

Regulatory Requirements For Medical Devices In China



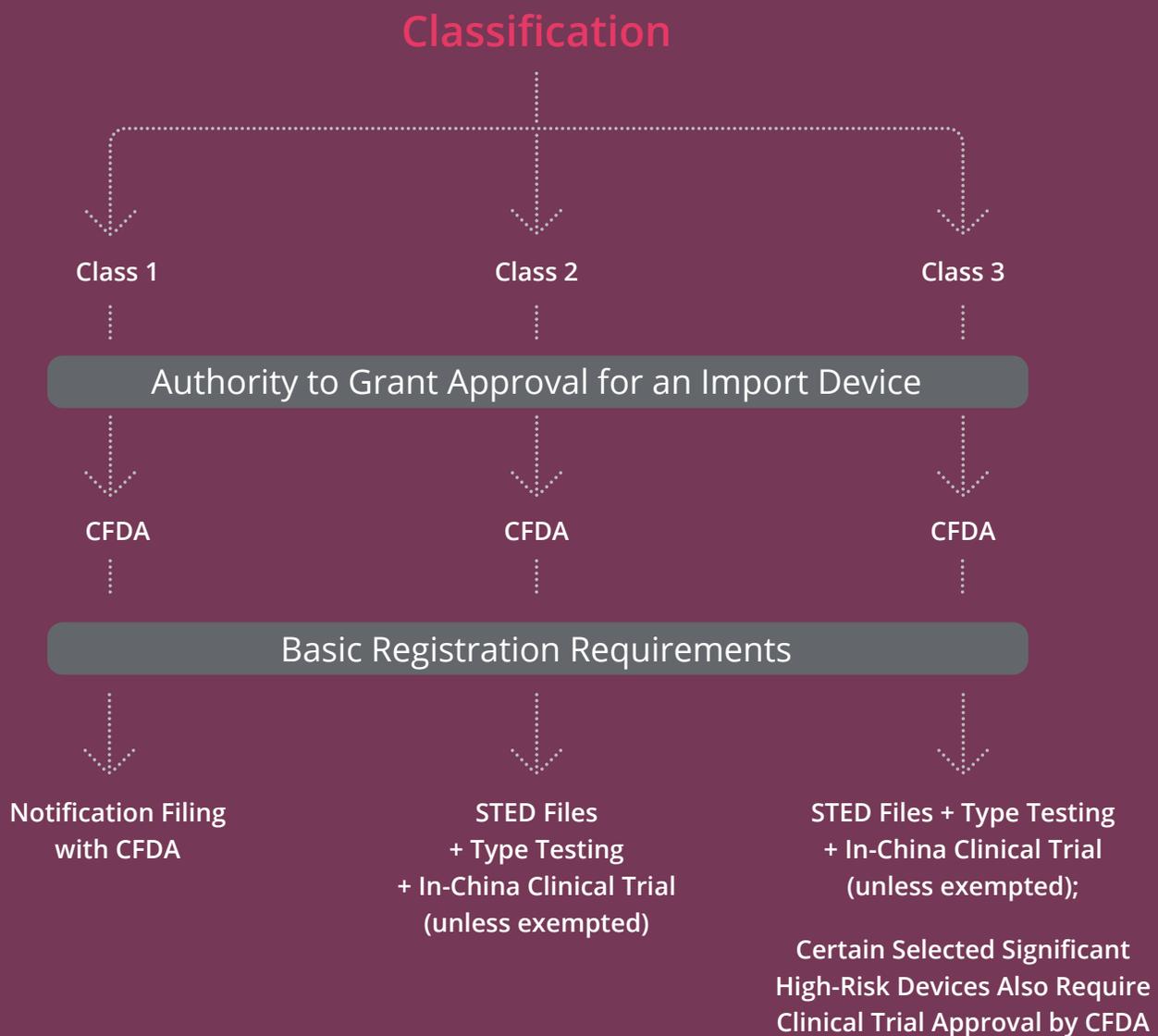


Regulatory Requirements for Medical Devices in China

As the most populous country in the world, China's medical device market has maintained a double-digit growth for more than 10 years. While there may be some economic challenges and uncertainties in the near future, due to its market size and aging population, China still offers a wealth of opportunities for foreign medical device companies.

One of the greatest difficulties for foreign medical device companies in China is its complicated and stringent regulatory requirements. Despite some improvements recently, gaining market access to China for medical device products still takes more than 18 months. As such, successful regulatory approval requires a deep understanding of the regulations, process and technical standards, as well as an appropriate regulatory strategy.

How to Register a Foreign Medical Device in China



CFDA: China Food and Drug Administration.
STED: Summary of Technical Essential Documents.
Type Testing: Sample Testing in China at CFDA certified lab.

What Is the Process for Product Registration Submission and the Associated Timeline?

China overhauled its medical device regulations in 2014. According to the new regulations, foreign medical device manufacturers shall submit their product registration application to CFDA directly. Even for the devices that are not high risk for which clinical trial data are not required, the whole process, from dossier preparation, to type testing, to final approval might still take longer than 18 months. So it is extremely important for the foreign manufacturer to understand the local technical and clinical requirements to properly conduct testing and clinical trial(s).



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What About the Application Fee?

Starting in May 2015, CFDA announced new policies for registration application fees. Looking at the table below, initial registration cost is no small amount. Technical improvement, software upgrade, site change, etc, will also generate costs during each revision application. So from a business point of view, foreign manufacturers need to evaluate their product development strategy for the Chinese market carefully, right from the outset, to minimize the number of iterative submissions and streamline product approval.



Types of Application Fee

Type of Application Fee	Class 2 (Import Device)	Class 3 (Import Device)
Initial Registration	30,511	44,674
Registration Revision	6,076	7,291
Registration Renewal (every Five years)	5,902	5,902
CTA for Significant High-Risk Class 3 Device	/	6,249

Currency: USD

How to Conduct a Medical Device Clinical Trial in China

Previously, most imported medical devices did not require in-China clinical trials. Foreign clinical data and clinical evidence were sufficient for product registration in China. However, according to the latest CFDA guideline, issued in January 2018 for the acceptance of foreign clinical data for medical devices, only well-designed multicenter-study data can be accepted for product registration in China. This results in more clinical investigations being conducted in China. The CFDA only announced a few devices of exemptions that allow some non-high risk Class 2 and Class 3 medical devices to waive local trial. For the products that are not on the exemption list, and also cannot provide sufficient foreign clinical data from well-designed multicenter studies, it is unlikely that a local trial can be waived. For such registration studies, CFDA now requests that the test device is compared with a marketed device in China to prove the clinical equivalence or superiority in terms of efficacy and safety. Although regulatory submission for a clinical trial is not required for most medical device studies, initiating a medical device study in China still takes quite a long time. Most study start-up activities are in sequential process, and some have unique local requirements. For multi-center studies, it takes at least 6 months to complete the start-up process from EC (European Community) & HGRAC (Human Gene Resource Materials and Collection, Preservation, Transaction and Exportation) approval, to study contract negotiation, to the CTN (Clinical Trial Notification).

What Are the Unique Requirements of Good Clinical Practice (GCP) in China?

China GCP for Medical Device studies became effective on June 1, 2016. This new GCP follows the similar concept of ISO (International Standards Organization) 14155, but also includes some specific local requirements that significantly impact the operation of the clinical trial.

CFDA Certified Site

For clinical investigations conducted in China for market approval, the studies have to select clinical sites with CFDA accreditation. Currently, medical device studies share the same GCP site list accredited by CFDA. But effective from January 1, 2018, GCP site notification platform for medical device studies was set up by CFDA. All sites have to complete this notification process before joining any medical device study in China. During this transition period, engaging enough qualified sites for a medical device study is always a challenge. This requires the company to have up to date information about the clinical resources of related therapeutic areas, and to have strong connections to the high performance sites in China.

HGRAC

Starting in October 2015, HGRAC approval is required for all research studies involving specimen collection in China or intended to export out of China. It affects almost all clinical trials sponsored by foreign companies because this regulation includes the use of local lab data. HGRAC applications should be submitted after EC approval. Although the process has been simplified since December 2017, the application process still takes around two months. Without HGRAC approval, clinical sites are not allowed to sign a study contract with the sponsor.



China GCP for Medical Device studies became effective on **June 1, 2016**.

CTN

CTN to the local provincial FDA (PFDA) is mandatory for a medical device registration trial. CTN must be submitted after EC approval and the study contract signed by all clinical sites. China GCP also requires that a medical device study must have the Leading Site EC submission within one year after a Type Testing report is issued. Start-up activities for a medical device study in China are much more complicated than most other countries, which includes site selection, EC submission, HGRAC application, site contract and CTN. Having an experienced local operation team, comprehensive and accurate project planning, and efficient execution of the project plan are all critical elements to the successful start-up of the study.

Critical Success Factors for Medical Device Studies in China

Conducting a medical device study successfully in China begins with understanding the unique local requirements: designing the study properly according to the local standards and guidelines; having the insights into the local clinical environment that help select suitable investigators and qualified clinical sites; and understanding local GCP requirements so that one can manage the study effectively while maintaining a high degree quality assurance are all critical elements to deliver a medical device study successfully in China. Utilizing a partner with successful experiences in running device trials in China is critical in ensuring that you are able to gain market access in the most time and cost efficient manner possible.

CFDA's On-site Inspection

Starting in July 2015, CFDA initiated intensive on-site inspections of drug and medical device clinical trials. Significant GCP compliance issues were found during these inspections, which led to more than 1,000 new drug or new device registration applications being withdrawn or rejected. These inspections clearly demonstrated that CFDA will no longer tolerate fake or fraud clinical data submitted for new product registrations. Furthermore, CFDA authorized CFDI (Center for Food and Drug Inspection) to conduct more routine on-site inspections on the clinical trials submitted to CMDE to support medical device registration. With the increasing attention of CFDA on the quality of clinical data, foreign medical device companies need to take great care over compliance in medical device studies conducted in China through effective site monitoring/management and strategic partnerships in the region.

In Conclusion

With the rapid emergence of new technologies, medical device companies are under increasing pressure to introduce and expand their new products to global markets as quickly as possible. China, with its fast growth and considerable market size, remains one of the high potential markets to foreign medical device companies. However, successfully building the business in China is not without challenges. One of the greatest difficulties is the complex local regulatory and clinical requirements. In-depth understanding of the local landscape, and the appropriate regulatory and clinical strategy, are extremely important to foreign medical device companies to achieve fast entry into China's market.



Want more advice on how the regulatory requirements for medical devices in China affect you? At Syneos Health, we can provide medical devices regulatory consulting services, specific to the Chinese market, to help you get your product approved. We have a dedicated business group focusing solely in this area, so you can benefit from their knowledge to guide you.

For more information, please contact us at syneoshealth.com or on one of the telephone numbers listed below:

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