Guide to China Medical Device Market Entry
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1. Introduction

When comparing all of the medical device markets, the Chinese medical device market has the highest potential for growth. Because of this, more and more overseas medical device manufacturers and producers are focusing on China market penetration.

It is estimated that the Chinese medical device market will be more than 340 billion RMB (about 57 billion US dollars) by 2015 and will surpass Japan to become the second largest medical device market behind the United States. However, China’s thriving economy and rapid population growth over the past 30 years have led China’s new leaders have to recognize that regulations for supervision and administration of medical devices are far from.

China’s regulatory framework for medical devices is undergoing drastic changes. Chinese state council issued the latest “Regulations for the Supervision and Administration of Medical Devices”, and China Food and Drug Administration issued the latest “Measures for the Administration of Medical Device Registration”. The exportation of overseas medical devices into the Chinese market has been subject to administration of overall new regulations since October 1, 2014.

The Guide to China Medical Device Market Entry aims to not only provide comprehensive and thorough knowledge of the overall new requirements for medical device registration in China, but to also provide the guidance of practical operation for how to achieve a successful approval for your products entry into the Chinese medical device market.

2. Regulation Framework

China joined in international medical device regulators forum (IMDRF) in 2013. In order to standardize legislative activities, guarantee the quality of legislation, and improve legislation efficiency, China Food and Drug Administration (CFDA) formulated the “Administrative Rules of CFDA on Legislative Procedure”. This was issued as Order of CFDA No.1 on October 24, 2013, and took effect on December 1, 2013.¹ The rules stipulate the approval of project proposal, drafting, review, deliberation and publication, filing and interpretation, evaluation, sorting and compilation, examination and sorting of normative documents, etc.

Since then, CFDA has been actively promoting harmonization and streamlining of the regulatory framework. This has led to the revision of its top tier regulation, “Regulations for the Supervision and Administration of Medical Devices”, which came into force on June 1, 2014. Key changes include:

¹ Refer to the following link: http://eng.sfda.gov.cn/WS03/CL0768/98109.html
• New risk-based classification adopted from guidance from International Medical Device Regulators Forum (IMDRF), European Union, and other classification related international standards.

• Class I devices now adopt a filing approach for both Good Manufacturing Practice (GMP) requirements and product registration, removing the need for technical review.

• Class II and III device registration should be supported by clinical trial data unless they are in the List of Exempted Devices. Clinical trial protocol of high risk Class III devices are required to get approval by CFDA prior to execution—a specific category shall be stipulated, adjusted, and published by CFDA.

• An increase from four to five years for the amount of time certifications are valid.

• A requirement for more information for submissions, such as, product risk management, product research and development (R&D) information, production information, clinical literature, etc.

• Allowance for on-site Quality Management System (QMS) audits of device manufacturers outside of China.

• Prohibition on contract manufacturing of selected high-risk devices—a specific category shall be stipulated, adjusted and, published by CFDA.

• Emphasis on risk evaluation and regulatory control throughout the device’s life-cycle, strengthening post-market monitoring and reporting.

• Medical device application fees—previously imported devices applications were free-of-charge.

Consequently, all underlying supporting provisions and guidelines should be revised to uphold consistency with the Regulation and framework shown in Figure 1.
Figure 1. China Medical Device Regulation Framework

Please note the rapid revamping is still undergoing. When starting business in China, be sure to check the CFDA website for the latest requirements as well as the administrative rules interpretations.

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Domestic Products</th>
<th>Import Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class II</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New registration</td>
<td>TBD*</td>
<td>¥210,900</td>
</tr>
<tr>
<td>Change of registration</td>
<td>TBD</td>
<td>¥42,000</td>
</tr>
<tr>
<td>Renew registration (Every 5 Years)</td>
<td>TBD</td>
<td>¥40,800</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial approval for high-risk products</td>
<td>¥43,200</td>
<td>¥43,200</td>
</tr>
<tr>
<td>New registration</td>
<td>¥153,600</td>
<td>¥308,800</td>
</tr>
<tr>
<td>Change of registration</td>
<td>¥50,400</td>
<td>¥50,400</td>
</tr>
<tr>
<td>Renew registration (Every 5 Years)</td>
<td>¥40,800</td>
<td>¥40,800</td>
</tr>
</tbody>
</table>

*TBD for China domestic Products will be determined by provincial FDA.

Table 1. Registration Fee
3. Working with CFDA

CFDA’s headquarters is located in Beijing. It is responsible for processing all new device filings/approvals as well as any subsequent changes for imported medical devices and high-risk domestic devices. The provincial CFDA are responsible for class I and class II domestic devices and monitoring clinical trials and distributors.

CFDA authorizes the Centre for Medical Device Evaluation (CMDE) to conduct technical reviews. CMDE is currently being restructured to include six scientific and technical review divisions, each responsible for a specific range of medical devices (Figure 2).

Figure 2. Organization Chart of CMDE

With questions related to registration, manufacturers can consult CMDE and/or CFDA on Opening Day, or can contact the lead reviewer directly. Detailed information for timing, venue, and reviewer contacts is published on the CFDA/CMDE website. However, all technical questions should be directed to CMDE, whereas those that are regulatory in nature should be addressed by CFDA. Formal face-to-face meetings may be appointed through the China Centre for Food and Drug International Exchange (CCFDIE).

The overseas manufacturer is required to conduct relevant business through their representative office located within the territory of China or designate Chinese legal entity as its legal agent to demonstrate compliance with local regulation in all stages of supply—from obtaining product clearance prior to distribution to vigilance reporting once a product has been
released to the market, including providing ongoing technical support to products distributed in China and reporting all adverse events to CFDA. Formerly, this responsibility was shared with the after-sales agent.

The overseas manufacturers may appoint a registration agent to correspond with CFDA and CMDE on behalf of them on all matters relating to product applications. Such an agent must be well versed with Chinese medical device regulation, technical guidelines, and application procedures. Working with reputable partners who have an established working relationship with Chinese authorities is the best strategy in minimizing complications and facilitating a smooth regulatory process. The manufacturers will be shown as the registration applicant on the registration certificate and hold legal liability for products.

In addition to appointing Chinese agents mentioned above, manufacturers wishing to enter the Chinese market must also demonstrate their device can be legally supplied in its country of origin.

All technical data and regulatory documents provided in a language other than Chinese should be accompanied by a simplified Chinese translation. All translated documents should be accompanied by the original version.

4. Regulatory Pathway

4.1 Classification and Pre-Market Requirement

In China, medical devices (including IVDs) are classified into three categories according to their risk profile:

- Class I Medical Devices—those with lower risk for which safety and effectiveness can be ensured through routine administration.
- Class II Medical Devices—those with medium risk for which strict control is required to ensure their safety and effectiveness.
- Class III Medical Devices—those with higher risk which special measures shall be taken and strict control is required to ensure their safety and effectiveness.

According to the classification decision table found on the CFDA website, the risk profile of a device is dependent on its intended use, and evaluated by structure characteristic, form of operation, conditions for use, and contacting/non-contacting.\(^2\) Specific conditions to consider are illustrated in the CFDA Classification Principles, such as combination with drug and absorbable devices.

\(^2\) Refer to the following link: http://www.sda.gov.cn/WS01/CL0053/124222.html.
The following CFDA device classification documents reflect the most current thinking on risk level associated with a particular device:

- Medical Device Classification Principles Associated with the Classification Decision Table,
- Catalogue for IVD Devices,\(^3\) and
- Catalogues for Medical Device Classification.\(^4\)

For medical devices newly invented and not yet listed in the classification catalogue, the applicant can directly apply for Class III medical device registration, or estimate the device classification according to the classification principles and apply for confirmation to CFDA.

The risk classification ultimately decides the applicable regulatory assessment pathway and quality system requirements (Figure 3). Generally speaking, Class II and Class III device registration must be supported by in-China type testing and clinical data (where applicable), and undergo technical review by CMDE. In the revised Regulation, imported Class I devices only require filing appropriate documentation with CFDA.

<table>
<thead>
<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Filing with CFDA</td>
<td>• Type testing</td>
<td>• Type testing</td>
</tr>
<tr>
<td></td>
<td>• Technical review</td>
<td>• Technical review</td>
</tr>
<tr>
<td></td>
<td>• Clinical Trial Data* (unless exempted)</td>
<td>• Clinical Trial Data* (unless exempted)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Clinical Trial Approval (selected high-risk device)</td>
</tr>
</tbody>
</table>

*The clinical trial data may be attained by the trial conducted out of the territory of China, but needs to meet CFDA Regulation and additionally analyze ethnic difference.

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3 Refer to the following link: http://www.sda.gov.cn/WS01/CL0845/94641.html.
4 Refer to the following link: http://www.sda.gov.cn/gyx02302/flml.htm which is to be updated and published in the form of a CFDA announcement.
4.2 Filling for Class I Devices

Only medical devices within the scope of the description and intended use given for a particular product category named in the “Catalogue of Class I Medical Devices” would be considered Class I by CFDA. Since June 2014, the Class I devices were exempted from technical review. The manufacturer may file the regulatory dossier with CFDA, and once accepted, would get the filings certificate.

The specifications for a Class I filing dossier are defined in the CFDA Announcement No. 2014-26: “CFDA notice on the Matters related to Filing of Class I Medical Devices”. These requirements that were finalized in May 2014 delineate that the filing content must include:

- Form for Class I medical device filing;
- Risk analysis report;
- Product technical requirements;
- Product self-testing report (in accordance with the above specifications);
- Clinical evaluation report;
- Instruction for Use (IFU) and labels (Imported devices should submit original and translated IFU & labels for its country of origin);
- Manufacturing process and manufacturing site(s);
- Business registration license at Country of Origin (COO), supporting documents of marketing authorization at COO, and Free Sales Certificates from country of origin;
- Business registration certificate from the Chinese representative; and
- Declaration of conformities (to Chinese regulation and standards).

Once CFDA verifies the format and completeness of the regulatory dossier, the Class I Medical Device Filing Certificate will be issued with an official filing number. This should be captured on the Chinese labels and IFUs. No renewal is required for Class I filing. In case any filing item that is reflected in the filing content is changed, the applicant should apply for amendment filing with the original filing regulatory authority.

4.3 Registration for Class II & III Devices

In addition to the documents requested for Class I device filing, Class II and III devices also need to provide information\(^5\) to support their safety and effectiveness, including:

- Chinese Essential Requirements Checklist (not required for IVD reagents)
- Product overview
  - Product description
  - Model and specification

\(^5\) Refer to the following link: [http://www.sda.gov.cn/WS01/CL0087/106095.html](http://www.sda.gov.cn/WS01/CL0087/106095.html).
✓ Packing instructions
✓ Applicable scope and contraindications
✓ Referenced clinical data of products of same kind or its predecessors (if any)
✓ Other contents to be specified

- Research documentation
  ✓ Product performance study
  ✓ Evaluation study on biocompatibility
  ✓ Biological safety study
  ✓ Sterilization/disinfection process study
  ✓ Study on shelf life and packaging
  ✓ Animal study
  ✓ Software study
  ✓ Other contents to be specified

- Type testing report (by authorized Chinese testing centers), and
- Justification for exemption from clinical trials or (if required) in-China clinical trials.

The application dossiers for Class II and III devices are subjected to full technical review by CMDE. During the technical review, supplemental questions may be asked or a request to retrieve more documentation may occur. The manufacture of samples for registration testing and clinical trials must comply with related requirements of quality management system.\(^6\) CFDA may organize inspection for quality management system regarding to product R&D and manufacturing during the technical evaluation.

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\(^6\) China GMP, refer to the following link: http://www.sda.gov.cn/WS01/CL0087/111642.html.

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Figure 4. Registration Process for Class II & III
4.4 Type Testing by Authorized Chinese Testing Centers

As part of the registration process, device manufacturers are required to write standards specific to your products. This is called Product Technical Requirement (PTR). The CFDA authorized testing centers are responsible for verifying the completeness and accuracy of PTR by conducting type testing. The PTR must comply with both the applicable Chinese national (GB; e.g. GB9706.1 idt IEC 60601-1) and industrial standards (YY). In many cases, they are also designated as recommended standards (GB/T or YYT). The testing center assesses PTR to ensure compliance with those applicable Chinese national and industrial standards.

There are 10 major CFDA-accredited testing centers (See Table 2) and 44 affiliated testing institutes (primarily at universities) CFDA uses to subcontract testing work to. Using good dialogue with these testing centers is crucial.

<table>
<thead>
<tr>
<th>TEST CENTERS</th>
<th>MAIN TESTING CAPABILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Medical Quality Surveillance and Test Institute</td>
<td>Biosocial Materials, artificial organs, tissue engineering</td>
</tr>
<tr>
<td>2. Beijing Medical Quality Surveillance and Test Institute</td>
<td>IVD, radiotherapy equipment</td>
</tr>
<tr>
<td>3. Dental Materials Quality Surveillance and Test Institute in Peking University</td>
<td>Dental material</td>
</tr>
<tr>
<td>4. Shanghai Medical Quality Surveillance and Test Institute</td>
<td>Anesthesia and respiratory equipment, surgical instrument, etc.</td>
</tr>
<tr>
<td>5. Jinan Medical Quality Surveillance and Test Institute</td>
<td>Medical polymer materials, sanitary materials</td>
</tr>
<tr>
<td>6. Shenyang Medical Quality Surveillance and Test Institute</td>
<td>X-ray diagnostic equipment</td>
</tr>
<tr>
<td>7. Tianjin Medical Quality Surveillance and Test Institute</td>
<td>Orthopedic material and equipment, medical equipment of physical therapy</td>
</tr>
<tr>
<td>8. Wuhan Medical Quality Surveillance and Test Institute</td>
<td>Ultrasonic diagnostic equipment</td>
</tr>
<tr>
<td>9. Hangzhou Medical Quality Surveillance and Test Institute</td>
<td>Optical equipment, medical laser equipment, medical equipment of deep hypothermia therapy</td>
</tr>
<tr>
<td>10. Guangzhou Medical Quality Surveillance and Test Institute</td>
<td>Dental equipment, disinfection equipment, etc.</td>
</tr>
</tbody>
</table>

Table 2. 10 Main Testing Centers for Medical Devices in China

The typical type testing process entails three key steps.
• Medical device and PTR are submitted for review.
• Once the PTR is accepted, the testing center will request samples. It is important to note that in the case there is a request for too many samples, it is usually acceptable to push back. Likewise, “over-testing”—applying standards that are too stringent for the product—may also occur, and it is best to consult an expert about the best path to take since you may need to balance time and cost for repeat testing versus time to market.
• Testing is completed and a final test report is issued with a “Pass” or “Fail”.

The sample(s) selected by the manufacturer for type testing should represent the device or entire range of devices pending registration. For Class III IVD reagents, CFDA Order No. 5: “Provision for In Vitro Diagnostic Reagents Registration” further demands that samples must be drawn from three consecutive batches.

Passing such testing could be technically challenging in certain areas where the applicable Chinese standards are different from their international counterparts—typically caused by a lag in adopting the most recent versions of the international standards. For example, most of the global markets have adopted the third edition of the electrical safety standards, IEC 60601-1:2005; China currently recognizes the second edition only. This is demonstrated in the Chinese electrical safety standards GB 9706.1-2007 which is identical to IEC 60601-1:1998. Consequently, considering the applicable standards early in the design would be highly valuable.

Another challenge faced in China pertains to whether or not certain tests need to be repeated on the finished product. Manufacturers are not always able to leverage raw material testing to mitigate testing conducted on the finished product; however, it can be possible if raw material testing was completed overseas in a globally recognized laboratory. In the US, raw materials can be submitted to FDA in a Master Access File (MAF) format. The MAF can be utilized by other medical device manufacturers that use the same raw material in their device to help diminish the amount of repeat testing needed for the finished product. This process currently does not exist in China. As a result, any raw material testing that a manufacturer wants to leverage should be presented to the testing lab to determine if it is appropriate or if additional testing will be required locally.

4.5 Clinical Trial Requirements

Previously, imported medical devices have been able to leverage the Clinical Evaluation Report (CER) used for market approval in its market of origin. As of October 2014, Class II and III medical device applications require in-China clinical trials for registrations unless listed in either the List of Class II Medical Devices Exempted from Clinical Trials or the List of Class III Medical Devices Exempted from Clinical Trials. These lists will be constantly updated and published in the form of a CFDA announcement. The most current list of Class III medical devices requiring
clinical trial was issued in August 2015. Presently, there is no list for Class II medical devices requiring clinical trial.

Alternatively, clinical trial exemption may also be granted if one of the following criteria is satisfied:

- The operating principle is well-defined, has an established design and mature manufacturing process, and there is no record of serious adverse events (SAEs) of substantially equivalent medical devices which have been marketed and in clinical use for years without changing the conventional purpose of use.
- The safety and efficacy can be proven through non-clinical assessment.
- The safety and efficacy can be demonstrated through analyzing and evaluating data obtained from clinical trials or clinical application.

In practice, such exemption would be based on substantial equivalence to a device available in China—typically from the same manufacturer.

For most Class II and III IVD reagents, in-China clinical trials are always required.

For medical devices that require in-China clinical data, the key points for Chinese clinical trials are as follows:

- The trials should be conducted at qualified clinical institutes. Data for Class II medical devices and IVD reagents must be generated from at least two qualified clinical institutes.
- All clinical trials must have ethics committee approval and a satisfactory type testing report for commencement. Selected Class III high risk implantable/absorbable devices in CFDA’s predetermined list must have their clinical trial plan pre-approved by CFDA prior to commencing trials in China.
- Chinese Good Clinical Practice (GCP) guidelines have been established for medical devices and IVD reagents respectively and should be followed accordingly.
- It is mandatory to notify the local (e.g. Provincial) FDA office of clinical trials underway in their jurisdiction—local FDA officers may audit the clinical sites.
- All adverse events should be monitored and reported (see below).

For imported IVD devices not exempted from clinical trial requirements, the manufacturer should supply the CER as well as the clinical report generated from targeted clinical trials conducted in China.

For imported devices exempted from clinical trials, the manufacturer should submit a rationale for exemption, as well as the CER used in its country of origin and the Chinese CER based on

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7 Refer to the following link: http://www.sda.gov.cn/WS01/CL0087/105374.html.
8 Qualified clinical institutes can be found in the CFDA database at: http://app1.sfda.gov.cn/datasearch(face3/dir.html).
CFDA notification 2015-14 “Guidance on Clinical Evaluation of Medical Devices”, issued on May, 2015, for Chinese registration.9

The following should be submitted for the clinical evaluation of products listed in "The Catalogue of Medical Devices Exempted from Clinical Trial":

- Comparative information about the products under application and the contents in the Catalogue.
- A description of comparison of the products under application and medical devices in the Catalogue having been approved for registration within the territory of China. The description must include a comparative table of the product under application and medical devices in the catalogue having been approved for registration within the territory of China and corresponding supportive information.

For the alternative way to obtain exemption from clinical trials, the manufacturer should submit the Analysis and Evaluation through data obtained in clinical trials or clinical use of medical devices of the same kind. The evaluation approach is shown in Figure 5. The analysis and evaluation should include:

- The product under application is the same as medical devices of the same kind. Describe the similarities.
- Supportive information proving the differences between the product under application and medical devices of the same kind have no impact on the safety and efficacy of the product under application (nonclinical studies, clinical literature data, clinical experience data, etc.).

To support the substantial equivalence, the information about collection and analysis of clinical literature and data of the product under application should include:

- Data sets of clinical studies,
- Data sets of complaints and adverse events,
- Data sets of corrective measures associated with clinical risk,
- Data sets of Chinese population, and
- Comprehensive evaluation and conclusion of multiple data sets.

A clinical trial protocol and a clinical trial report on differences conducted within the territory of China are required as well.

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9 Refer to the following link: http://www.sda.gov.cn/WS01/CL0087/119643.html.
Figure 5. Evaluation Approach

- **Medical device**

  - **Is there any difference from medical devices of the same kind?**
    - **No**
      - Collect and analyze clinical literature and/or clinical experience data of medical devices of the same kind
    - **Yes**
      - Can it be proved that the differences between the product under application and products of the same kind impact the safety and efficacy of the product under application through nonclinical study data, clinical literature data, clinical experience data and clinical trials on differences conducted within the territory of China?
        - **No**
          - Analysis and evaluation cannot be conducted through data obtained in clinical trials or clinical use of medical devices of the same kind. The registration applicant shall submit related clinical trial information as required.
        - **Yes**
          - Prepare the clinical evaluation report and complete clinical evaluation
4.6 Chinese Labelling

CFDA issued Order No. 6 “Provisions on the Management of Instructions and Labels of Medical Devices” on July 30, 2014. The IFU and labelling for medical devices and the amendments to them should be consistent with the package submitted to CFDA for registration (class II and III device) and filing (class I device). When the applicant submits a product registration or filing application to CFDA, they also need to lodge a usage instruction and labelling (in simplified Chinese) for review and approval (class II and III device).

Medical device instructions should generally include the following:

- Name, model, and specification of product.
- Name, address, contact, and after-sales service unit of registrant or filer; the name, address, and contact of agent should also be indicated for imported medical devices.
- Name, address, production address, contact, and production certificate number or production filing certificate number of manufacturing enterprise; the name, address, production address, production certificate number or production filing certificate number of entrusted enterprise should also be indicated for subcontract production.
- Medical device registration certificate number or filing certificate number.
- Number of technical specification of product.
- Product performance, main structure and composition or ingredient, and scope of application.
- Contraindication, precaution, warning, and prompting contents.
- Instruction or graphic representation for installation and use; special instruction for safety use should be provided for the medical device used by the individual consumer.
- Product repair and maintenance method, special storage, and transportation conditions and methods.
- Production date and either service life or expiration date.
- List of parts, including explanation of the replacement cycle and replacement method of spare parts, accessories, and consumables.
- Interpretation of contents—such as the graphics, symbols, abbreviations, etc.—used by medical device label.
- Compilation or revision date of instructions.
- Other contents to be indicated.

The medical device label should generally include:

- Name, model, and specification of product.
- Name, address, and contact of registrant or filer; the name, address, and contact of agent should also be indicated for imported medical devices.
- Medical device registration certificate number or filing certificate number.
• Name, address, production address, contact, and production certificate number or production filing certificate number of manufacturing enterprise; the name, address, production address, production certificate number or production filing certificate number of entrusted enterprise should also be indicated for subcontract production.
• Production date and either service life or expiry date.
• Connection conditions and input power of power supply;
• Graphics, symbols, and other relevant contents to be indicated according to characteristics of product.
• Necessary warnings and precautions.
• Special storage and operating conditions or explanations.
• Warning marks or Chinese warning indications if the medical device has destructive or negative effects on environment in use or is radioactive.

4.7 Timeframe for CMDE Review

The review timeline discussed below is applicable for initial device registration as well as significant changes to Class II and Class III.

The official review timeline from submission to obtaining the registration certificate is approximately four to five months for Class II and six months for Class III. This timeframe does not include any time taken by the applicant to respond to review questions. It also does not consider the optional QMS audit or consultation with the Medical Device Expert Committee—typically only required for technically challenging products.

Starting in late 2013, CFDA implemented a streamlined review process, which limits the number of question-and-answer cycles. Only one set of formal review questions would be issued by the CMDE reviewer in writing. The manufacturer should submit a full response within the allocated timeframe, or request an extension—up to one year is allowed. Based on the adequacy of the response, the reviewer could either make a decision or request simple clarification.

5. Innovative Device Pathway

In order to increase the availability of premium technology in the Chinese market, CFDA published the “Special Review and Approval Procedure for Innovative Medical Devices”, which came into effect in March 2014. This fast-tracked regulatory process is available to innovative products meeting all three of the following eligibility criteria:

• Chinese patent – the applicant must hold a Chinese (invention) patent for innovative technology, or be licensed to use such a patent in China. Alternatively, the applicant could have a patent application under review with preliminary approval from the China Patent Regulatory Authority.
• Innovative product – the product must be the first-of-its-kind in China, and technically advanced in the global market; it should fundamentally improve product functionality and/or safety when compared to predicate devices, and have significant clinical value.
• R&D progress and records – the applicant should have a prototype developed under a controlled process with a fully traceable R&D dossier.

This fast-track approval process means the registration application has priority over other device applications, and the applicant is granted permission to communicate or consult with CFDA to obtain guidance prior to submission and during the scientific review/approval process.

Typically, preliminary patent reviews are granted 18 months from submission lodgment, whereas full approval takes approximately three years. To help reduce timelines, the fast-track pathway is encouraged for multinational manufacturers; however, to succeed in this pathway, manufacturers should consider Chinese patents more strenuously. As China is a member of the Paris Convention, international applicants can take advantage of the priority right—e.g., the first filing date can be leveraged from the first internal filing date if the Chinese patent application is submitted within 12 months.

Despite the initial time and resources invested into patent applications, this direct line of communication to CFDA throughout the application preparation and review process could save much frustration in the ‘race’ to commercialization. In a country where relationship building is crucial to a company’s credibility and commercial success, the chance to engage the regulator early in the design and innovation process would be highly valuable.

6. Post-Market Compliance

6.1 Extension and Change

CFDA and its local branches monitor post-market compliance by:
• Sampling devices in the market place for labelling and technical conformance;
• Certifying and auditing medical device enterprises (e.g. distributors) and traceability of devices supplied;
• Surveying medical device users (e.g. hospitals and clinics);
• Coordinating review for particular groups of devices—especially after SAE reports for this kind of devices; and
• Re-evaluating product clinical experiences, and adjusting risk classification accordingly.

To conform to the most current Chinese regulation, manufacturers should maintain post-market vigilance and well-defined procedures to receive feedback from and direct ongoing regulatory actions to its partners in China.

For Class I medical devices, and IVDs, manufacturers should monitor any CFDA classification update that may affect its products.
The in-China sponsor or domestic manufacturer is responsible for the post-market surveillance report, which should include reporting and investigating adverse events in China. For high-risk Class II and III devices, a summary adverse events report is mandatory for certificate extension.

For Class II and III medical devices, Medical Device Registration Certificates are valid for five years, and need to be extended six months prior to their expiry. If there are changes or amendments made to the marketing authorization/license after it is issued, the sponsor needs to file these changes to CFDA or its subsidiaries and get approval. Different types of changes have different filing requests by CFDA.

Any changes to the product or administrative details must first be approved in its market of origin before they can be approved in China. Technical changes are assessed for their associated risks and mitigation. Significant product or production changes may require type testing and/or a clinical trial to be conducted. On the other hand, change to administrative details (e.g., a new authorized in-China representative) does not need to be supported by technical documentation.

Changes to the following items are considered significant and must be reviewed and approved by CFDA, or provincial FDA for domestic registrations, as changes to approved items:

- Product name,
- Model number,
- Specifications,
- Structure and components,
- Indications,
- Technical requirements, and
- Manufacturing site changes.

Changes to the name and address of the applicant (i.e., manufacturer) and the sponsor are administrative in nature and can be filed with CFDA, or provincial FDA for domestic registrations, as changes to registered items.

Significant changes requiring technical review typically take 6-15 months for approval. Simple administrative changes are assessed without detailed technical review and can be approved within a few weeks.

6.2 Adverse Events and Recalls

After product launch, domestic medical device makers and China agencies of foreign device manufacturers should track their product quality, monitor the adverse events and re-evaluate their products, if necessary.10

The medical device makers, or their agency in China, must report the SAEs to CFDA and the CFDA’s provincial affiliates within the timeline required by the government—for death, report

10 Refer to http://www.sda.gov.cn/WS01/CL0059/34994.html
within five working days; for serious injury or possibly leading to serious injury or death, report within 15 working days. Additionally, when the domestic and foreign medical device makers renew their product marketing authorization, the extension application dossier must include the adverse event report.

China’s National Health and Family Planning Commission of the People Republic of China (PRC), formerly known as the Ministry of Health (MOH), publishes the regulations for medical device recalls. This regulation gives the definition of medical device recalls and defects; it also clarifies that the medical device maker is responsible for the control and removal of medical device defects and for taking charge of product safety.

Medical device distributors and hospitals/units using medical devices should immediately suspend the sale and use of the devices if they find the devices they are distributing or using are with defect, and inform medical device makers and/or suppliers accordingly. Meanwhile, the defect should be reported to local and relevant provincial FDA, which is responsible for the supervision and administration of device recalls. CFDA takes charge of management in the event of a nationwide device recall. Hospitals should also report to local provincial health authority at the same time.

Medical device manufacturers should establish a QMS and an adverse event monitoring system to collect and record device quality issues and device adverse events. The collected device adverse events are to be reported to CFDA. Device makers should also analyze the collected information, and investigate and assess the potential defect related to devices.

In terms of the defect severity, the recall can be divided into three levels:

- First class recall – the use of the device(s) possibly causes or has caused severe health hazard.
- Second class recall – the use of device(s) possibly causes or has caused a temporary or reversible health hazard.
- Third class recall – the use of the device(s) causes little possibility of health hazard, but still needs to be recalled.

There are two different types of device recalls: initiative recall and a recall mandated by CFDA. CFDA revises the product classification catalogue from time to time, and adjusts particular device classifications depending on market experience gained over time. Should the risk classification change for a particular category of devices, the manufacturer will need to submit a change application to CFDA.

7. Reimbursement and Tendering

7.1 Reimbursement

Getting listed on the reimbursement catalog is preferred to assure the sales of your medical device in China. Reimbursement and medical device pricing is regulated by the National
Development and Reform Commission (NDRC) and the National Health and Family Planning Commission (NHFPC).

Reimbursement mechanisms and pricing is complicated since reimbursement amounts can differ depending on the specific province/municipality and/or different hospitals in the same province/municipality. In general, reimbursement schemes treat medical devices differently by classifying them into two types: implantable or disposable.

Only medical devices that are approved by CDFA and put in the pricing formulary (reimbursement catalogue) regulated by the government can be reimbursed under the medical insurance coverage.

7.2 Tendering

To reduce fees while providing increased healthcare, China has adopted a tendering process. Tendering in China is full of diverging methods and varying scoring systems. Complex as it may seem, a December 2012 regulation issued by the NHFPC mandates that all public hospitals participate in the provincial centralized procurement process for high-value consumables, replacing a more localized system that gave greater discretion to cities and hospitals to select the devices that met their needs. Because this two-year tendering cycle is the only route to market in provinces where it has been adopted, success in these provincial tenders is critical to market access and financial performance.

The process for the tendering system is quite similar from province to province:

- A policy/tender list is announced,
- Manufacturers enroll,
- Qualification review takes place,
- Ceiling price is set, and
- Manufacturers submit bids based on the set ceiling price.

Most provinces employ a two-round qualification system before settling on the results and awarding the winning bidders.

The tendering process confers the right to sell, but does not come with guaranteed volume. While the tendering process does serve the purpose of filtering the number of manufacturers that a hospital can choose from for specific products, there will always be multiple winners. There are filters in place that may lead to disqualification from a tender, but the purpose of understanding the tendering process is not necessarily to learn how to get in, but to prevent from being left out.

Successfully tendering at the provincial level only allows a device manufacturer to compete for a place on a hospital’s list of approved devices. But once approved, the manufacturer, or its distributor/sales representative, must still persuade individual physicians of the relative benefits of the product over any competing devices that have also been approved for that
hospital. Surgeons will then discuss these various product options with their patients, but as such, there is no guarantee that they will use a particular device or product.

The bid process starts with the setting of a ceiling price. After the ceiling price is set and the bidding process is completed, an expert panel will score all submissions based on detailed tender evaluation criteria. This is where things get a bit more complicated. For medical device companies, the key to tendering is to avoid being the worst, so to speak, with either the highest bidding price or the lowest overall score.

Since the tender evaluation criteria are decided at the provincial level, increased participation from the manufacturer provides multiple opportunities to help shift the conversation from price to quality, as well as ensure greater fairness throughout the scoring process. Furthermore, in most provinces, a number of the criteria tend to be subjective (e.g., brand reputation and even company scale); therefore, being in good repute with the tender evaluation panel is key to maximizing the odds of success and obtaining an achievable price point during the process.