

A medical device registration guidance for China on the example of an Chinese Class III device

Degree programme: MAS Medical Technology

Distribution of medical devices (MD) in China, confronts western companies to a different business culture, language and market rules. However, due to the positive projection of the Chinese medical market and increase of preventative health care, western companies are increasingly interested in entering the Chinese market the sooner the better. Adequate Chinese Food and Drug Administration (CFDA) medical device registration knowledge is a key factor to success.

CFDA Registration Process

The CFDA registration is currently based among others on the CFDA State Council Decree No. 650. In total 4-pre-market approval process steps were identified based on the example of a CE-marked Chinese Class III medical device (according to Chinese classification rules), shown in Figure 1.

Registration Dossier

The CFDA Registration Dossier is more or less comparable to the Summary Technical Documentation-file, also known as STED-file. Due to CFDA regulation additional in-China studies are required such as:

- Technical Testing: all device tests performed for previous CE-marking needs to be re-tested including the methods used by a qualified Chinese lab.

- Clinical Trial, if neither a Chinese predicate device nor a comparable device listed on the Catalogue of Medical Device Exempt is available.

Registration Timeline

Typical registration timelines are between 34 and 61 months, including in our example a 10-month clinical trial and follow up. This timeline is influenced by several factors such as

- Device design (state-of-the-art vs. novel design / material and/or manufacturing processes etc.);
- Relationship and dialogue with the CFDA and CFDA reviewer, the China Agent or companies affiliate, the testing lab and clinical trial personnel. Frequent visits are beneficial;
- Quality of Registration Dossier and translations;
- Clinical Trial study design, device design and indications, collaboration with the investigator and patient follow up, among others;
- Notifications by CFDA or Center for Medical Device Evaluation (CMDE) to correct data or providing supplemental documentation.

CFDA Registration Cost

At minimum, CFDA Registration fees come to 348'800 ¥ or 49'263CHF (1 ¥ = 0,1412 CHF, State: 03.06.2017), without a clinical trial study. Commercial costs for both the China Agent and China Distribution Agencies are charged in addition.

Conclusion

An informed decision-making process for MD registration in China is essential, prior to spending too much time and money on a market, which does not meet the companies' expectations. Execution of due diligence and investigation of both marketing and sales opportunities for the individual medical devices on the Chinese market shall be performed in advance. Without the right tools in place a lot of resources might be invested before a business case decision is taken. For manufacturers without the adequate infrastructure and knowledge, an external regulatory affairs consultant might be advantageous.



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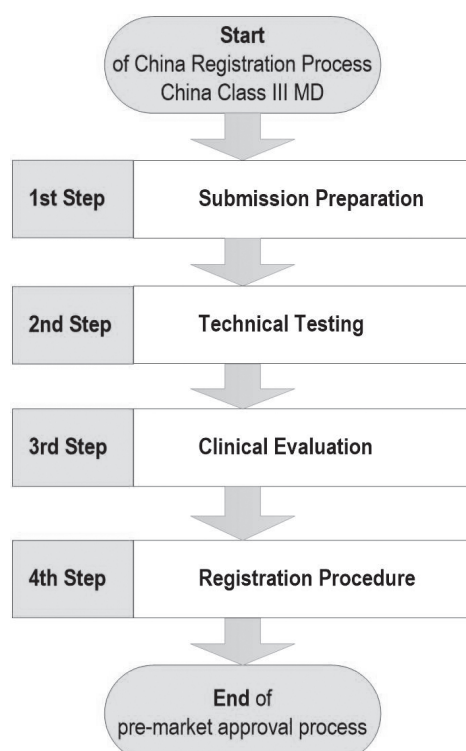


Figure 1: China Class III Registration Process Overview