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Latest Regulations on Pharmaceutical International Multi-Center Clinical Trials in China

https://marketpublishers.com/r/LE1DCC86717EN.html
Date: March 2015
Pages: 101
Price: US$ 1,495.00 (Single User License)
ID: LE1DCC86717EN

Abstracts

China is one of the fastest growing global economies with one fifth population in the world, and is one of the largest healthcare markets around the world. Along with sustained economic and population growth as well as an ageing population, Chinese healthcare market has maintained annually average growth rate above 16 % since 1990s. By 2014, total value of drugs on Chinese healthcare market has reached RMB 1332.6 billion (about US$214.9 billion). On the Chinese healthcare market, imported drugs made by overseas and multinational pharmaceutical manufacturers account for about a fourth. It is estimated that total value of drugs on Chinese healthcare market will be likely to be more than RMB 1559 billion (about US$251.5 billion) by 2015, and will surpass Japan to become the second largest drug market following the United States. It’s definitely a field worth playing on. The Chinese drug market is attracting more and more overseas and multinational pharmaceutical manufacturers and producers to penetrate such market.

Chinese regulations on pharmaceutical clinical trials are undergoing sharp changes, like the country’s medical devices. International drug companies operating in China have already felt the sting of tighter regulation enforcement. This is first time in history, Chinese pharmaceutical authorities officially issued a guidance on international multi - center clinical trials of drugs in China, which has begun to be implemented on March 1, 2015. The guidance provides an opportunity to reduce risk from the examination uncertainty and approval delays to eat up your time and energy to achieve a successful entry into such a lucrative drug market, and to avoid trouble for your business smoothly in China. The overseas and multinational pharmaceutical manufacturers must be compliance with the latest regulations.

How to grasp the opportunity to smoothly conduct international multi - center clinical

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trials of drugs in China and speed up your drug approval time? The overseas and multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs must have a comprehensive and thorough knowledge of the Guidance on Chinese international multi - center clinical trials of drugs.

Latest Regulations on Pharmaceutical International Multi - Center Clinical Trials in China provided a comprehensive and thorough knowledge of the Guidance on international multi - center clinical trials of drugs in China and guide you use the Chinese trial venues to keep drug development lean and to smoothly operate in China.

The organizations of this guidebook are arranged as follows. Chapter 2 provides an overview of the Chinese regulatory authorities - China Food and Drug Administration (CFDA) being responsible for application and approval for international multi - center clinical trials of drug registration to give the direction of gateway for application for approval of clinical trial of imported overseas drug registration. Chapter 3 elaborates the background of promulgating Guidance. Chapter 4 introduces the applicable scope of Guidance. Chapter 5 introduces the general requirements of international multi - center clinical trials of drugs in China. Chapter 6 elaborates a series of scientific issues that Guidance requires sponsors to be considered. Chapter 7 elaborates a series of compliance issues that Guidance requires sponsors to be considered. Chapter 8 elaborates the clinical trial protocol amendment. Chapter 9 introduces the requirements for using the data from international multi - center clinical trials to support the application for drug registration in China. Chapter 10 introduces the authority, objects, contents, scope and requirements of Chinese drug regulatory authorities implementing inspection and verification on clinical trial sites. Chapter 11 provides a comprehensively and thoroughly practical guidance for application and approval of pharmaceutical international multi - center clinical trials in China, from the knowledge preparation and operation preparation before application, the specific regulations on overseas applicant and application, to the practical operation of application for approval as well as registration and information disclosure of international multi - center clinical trials of drugs in China to smoothly navigate complex regulatory requirements step by step. Chapter 12 provides a comprehensively comparative analysis to reveal the opportunities and challenges of international multi - center clinical trials of drugs in China, and to tell overseas and multinational pharmaceutical companies how to respond to challenges. Chapter 13 Appendices provide a complete set of full text in English of application forms involved in application for approval of pharmaceutical international multi - center clinical trials in China, which include “Application Form of Drug Registration”, “Application Form for Special Examination and Approval of New Drug Registration”, and “Application Form for Communication of Special Examination and

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Approval of New Drug Registration".

The audiences of this guidebook are overseas pharmaceutical manufacturers wishing to enter into the Chinese drug market, and multinational pharmaceutical companies have penetrated into the Chinese drug market, and their senior executive officers engaging in regulatory affairs expecting to understand how to apply for international multi - center clinical trials and registration of their pharmaceutical products in China, how to comply with the latest guidance on international multi - center clinical trials of drugs in China.

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

Report Highlights

An overview of organizational structure of Chinese regulatory authorities - China Food and Drug Administration (CFDA) for approval for international multi - center clinical trials in China to give the direction of gateway for clinical trials of imported drugs.

The background of promulgating Guidance.

The applicable scope of Guidance.

The general requirements of international multi - center clinical trials of drugs in China.

A series of scientific issues that overseas sponsors must be considered.

A series of compliance issues that overseas sponsors must be considered.

The detailed requirements for using the data from international multi - center clinical trials to support the application for imported overseas drug registration in China.

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Chinese drug regulatory authorities how to implement the inspection and verification on clinical trial sites.

A comprehensively and thoroughly practical guidance for application and approval of pharmaceutical international multi - center clinical trials in China, from the knowledge preparation and operation preparation before application, the specific regulations on overseas applicant and application, to the practical operation of application for approval as well as registration and information disclosure of international multi - center clinical trials of drugs in China to smoothly navigate complex regulatory requirements step by step.

An entrie process of application and approval procedures for international multi - center clinical trials of drugs in China.

The detailed regulations on registration and information disclosure for international multi-center clinical trials of drugs in China.

A comprehensively comparative analysis to reveal the opportunities and challenges of international multi-center clinical trials of drugs in China, and to tell overseas and multinational pharmaceutical companies how to respond to challenges.

A complete set of full text in English of application forms involved in application for approval of pharmaceutical international multi-center clinical trials in China, which include “Application Form of Drug Registration”, “Application Form for Special Examination and Approval of New Drug Registration”, and “Application Form for Communication of Special Examination and Approval of New Drug Registration”.

Who should buy this report?

Overseas pharmaceutical companies wishing to enter into the Chinese drug market.

Multinational pharmaceutical companies have penetrated into the Chinese drug market.

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Companies interested in understanding the latest Chinese laws and regulations for international multi-center clinical trials of drugs in China.

Senior executive officers engaging in regulatory affairs for imported drugs into Chinese lucrative drug market.

Senior executive officers engaging in conducting clinical trials for imported drugs in China.

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