What are the Requirements for CERs in CFDA Medical Device Registration?

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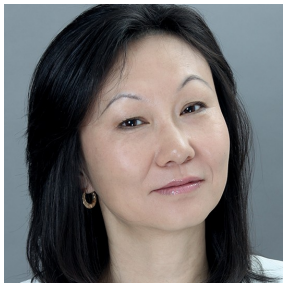

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What are the Requirements for CERs in CFDA Medical Device Registration?

Grace Fu Palma, founder and CEO of Boston-based China Med Device, a firm specializing in commercialization and funding for U.S. medtech companies entering China, offers some tips for submitting Clinical Evaluation Reports in the CFDA registration process.

China introduced new requirements for clinical evaluation reports in 2015. Understanding the China Food and Drug Administration's new CER requirements can help companies to be better prepared in their CFDA submissions.

The CER must summarize the data from clinical literature, clinical experience, and clinical trials, etc. This requirement applies to clinical evaluations of Class II and III medical devices for registration and declaration but does not apply to IVDs. The CER may also require specific technical information for particular products.

CERs must comply with CFDA Technical Guidelines for the Clinical Evaluation of Medical Devices (No. 14 of 2015). For low risk, mature devices where there is an established manufacturing process and a large amount of available safety and clinical effective data, a CER is a viable option.

One key requirement that most often blocks approval of a CER is proof of equivalency with the predicate device in China. Equivalency must be shown in terms of the product's basic principle, structure, manufacturing materials, production processes, performance requirements, safety evaluation, alignment with national / industry standards, intended use, and other aspects of basic equivalency.

You need sufficient technical and clinical information for the predicate device. The predicate device must have been approved by CFDA and must be within its validity period (all devices in China must be renewed every 5 years in order not to lose their validity). If a manufacturer does not have its own predicate device approved by CFDA to show equivalency, the manufacturer must obtain the authorization of a third-party manufacturer with a similar device. Getting this authorization can be very challenging.

In addition to searching the common English clinical literature database, you must also search the Chinese clinical database and also demonstrate that you have performed sufficient search and analysis in the local Chinese database.

You will also need to show that the clinical trial data is sufficient in terms of the sample size, indication, coverage, and the Asian/Chinese data subgroup.

A CER typically takes 3 to 4 months and costs $40,000 to $100,000 in China.

In summary, China's new CER requirements present device manufacturers with some challenges, but knowing what's required helps move the process forward.