China Targets Sterile Devices, Implant and IVDs for Inspection

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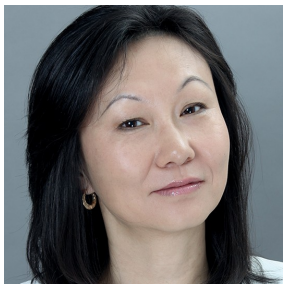

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Grace Fu Palma, founder and CEO of Boston-based China Med Device, a firm specializing in commercialization and funding for medtech companies entering China, explains how medtech companies can use a new guideline from the China FDA to help secure fast track approvals for innovative medical devices.

In the previous column, I talked about China's fast track for innovative medical device approvals and how products can qualify under a new guideline issued in December 2016. This time I will look at how China's regulatory system is structured and at the China Food and Drug Administration's approach to medical devices.

China's State Council is the highest authority so it is above the CDFA, which is the national authority for food and drugs. But each province has its own food and drug authority, and it is the provincial authorities, not the national authority, that have oversight of Class I and Class II medical devices.

Medtech is heavily regulated in China but the QMS and GMP requirements only date back to the 2000s, with major updates in 2009, 2013 and 2014. Compared to the mature U.S. regulatory system the Chinese system is still in development – a teenager, I would say.

But there is a lot of regulatory activity. The CDFA released 71 documents related to medical devices in 2016, including 19 decrees, 6 working reports, and 46 guidelines. Under China's centralized government, anything the CFDA says is mandatory, whether it's called a working document or whatever.

CFDA's main inspection focus is on sterile devices, implants and IVDs. Because they are high risk and invasive devices, they have well-defined requirements and are especially targeted for onsite inspection.

CFDA follows ISO standards, but it is often an older version of the ISO standard. For medical devices, China follows ISO 13485, but it follows the 2003 version, not the 2016 version, which means the requirements are different. Under the China GMP there are more inspections, for example. It's very important to know the revision differences as it impacts how you prepare and test your equipment in China, which in turn impacts your approval schedule.

There are many differences in inspection requirements in China compared with other countries. For a 510(k) in the U.S., for example, there is no requirement for an onsite inspection. But in China, if a domestic manufacturer wants to register a new product, there is onsite inspection, especially for new products.

More detailed standards of production, manufacturing and quality systems started to be introduced in 2009, but actual supervision and monitoring from CFDA was very weak. In February 2014, the state Council issued Medical Device Supervision and Administration Regulation (State Council #650), which went into effect on June 2014. The CFDA also issued a series of new regulations, guidelines and updates for medical devices. GMP is one of the key areas, with more than 18 regulations released already.

In summary, China's revised GMP and overseas on-site inspections and domestic unannounced inspections call for manufacturers to be more diligent and to make sure they are in compliance with the regulations.