

Guide to Prepare Application Dossiers for Oversea Medical Device Registration and Recordation in China (2014 Edition)

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Abstracts

SYNOPSIS

Guide to Prepare Application Dossiers for Oversea Medical device registration and recordation in China (2014 Edition) not only provided a comprehensive and thorough knowledge of the overall new requirements of application dossiers for medical device registration or recordation in China but also provided the guidance of practical operation for how to achieve a successful approval for your products entry into the Chinese medical device market.

SUMMARY

Executive Summary

The Chinese medical device market is one of segment market of the most growth potentiality, which is attracting more and more overseas medical device manufacturers and producers to penetrate such market. It is estimated that Chinese medical device market will be likely to be more than 340 billion RMB (about 57 billion US dollars) by 2015, and will surpass Japan to become the second largest medical device market behind the United States.

However, China's regulatory framework for medical devices is undergoing radical changes. China's new leaders have recognized that the regulations for supervision and administration of medical devices are far from perfect along with rapid population growth and thriving economy over the past 30 years. Chinese state council issued the latest "Regulations for the Supervision and Administration of Medical Devices" on February

12, 2014, and it has come into force as of June 1, 2014. China Food and Drug Administration issued the latest “Measures for the Administration of Medical Device Registration”, and it has come into force as of October 1, 2014. The overseas medical devices exporting into China market should be subject to administration of overall new regulations since October 1, 2014.

The Chinese administration system for medical device registration undergone significant changes. Chinese authorities have begun to strengthen the supervision and administration of its medical device market. To strictly examine and approve the application dossiers for oversea medical device registration in China has become as the key threshold of oversea medical device exporting into China. The Chinese approach to administer medical device registration is unique. The application and approval process, clinical evaluation and clinical trial, the requirements for application dossiers are distinct from in U.S. and EU countries. 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 preparation of application dossiers compliance with overall new regulations becomes as the key for oversea medical device entry into 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.

Guide to Prepare Application Dossiers for Oversea Medical device registration and recordation in China (2014 Edition) not only provided a comprehensive and thorough knowledge of the overall new requirements of application dossiers for medical device registration or recordation in China but also provided the guidance of practical operation for how to 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 a comprehensively comparative analysis to introduce what the Chinese regulations on medical device are undergoing radical changes. Chapter 3 introduces the framework of the latest applicable Chinese regulations for medical device registration and recordation to provide a comprehensive and thorough knowledge of the latest Chinese regulations for medical device registration and recordation. Chapter 4 elaborates the knowledge preparation before application of imported overseas medical device registration or recordation to let overseas medical device manufacturer understand the unique

Chinese approach for medical device registration or recordation and lay the knowledge foundation for the practical operation. Chapter 5 introduces how many application dossiers for imported overseas medical device recordation should be prepared. Chapter 6 introduces the comprehensive and detailed requirements for application dossiers of imported overseas medical device recordation. Chapter 7 introduces how many application dossiers for imported overseas medical device registration should be prepared. Chapter 8 introduces the comprehensive and detailed requirements for application dossiers of imported overseas medical device registration. Chapter 9 provides a list of basic requirements for safety and effectiveness of medical device product, which is overall new requirements for imported overseas medical device registration in China. Chapter 10 elaborates the compilation of product technical requirements, which are also overall new requirements for imported overseas medical device registration in China. Chapter 11 introduces how to apply for registration test of imported overseas medical device. Chapter 12 elaborates the compilation of the instructions and labels of medical device. Chapter 13 provides the practical guidance for conducting the unique clinical evaluation for imported overseas medical device registration in China to help overseas medical device manufacturers to remove their confusion. Chapter 14 provides the practical guidance for conducting the clinical trials for imported overseas medical device registration in china, from what imported overseas medical devices need to conduct clinical trial and approval within Chinese territory, how to apply for clinical trial of imported medical device registration, how to compile application documents, how to select the clinical trial institutions and define every party's responsibilities in clinical trials to how to acquire the approval document for clinical trial of imported medical device registration to smoothly navigate complex regulatory requirements step by step. Chapter 15 introduces the approval process for imported overseas medical device registration to guide overseas and multinational medical device manufacturers how to submit the application dossiers, ultimately achieve a successful approval for products entry into the Chinese medical device market. Chapter 16 Appendices provide a complete set of full text in English of the latest Chinese regulations on medical devices, which over “Measures for the Administration of Medical Device Registration (2014Edition)”, “Regulations on the Administration of the Instructions and Labels of Medical Devices (2014 Edition)” “Rules for Medical Device Classification (2014Edition)”, “Compiling Guidelines of Product Technical Requirements for Medical Devices” and “Technical Guidance Principles for Clinical Evaluation of Medical Devices”.

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 or recordation of their medical device products in China, how to comply with the overall new Chinese regulations for medical device registration or recordation.

After having skimmed through this guidebook, audiences can clearly acquire not only a comprehensive and thorough knowledge of the overall new Chinese regulations on imported medical device registration and recordation but also the practical operation how to comply with the overall new requirements of application dossiers for overseas medical device registration and recordation in China. 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

Guide to Prepare Application Dossiers for Oversea Medical device registration and recordation in China (2014 Edition) not only provided a comprehensive and thorough knowledge of the overall new requirements of application dossiers for medical device registration or recordation in China but also provided the guidance of practical operation for how to achieve a successful approval for your products entry into the Chinese medical device market.

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REASONS TO BUY

China's regulatory framework for medical devices is undergoing radical changes. China's new leaders have recognized that the regulations for supervision and administration of medical devices are far from perfect along with rapid population growth and thriving economy over the past 30 years. Chinese state council issued the latest “Regulations for the Supervision and Administration of Medical Devices” on February 12, 2014, and it has come into force as of June 1, 2014. China Food and Drug Administration issued the latest “Measures for the Administration of Medical Device Registration”, and it has come into force as of October 1, 2014. The overseas medical devices exporting into China market should be subject to administration of overall new

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Guide to Prepare Application Dossiers for Oversea Medical device registration and recordation in China (2014 Edition) not only provided a comprehensive and thorough knowledge of the overall new requirements of application dossiers for medical device registration or recordation in China but also provided the guidance of practical operation for how to achieve a successful approval for your products entry into the Chinese medical device market.

KEY HIGHLIGHTS

A comprehensively comparative analysis to introduce what the Chinese regulations on medical device are undergoing radical changes.

A framework of the latest Chinese applicable regulations for medical device registration and recordation to provide a comprehensive and thorough knowledge of the latest Chinese regulations for medical device registration and recordation.

The knowledge preparation before application of imported overseas medical device registration or recordation to let overseas medical device manufacturer

understand the unique Chinese approach for medical device registration or recordation and lay the knowledge foundation for the practical operation.

How many application dossiers for imported oversea medical device recordation should be prepared, and What are comprehensive and detailed requirements for application dossiers of imported oversea medical device recordation to guide the overseas and multinational medical device manufacturers to smoothly operate recordation for Class I imported oversea medical devices in China.

How many application dossiers for imported oversea medical device registration, what are comprehensive and detailed requirements for application dossiers of imported oversea medical device registration to guide the overseas and multinational medical device manufacturers to smoothly operate registration for Class II and III imported oversea medical devices in China.

A list of basic requirements for safety and effectiveness of medical device product to reveal latest requirements for imported overseas medical device registration in China.

How to compile product technical requirements to guide the overseas and multinational medical device manufacturers to comply with another latest requirements for imported overseas medical device registration in China.

The practical guidance for conducting the unique and complicated clinical evaluation for imported overseas medical device registration in China to help overseas medical device manufacturers to remove their confusion.

The the practical guidance for conducting the clinical trials for imported overseas medical device registration in china, from what imported overseas medical devices need to conduct clinical trial and approval within Chinese territory, how to apply for clinical trial of imported medical device registration, how to compile application documents, how to select the clinical trial institutions and define every party's responsibilities in clinical trials to how to acquire the approval document for clinical trial of imported medical device registration to smoothly navigate complex regulatory requirements step by step.

The approval process for imported overseas medical device registration to guide overseas and multinational medical device manufacturers how to submit the application dossiers, ultimately achieve a successful approval for products entry

into the Chinese medical device market.

A complete set of full text in English of latest Chinese regulations on medical devices closely related to preparing application dossiers for imported overseas medical device registration and recordation, which cover “Measures for the Administration of Medical Device Registration (2014Edition)”, “Regulations on the Administration of the Instructions and Labels of Medical Devices (2014 Edition)” “Rules for Medical Device Classification (2014Edition)”, “Compiling Guidelines of Product Technical Requirements for Medical Devices” and “Technical Guidance Principles for Clinical Evaluation of Medical Devices”.

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