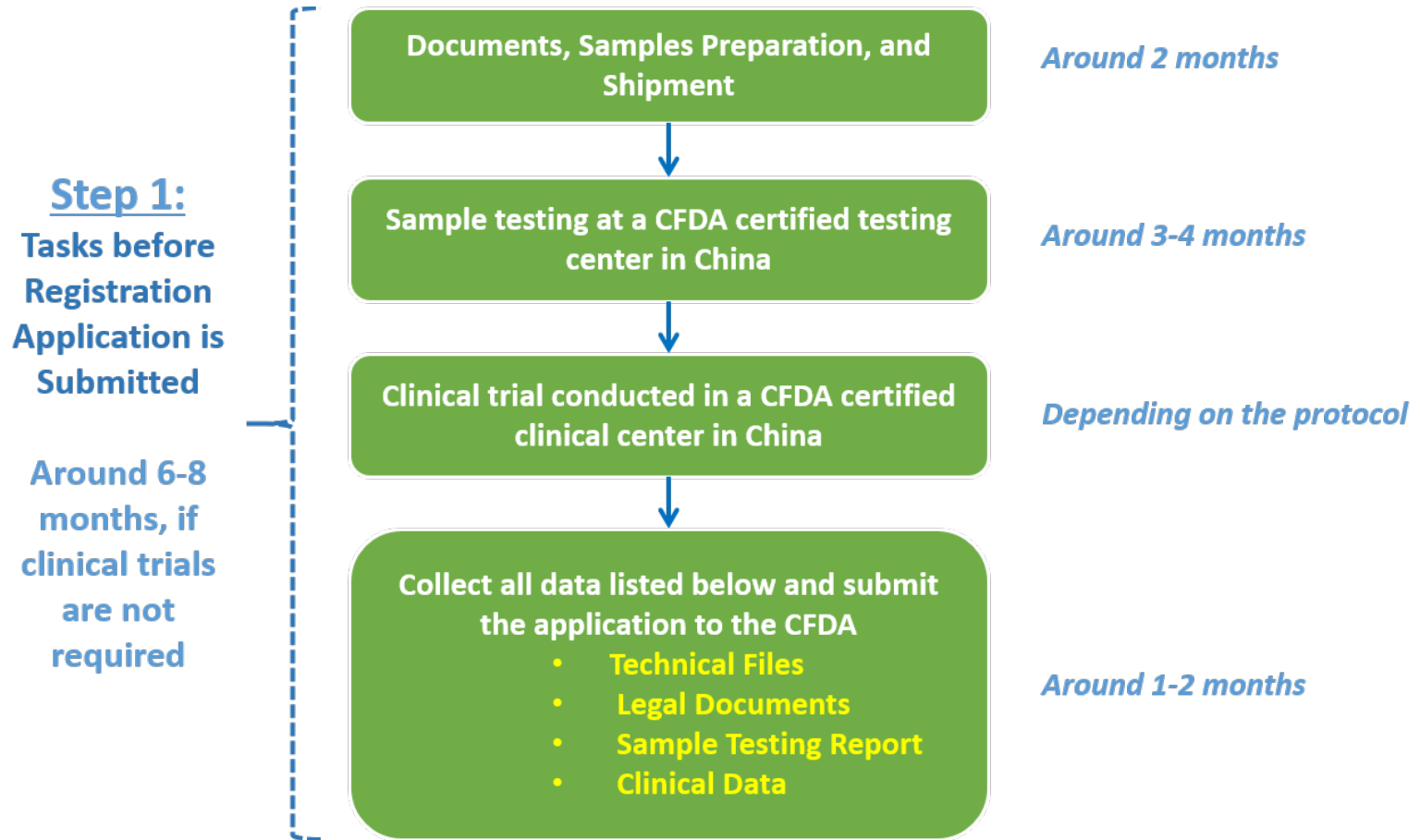
IVD Product Registration / NEW

- The majority of IVD products are regulated as Medical Devices in China as an independent sub-category. Only a few IVDs are regulated as a drug.
- For IVD products under the medical device category, they must also conform to the new State Council Order No.650, which became effective on Oct. 1, 2014.
- All previous 2007 versions of IVD product registration regulations are now replaced with new versions.

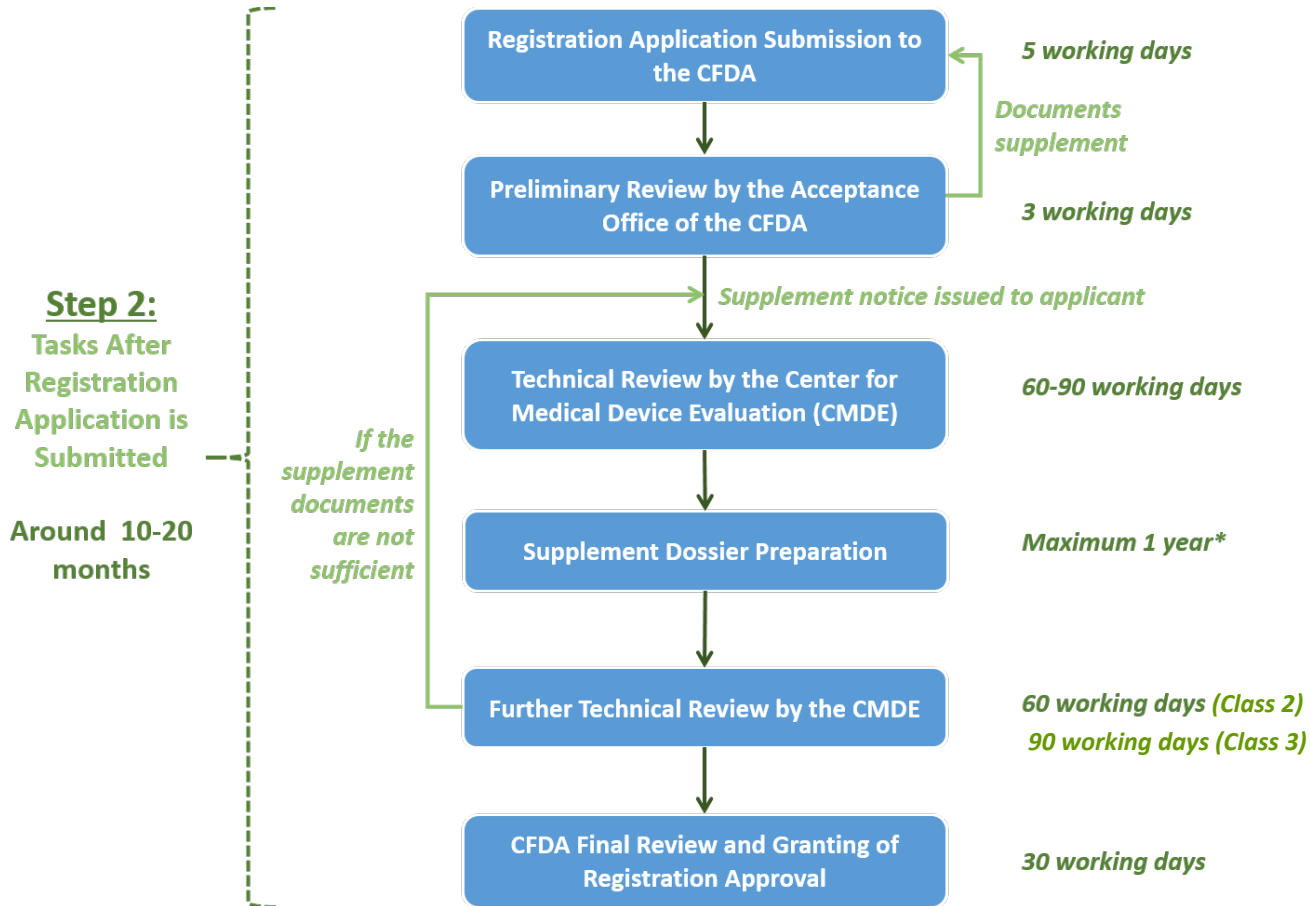
IVD Product Registration

- IVD registration process and review timeline follows the same requirements as Medical Device products:
 - Class I IVDs no longer require registration, just filing a notification application with the CFDA. The filing process and requirements are exactly the same as a Class 1 Medical Device.
 - Class II and III IVD registration processes follow the same processes as Class II and III Medical Devices.

Registration Timeframe for Imported Class II and III IVDs



Registration Timeframe for Imported Class II and III IVDs



IVD Product Registration Process:

Sample Testing / NEW

- Now, Type Testing requirements for import IVDs also follow the same requirements as Medical Devices:
- Also similar to Medical Devices, CFDA testing centers will follow the specifications and testing methods set in the Product Technical Specification File which is drafted by the foreign company.
- Just like Medical Devices, only performance and safety specifications on the finished product are requested to be included in the Product Technical Specification.

IVD Product Registration: Clinical Trials for Class III IVDs / NEW

- ❑ Foreign data and samples not accepted
- ❑ Minimum sample size: 1000 samples
- ❑ Samples may be collected from healthy volunteers or patients
- ❑ Comparison study required

IVD Clinical Trials / NEW

- For Class II and III IVDs, local clinical trials will normally be required for product approval.
- Clinical trial exemptions will apply if:
 1. The manufacturing process is mature and the working mechanisms are clear;
 2. The safety and efficacy can be proved by non-clinical evaluations;
 3. The safety and efficacy can be approved via clinical trials or data from similar products
- According to the new IVD clinical trial regulation (CFDA Decree No. 16), the CFDA sets much clear requirements on protocol design, number of clinical sites, sample size, report format and statistical analysis.

Requirements for IVDs / NEW

- ❑ Time to register is longer
- ❑ Class I IVDs do not need to be registered, just filed
- ❑ License is good for 5 years instead of 4 years
- ❑ Risk analysis report and a Technical analysis of product performance are requested, while before they were exempt
- ❑ Supplementary time limit increased from 60 days to 365 days
- ❑ Fast track IVD approval is now possible
- ❑ Some local clinical trials are not needed if IVD is on exception list



Stem Cell Therapy Update

- It is not clear how stem cell therapy will be regulated, or whether it will be regulated by the CFDA or MOH.
- Some companies are trying to explore the market with leading doctors in China, but such activities are normally initiated by doctors as their own research program.

Update – GMP in China / NEW

- CFDA released new GMP regulations for medical devices in 2014:
 - Good Manufacturing Practice (GMP) for Medical Devices: announced on December 29, 2014 (CFDA 2014 Notice No.64), effective date: March 1, 2015.
 - Regulations on Medical Device Manufacturing: CFDA Decree No.7, effective date: Oct. 1, 2014.

GMP in China

- For **domestic** manufacturers, the CFDA issues GMP qualification certificates
- There are differences between international (U.S. FDA and ISO) and CFDA GMP, QC and QA standards
- The CFDA requires **foreign** manufacturers who export medical devices to China to conform to quality system standards

Adverse Event Reporting for Medical Devices

- ❑ The medical device AE monitoring network and reporting system began in 2010, but is often ignored
- ❑ CFDA Decree 425, issued in 2011, is the current medical device AE guidance
- ❑ All manufacturers, distributors, and medical institutions must establish internal supervision systems for medical device adverse event monitoring
- ❑ The following parties are responsible for filing a “**Report on Suspicious Medical Device Adverse Event**” for any adverse event, no matter its seriousness, with their local medical device monitoring institution and legal agent

Adverse Event Reporting for Medical Devices

- ❑ Serious AEs *outside* of China must be reported to the CFDA within 15 working days
- ❑ Additionally, manufacturers of Class II and III medical devices must file an “Annual Report on Medical Device Adverse Events” with their local monitoring institution each year by the end of January, summarizing and analyzing the AEs over the past year

Adverse Event Reporting for Devices – Update

- In July 2013, the CFDA released a guidance update entitled “Further improvement on construction of a medical device adverse event monitoring system (draft)”
- In October 2013, the CFDA released a guidance document that sets out a 2 year plan to increase local government capacity to report, evaluate, inform, and control adverse events
- The CFDA aims to have a functioning system in place by the end of 2014 followed by a 1-year trial period before the system’s official start in 2015

Recalls of Medical Devices

- CFDA Decree 82, effective July 1, 2011, has 38 articles regarding the Medical Device Recall Management Guidelines
- Liability and responsibility is shared by everyone, extending from the distributor to the manufacturer
- Three levels of recalls:
 - Class I: If the device has caused or could cause serious and permanent hazards to health
 - Class II: If the device could cause a temporary health issue
 - Class III: If the device is defective but is not likely to cause any harm
- How do you know if a recall is required?
 - The foreign manufacturer and the distributor must research and report to the CFDA before a potential recall



Device Reimbursement in China

- Medical devices can be reimbursed
 - They are commonly reimbursed as a part of a medical procedure
- Certain medical devices (such as stents, bone plates) are reimbursed separately on their own

Device Reimbursement in China

- ❑ Local hospitals submit coding and pricing at the provincial level
- ❑ May include procedure fees
- ❑ High prices where hospitals can make some profit is best
- ❑ Imported medical devices have very limited reimbursement via medical procedures and almost always require some self-pay

Updates – Unannounced CFDA Inspections / NEW

- The CFDA announced in June 2012 that all medical device manufacturing facilities are now subject to unannounced inspections
- According to the new regulation State Counsel Decree No.650 and CFDA Decree No.5 on MD registration, QMS inspection to foreign manufacturer may occur, if CFDA feels necessary.

Updates – High Value Device Purchasing

China's Ministry of Health (MOH) announced that centralized purchasing would take place for specific high value medical devices. Furthermore:

- The purchasing process will be organized and monitored by centralized purchasing agencies established by local governments
- All public hospitals are to follow the new procedure, submitting in advance their purchasing plan for high value medical devices

Updates – Advertisement Monitoring

The CFDA launched a national database in January 2013 for monitoring the *illegal advertising* of drugs, medical devices and health food products. Furthermore:

- Local CFDA offices must use the database to file quarterly reports
- Local CFDA offices are encouraged to *strictly* interpret the law if they encounter false advertising in the following categories: exaggerated product indications, fake seals of approval or misleading testimony from patients, doctors, medical professionals, officials or academics

Updates – Fast Track Approval / NEW

- On February 7, 2014, the CFDA released the “Procedure for Examination and Approval of Innovative Medical Devices (Trial),” which will go into effect starting March 1, 2014
- To qualify:
 - The company applying needs to be a legal entity in China
 - The device must be manufactured in China
 - The device must be the first of its kind functionally in China
 - The device must provide significant improvement in safety or efficacy
 - The device must have significant clinical application value
 - The intellectual property must be *owned in China* by the applicant

Updates – Fast Track Approval Application Process / **NEW**

- ❑ Domestic applicants submit the special application form and accompanying data to the Provincial FDA
- ❑ If the application has passed the preliminary examination, the Provincial FDA submits the application to the CFDA
- ❑ Overseas applicants should submit their application and data directly to the CFDA
- ❑ The CFDA's new Examination Office for Innovative Medical Devices will review the application and provide a review comment within 40 working days
- ❑ The testing lab will pre-assess the product standards and suggest modifications, followed by testing of the device
- ❑ Clinical trials will be the same

Fast Track Approval / NEW

- Key point: What's the definition of “innovative medical devices?”
- 1 of 3 qualifications must be met:
 1. Patent Qualification
 - Invention patents obtained in China
 - Applicant has acquired inventive patents as a transferee
 - The invention patent application has been applied for & made public by Chinese patent authorities
 2. Product Value
 - Key mechanism first created in China
 - Its technology is superior; international leader
 - Innovative activities were in or acquired in China

Fast Track Approval / NEW

3. Research Progress
 - The research process is **genuine**
 - The research data is complete & traceable
- Processing priority: Test quicker, prioritize technical reviews
- Better, faster communication: CFDA will have designated period for all issues
- Specified list of documents

Updates – Increased Penalties for Violations

- ❑ The National Health and Family Planning Commission announced in December 2013 that a national bribery blacklist will be published online starting in March 2014
- ❑ Healthcare institutes that accept public financial subsidies would be prohibited from buying medical devices, consumables, or drugs for 2 years from blacklisted companies in the region(s) in which the companies were implicated
- ❑ If these companies make bids on public tenders, public healthcare institutes must assign a lower grade to the bid
- ❑ If a firm is blacklisted twice, it will not be allowed to sell its products for 2+ years
- ❑ Punishment will also be given to medical practitioners who accept bribes

Update – Good Supply Practice (GSP) / NEW

- On July 30, 2014, the CFDA promulgated a Good Supply Practice (GSP) regulation for medical devices (CFDA Decree No.8), effective Oct.1, 2014:
 - Gives specific regulations for Class I, II, and III distributors
 - 66 articles in 9 chapters
 - Improves quality management system for device distribution
 - Equipment and facilities standards
 - Training and qualification of personnel

Updates – Expected CFDA Regulation Changes / NEW

- Following regulations, CFDA recently posted a new draft version on its website for public comments. These regulations may be updated in 2015 when public comment collection is complete.
 - Medical Device Clinical Study Evaluation Guideline, posted for comment in Aug. 2014.
 - Administration Regulation on Medical Device Standards, posted for comment in Oct. 2014.
 - Updated version on Medical Device Classification Criteria, posted for comment in Dec. 2014.

Contract Manufacturing

- A foreign device company contracts with a Chinese medical device manufacturer and your own company sells their products in China.
- Key information under this option:
 - The legal manufacturer will be the Chinese manufacturer
 - Your company's China office then acts as the distributor to sell the product in China

Contract Manufacturer as a Supplier

- The foreign device company has its own factory in China and would like to contract another Chinese manufacturer too.
- Foreign company can have registration in their name:
 - The foreign device company's facility in China must be China GMP

Transfer Manufacturing Site from One Location to Another in China (Capacity Issues)

- Class III device
- Initial registration may take 20 months plus 12 months: 32 months or more
- Set up exact same factory at a different site (must re-register) – another 20 months
 - Total now: 52 months
- Best to set up new site with capacity originally only 32 months
- Site can be idle waiting for product registration



Thank you for your consideration!

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