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# Latest Chinese Guidebook for Application and Approval of Imported Medical Device Registration: From Regulations to Practices (2014 Edition)

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## Abstracts

### Summary

Now, Chinese regulations on medical devices are undergoing earthshaking changes. China's new leaders have recognized that the regulations for supervision and administration of medical devices are far from perfect along with rapid economic and population growth over the pasted three decades. Chinese state council issued the latest "Regulations for the Supervision and Administration of Medical Devices" to try to completely change such imperfect status. China Food and Drug Administration issued the latest "Measures for the Administration of Medical Device Registration", "Regulations on the Administration of the Instructions and Labels of Medical Devices", "Measures for the Supervision and Administration of Medical Device Production", "Measures for the Supervision and Administration of Medical Device Distribution" and "Measures for the Administration of IVD registration" on July 30, 2014 respectively, and they will come into force as October 1, 2014. The radical change of regulations on medical devices, especially for the latest "Measures for the Administration of Medical Device Registration" will bring overseas and multinational medical device manufacturers the maximum challenges and opportunities.

Those medical devices have not been granted the certificate of marketing authorization of medical device issued by the government authorities of the country or region of origin will be intercepted outside the door of Chinese medical device market. How do you in compliance with the latest Chinese regulations on medical devices? How do you operate business smoothly in China? How to seize a bigger Chinese medical device market? The overseas and multinational medical device manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on medical

device registration. Otherwise, the restrictive legal requirements and approval delays eat up your time and energy to achieve a successful entry into such a lucrative medical device market, and cause trouble for your business smoothly in China.

Latest Chinese Guidebook for Application and Approval of Imported Medical Device Registration: From Regulations to Practices (2014 Edition) not only provided a comprehensive and thorough knowledge of the latest Chinese regulations for imported medical device registration but also introduced the practical operation how to comply with the Chinese regulations to guide you achieve a successful approval for your products entry into the Chinese medical device market.

The organizations of this guidebook are arranged as follows. Chapter 2 provides the analysis and research for radical change of Chinese regulations on medical devices. Chapter 3 introduces the framework of the latest applicable Chinese regulations for medical device registration to provide a comprehensive and thorough knowledge of the latest Chinese regulations for medical device registration. Chapter 4 provides an overview of the Chinese regulatory authorities -- China Food and Drug Administration (CFDA) being responsible for application and approval for imported overseas medical device registration and recordation to give the direction of gateway for imported overseas medical devices registration and recordation. Chapter 5 elaborates the knowledge preparation before application of imported overseas medical device registration to let overseas medical device manufacturer understand the unique Chinese approach for medical device registration and lay the knowledge foundation for the practical operation. Chapter 6 elaborates the medical device classification to let overseas medical device manufacturer understand the Chinese medical device classification, because the imported overseas medical device registration must be in compliance with such classification of medical devices. Chapter 7 introduces the rights of human subjects and every party’s responsibilities in clinical trials for imported overseas medical devices in China. Chapter 8 introduces the regulations for application for imported medical device recordation, which is applicable to Class I imported overseas medical devices. Chapter 9 provides the regulations for application and approval for imported medical device registration, which is applicable to Class II and II imported overseas medical devices. Chapter 10 introduces the regulations for application and approval for alteration registration of imported overseas medical devices. Chapter 11 introduces the regulations for renewal registration of imported overseas medical devices. Chapter 12 introduces the regulations for supervision and administration for application and approval of imported overseas medical device registration. Chapter 13 provides the practical guidance for application of imported overseas medical device recordation, from how to compile recordation documents, how

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to apply for recordation to how to handle alteration recordation to smoothly navigate complex regulatory requirements step by step. Chapter 14 provides the practical guidance for application and approval of imported overseas medical device registration, from how to compile application documents, how to conduct clinical trials for imported overseas medical devices to the application for approval of imported overseas medical device registration to smoothly navigate complex regulatory requirements step by step. Chapter 15 provides the practical guidance for alteration registration and renewal registration of imported overseas medical devices, also from how to compile application documents to how to submit application documents step by step. Chapter 16 Appendices provide a complete set of full text in English of the latest Chinese regulations involving with the imported overseas medical device registration

The audiences of this guidebook are overseas medical device manufacturers wishing to enter into the Chinese medical device market, and multinational medical device companies have penetrated into the Chinese medical device market, and their senior executive officers engaging in regulatory affairs expecting to understand how to apply for registration of their medical device products in China, how to comply with the latest Chinese regulations for medical device registration.

After having skimmed through this guidebook, audiences can clearly acquire not only a comprehensive and thorough knowledge of the latest Chinese regulations on imported medical device registration but also the practical operation how to comply with the latest Chinese regulations. Access China Management Consulting Ltd hopes this guidebook, based on full and accurate regulations, can guide overseas and multinational medical device manufacturers and producers to achieve a successful entry into the Chinese medical device market, and smoothly operate their products in China.

**Scope**

The latest Chinese regulations for imported medical device registration and the practical operation how to comply with the Chinese regulations to guide you achieve a successful approval for your products entry into the Chinese medical device market.

**Reasons to buy**

Now, Chinese regulations on medical devices are undergoing earthshaking changes. Those medical devices have not been granted the certificate of marketing authorization of medical device issued by the government authorities of the country or region of origin will be intercepted outside the door of Chinese medical device market. How do you in

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compliance with the latest Chinese regulations on medical devices? How do you operate business smoothly in China? How to seize a bigger Chinese medical device market? The overseas and multinational medical device manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on medical device registration. Otherwise, the restrictive legal requirements and approval delays eat up your time and energy to achieve a successful entry into such a lucrative medical device market, and cause trouble for your business smoothly in China.

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**Who should buy this report?**

Overseas medical device manufacturers wishing to enter into the Chinese medical device market.

Multinational medical device manufacturers have penetrated into the Chinese medical device market.

Companies interested in understanding the latest Chinese laws and regulations for medical device product clinical trials.

Senior executive officers engaging in regulatory affairs for exporting medical devices into Chinese lucrative medical device market.

Senior executive officers engaging in conducting clinical trials for exporting medical devices into Chinese lucrative medical device market.

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