

Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition)

<https://marketpublishers.com/r/LC13DEED5CEEN.html>

Date: October 2014

Pages: 199

Price: US\$ 1,495.00 (Single User License)

ID: LC13DEED5CEEN

Abstracts

Synopsis

China's regulatory framework for medical devices is undergoing radical changes. The country'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, which has come into force as of June 1, 2014. Before long, China Food and Drug Administration (hereafter called as CFDA) issued the latest "Measures for the Administration of Medical Device Registration", which has come into force as of October 1, 2014. The overseas medical devices exporting into China market are subject to administration of overall new regulations on medical device registration since October 1, 2014.

The Chinese concept of clinical evaluation and clinical trial for medical device registration is unique, which is distinct from the clinical trial 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 do you conduct the clinical evaluation and clinical trial for your products exporting into the Chinese market?

To enter such a lucrative medical device market, overseas and multinational medical device manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on medical device clinical evaluation and clinical trial. Otherwise, the restrictive legal requirements and approval delays eat up your development time and budget.

Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition) not only provided a comprehensive and thorough knowledge of the latest Chinese regulations on clinical evaluation and clinical trial for imported medical device registration but also introduced the practical operation how to comply with the Chinese GCP to guide you use the Chinese trial venues to keep medical device development lean and achieve a successful approval for your products entry into the Chinese medical device market.

Executive Summary

China's regulatory framework for medical devices is undergoing radical changes. The country'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, which has come into force as of June 1, 2014. Before long, China Food and Drug Administration (hereafter called as CFDA) issued the latest "Measures for the Administration of Medical Device Registration", which has come into force as of October 1, 2014. The overseas medical devices exporting into China market are subject to administration of overall new regulations on medical device registration since October 1, 2014.

In 2009, the Chinese government vigorously launched "China's Health-Care Reform", developed an ambitious blueprint, in which health care system covered about 1.2 billion people by 2011. Along with sustained economic and population growth, Chinese healthcare market has maintained annually average growth rate above 16 % since 1990s. Among them, medical devices represented dynamical growth since 2000s. By 2013, total value of medical devices on Chinese healthcare market has reached 179 billion RMB (about 29 billion US dollars). Medical devices have been widely used in the process of disease prevention, diagnosis, therapy, care and rehabilitation. On the Chinese medical device market, imported medical devices made by overseas and multinational medical device manufacturers account for about a half, in which the high-tech and high-valued medical devices, such as magnetic resonance imaging, CT are almost monopolized by GE, Siemens, Philips and other overseas and multinational companies. 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. 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.

China's radical change of regulatory framework for medical devices brings overseas and multinational medical device manufacturers the maximum challenges and opportunities. Those overseas 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 have been intercepted outside the door of Chinese clinical trial market not only, and be blocked outside the door of Chinese medical device market also. Nonetheless, Chinese authorities relaxed the admittance license of overseas medical devices. The overseas medical device manufacturer exporting Class I medical devices into China only need to file the archives and the certificate of marketing authorization of the government authorities of the country or region of origin to the CFDA for recordation. The overseas medical device manufacturer exporting Class II and Class III medical devices into China should be subject to be examined and approved by the CFDA. The Chinese authorities will strengthen the supervision and administration for medical devices, including their registration, production, distribution and use. How do you in compliance with the latest Chinese regulations on medical devices? How do you operate business smoothly in China? How do you conduct the clinical evaluation and clinical trial for your products exporting into the Chinese market?

The Chinese concept of clinical evaluation and clinical trial for medical device registration is unique, which is distinct from the clinical trial in U.S. and EU countries.

In China, the process of application and approval for clinical evaluation and clinical trial of imported medical device registration is very complex, because the Chinese medical device authorities administer and control this process by exorbitant administrative measures and regulations, even the guidances. Moreover, these exorbitant administrative measures and regulations, and the guidances are variable and lack of transparency. In addition, the cultural difference between China and Western countries as well as the language barriers will increase the challenge faced by overseas and multinational medical device manufacturers and producers.

To enter such a lucrative medical device market, overseas and multinational medical device manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on medical device clinical evaluation and clinical trial. Otherwise, the restrictive legal requirements and approval delays eat up your development time and budget.

Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition) not only provided a comprehensive and thorough knowledge of the latest Chinese regulations on clinical evaluation and clinical trial for imported medical device registration but also introduced the practical operation how to comply with the Chinese GCP to guide you use the Chinese trial venues to keep medical device development lean and 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 introduces the framework of the latest Chinese applicable regulations for clinical evaluation and clinical trial of medical device registration to provide a comprehensive and thorough knowledge of the latest Chinese regulations for clinical evaluation and clinical trial of medical device registration. Chapter 3 provides a comprehensive comparative analysis to tell overseas medical device manufacturer what Chinese regulations on medical device registration are undergoing radical changes, from what Chinese regulations on imported medical device registration are undergoing radical changes to what overseas medical devices need to conduct the clinical evaluation or clinical trial for imported 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 clinical evaluation and clinical trial of imported medical device registration to give the direction of gateway for application for approval of clinical trial of imported overseas medical device registration. Chapter 5 elaborates the knowledge preparation before conducting the clinical evaluation and clinical trial for imported 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 unique Chinese regulations for clinical evaluation and clinical trial of imported medical device registration to help overseas medical device manufacturers to remove their confusion. Chapter 9 provides the practical guidance for applying for clinical trials of imported overseas medical device registration, from what imported overseas medical devices need to conduct clinical trial and approval within Chinese territory, how to apply for clinical trial of imported overseas medical device registration, how to compile the product technical requirements, how to compile application documents to how to acquire the approval document for clinical trial of imported overseas medical device registration to smoothly

navigate complex regulatory requirements step by step. Chapter 10 provides the practical guidance for conducting clinical evaluation of imported overseas medical device registration, also from what imported overseas medical devices need to conduct clinical evaluation of imported overseas medical device registration, what requirements are for conducting clinical evaluation of imported overseas medical device registration, how to conduct the clinical evaluation of imported overseas medical device registration to how to compile application documents to smoothly navigate complex regulatory requirements step by step. Chapter 11 Appendices provide a complete set of full text in English of the latest Chinese applicable regulations for medical device clinical evaluation and clinical trial of imported overseas medical device registration, which include “Regulations for the Supervision and Administration of Medical Devices (2014 Edition)”, “Measures for the Administration of Medical Device Registration (2014 Edition)”, “Regulations on the Administration of the Instructions and Labels of Medical Devices (2014 Edition)”, “Rules for Medical Device Classification (2014 Edition)”, “Provisions for Clinical Trials of 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 smoothly conduct clinical evaluation and clinical trial for their medical device product registration in China, and how to comply with the Chinese GCP.

After having skimmed through this guidebook, audiences can clearly acquire not only a comprehensive and thorough knowledge of latest Chinese regulations on clinical evaluation and clinical trial for imported overseas medical device registration but also the practical operation how to comply with the Chinese GCP, how to conduct the clinical evaluation and clinical trial for imported overseas medical device registration. Access China Management Consulting Ltd hopes this guidebook, based on full and accurate laws and 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 the clinical evaluation and the clinical trial for their products in China.

Scope

Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition) not only provided a comprehensive

and thorough knowledge of the latest Chinese regulations on clinical evaluation and clinical trial for imported medical device registration but also introduced the practical operation how to comply with the Chinese GCP to guide you use the Chinese trial venues to keep medical device development lean and 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 introduces the framework of the latest Chinese applicable regulations for clinical evaluation and clinical trial of medical device registration to provide a comprehensive and thorough knowledge of the latest Chinese regulations for clinical evaluation and clinical trial of medical device registration. Chapter 3 provides a comprehensive comparative analysis to tell overseas medical device manufacturer what Chinese regulations on medical device registration are undergoing radical changes, from what Chinese regulations on imported medical device registration are undergoing radical changes to what overseas medical devices need to conduct the clinical evaluation or clinical trial for imported 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 clinical evaluation and clinical trial of imported medical device registration to give the direction of gateway for application for approval of clinical trial of imported overseas medical device registration. Chapter 5 elaborates the knowledge preparation before conducting the clinical evaluation and clinical trial for imported 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 unique Chinese regulations for clinical evaluation and clinical trial of imported medical device registration to help overseas medical device manufacturers to remove their confusion. Chapter 9 provides the practical guidance for applying for clinical trials of imported overseas medical device registration, from what imported overseas medical devices need to conduct clinical trial and approval within Chinese territory, how to apply for clinical trial of imported overseas medical device registration, how to compile the product technical requirements, how to compile application documents to how to acquire the approval document for clinical trial of imported overseas medical device registration to smoothly navigate complex regulatory requirements step by step. Chapter 10 provides the practical guidance for conducting clinical evaluation of imported overseas medical

device registration, also from what imported overseas medical devices need to conduct clinical evaluation of imported overseas medical device registration, what requirements are for conducting clinical evaluation of imported overseas medical device registration, how to conduct the clinical evaluation of imported overseas medical device registration to how to compile application documents to smoothly navigate complex regulatory requirements step by step. Chapter 11 Appendices provide a complete set of full text in English of the latest Chinese applicable regulations for medical device clinical evaluation and clinical trial of imported overseas medical device registration, which include “Regulations for the Supervision and Administration of Medical Devices (2014 Edition)”, “Measures for the Administration of Medical Device Registration (2014 Edition)”, “Regulations on the Administration of the Instructions and Labels of Medical Devices (2014 Edition)”, “Rules for Medical Device Classification (2014 Edition)”, “Provisions for Clinical Trials of Medical Devices” and “Technical Guidance Principles for Clinical Evaluation of Medical Devices”.

Reasons To Buy

China’s regulatory framework for medical devices is undergoing radical changes. The country’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, which has come into force as of June 1, 2014. Before long, China Food and Drug Administration (hereafter called as CFDA) issued the latest “Measures for the Administration of Medical Device Registration”, which has come into force as of October 1, 2014. The overseas medical devices exporting into China market are subject to administration of overall new regulations on medical device registration since October 1, 2014.

The Chinese concept of clinical evaluation and clinical trial for medical device registration is unique, which is distinct from the clinical trial 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 do you conduct the clinical evaluation and clinical trial for your products exporting into the Chinese market?

To enter such a lucrative medical device market, overseas and multinational medical device manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on medical device clinical evaluation and clinical trial. Otherwise, the restrictive legal requirements and approval delays eat up your

development time and budget.

Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition) not only provided a comprehensive and thorough knowledge of the latest Chinese regulations on clinical evaluation and clinical trial for imported medical device registration but also introduced the practical operation how to comply with the Chinese GCP to guide you use the Chinese trial venues to keep medical device development lean and achieve a successful approval for your products entry into the Chinese medical device market.

The overseas medical device manufacturers wishing to enter into the Chinese medical device market, the multinational medical device manufacturers have penetrated into the Chinese medical device market, and their senior executive officers engaging in regulatory affairs for clinical evaluation and clinical trial of exporting overseas medical device into Chinese lucrative medical device market, senior executive officers engaging in applying for approval of exporting overseas medical device registration in China need to understand these latest Chinese registrations and the practical operation. Otherwise, the restrictive legal requirements and approval delays eat up your development time and budget, and cause trouble for your business smoothly in China.

Contents

CHAPTER 1 EXECUTIVE SUMMARY

CHAPTER 2 LATEST CHINESE APPLICABLE REGULATIONS FOR CLINICAL EVALUATION AND CLINICAL TRIAL OF MEDICAL DEVICE REGISTRATION

CHAPTER 3 WHAT CHINESE REGULATIONS ON MEDICAL DEVICE REGISTRATION ARE UNDERGOING RADICAL CHANGES - A COMPREHENSIVE COMPARATIVE ANALYSIS

3.1 What Chinese Regulations on Imported Medical Device Registration are Undergoing Radical Changes?

3.2 What Overseas Medical Devices Need to Conduct the Clinical Evaluation or Clinical Trial for Imported Medical Device Registration?

CHAPTER 4 AN OVERVIEW OF CHINESE REGULATORY AUTHORITIES FOR CLINICAL EVALUATION AND CLINICAL TRIAL OF IMPORTED MEDICAL DEVICE REGISTRATION

4.1 CFDA's Main Responsibilities

4.2 CFDA's Organizational Structure

CHAPTER 5 KNOWLEDGE PREPARATION BEFORE CONDUCTING CLINICAL EVALUATION AND CLINICAL TRIAL FOR IMPORTED MEDICAL DEVICE REGISTRATION

5.1 Definitions

5.2 Classified Administration for Registration and Recordation of Medical Devices

5.3 What Medical devices may be exported into China?

5.4 Regulations on Applicant or Filer for Imported Medical Device Registration or Recordation

5.5 Product Technical Requirements

5.6 Registration Tests

5.7 Clinical Evaluation

CHAPTER 6 MEDICAL DEVICE CLASSIFICATION

6.1 Guidelines and Principles for Medical Device Classification

- 6.1.1 Guidelines for Medical Device Classification
- 6.1.2 Principles for Medical Device Classification
- 6.2 Judgment Table for Medical Device Classification

CHAPTER 7 RIGHTS OF HUMAN SUBJECTS AND EVERY PARTY'S RESPONSIBILITIES IN CLINICAL TRIALS FOR IMPORTED MEDICAL DEVICES

- 7.1 Rights and Interests of Human Subject
- 7.2 The Responsibilities for Implementer of Clinical Trials
- 7.3 The Responsibilities for Clinical Trial Institutions and Personnel of Clinical Trials

CHAPTER 8 CLINICAL EVALUATION AND CLINICAL TRIAL OF IMPORTED MEDICAL DEVICE REGISTRATION

CHAPTER 9 PRACTICAL GUIDANCE FOR APPLYING FOR CLINICAL TRIALS OF IMPORTED MEDICAL DEVICE REGISTRATION

- 9.1 Application Form for Approval of Medical Device Clinical Trial
- 9.2 Requirements for Application Documents for Approval of Medical Device Clinical Trial
- 9.3 How to Compile the Product Technical Requirements
- 9.4 Notice of Medical Device Clinical Trials
- 9.5 Clinical Trials Protocol and Format of Clinical Trial Protocol for Medical Devices
- 9.6 How Many of Medical Devices need to Conduct Clinical Trial and Approval within Chinese territory
- 9.7 Submission of Application Documents
- 9.8 Approval Document for Medical Device Clinical Trial

CHAPTER 10 PRACTICAL GUIDANCE FOR CONDUCTING CLINICAL EVALUATION OF IMPORTED MEDICAL DEVICE REGISTRATION

- 10.1 Requirements for Clinical Evaluation of Product listed into the Catalogue of Exempted Clinical Trial Medical Devices
- 10.2 General Requirements for Conducting Clinical Evaluation by Comparison of Clinical Data of Medical Device with Same Varieties
 - 10.2.1 Basic Principles
 - 10.2.2 Comparison and Judgment of Clinical Data of Medical Device with Same Varieties
 - 10.2.3 Path of Evaluation

- 10.2.4 Collection of Clinical Data for Medical Devices of Same Varieties
- 10.2.5 Clinical Evaluation based on Clinical Data of Medical Devices of Same Varieties
- 10.3 Requirements for Clinical Evaluation by Conducting Clinical Trials
- 10.4 Practical Guidance for Conducting Clinical Evaluation of Imported Medical Device Registration
 - 10.4.1 Clinical Evaluation of Contrasting Product Applying for Registration with Products listed into the Catalogue of Exempted Clinical Trial Medical Devices
 - 10.4.2 Clinical Evaluation based on Clinical Data of Medical Devices with Same Varieties

CHAPTER 11 APPENDICES

- Appendix 1 Regulations for the Supervision and Administration of Medical Devices (2014 Edition)
- Appendix 2 Measures for the Administration of Medical Device Registration (2014 Edition)
- Appendix 3 Regulations on the Administration of the Instructions and Labels of Medical Devices (2014 Edition)
- Appendix 4 Rules for Medical Device Classification (2014 Edition)
- Appendix 5 Provisions for Clinical Trials of Medical Devices
- Appendix 6 Technical Guidance Principles for Clinical Evaluation of Medical Devices

List Of Tables

LIST OF TABLES

Table 4.2.1 CFDA's affiliated organizations

Table 6.2 Judgment Table for Medical Device Classification

Table 9.1 Application Form for Approval of Medical Device Clinical Trial

Table 9.3 Format of Product Technical Requirements of Medical Devices

Table 9.5 Format of Clinical Trial Protocol for Medical Devices

Table 9.6 Catalogue of Class III Medical Devices Need to Clinical Trial Approval

Table 9.8 Approval Document for Medical Device Clinical Trial

Table 10.4.1 Contrast Table of Content between the product applying for registration and the product listed into the Catalogue of Exempted Clinical Trial Medical Devices

Table 10.4.2.1. Contrast Items and Conclusion Requirements for the product applying for registration comparing with the products of same varieties

Table 10.4.2.2 Contrast Content between the product applying for registration and the products of same varieties

Table 10.4.2.4 Path of Clinical Evaluation based on Clinical Data of Medical Devices with Same Varieties

Table 10.4.2.6 Scheme of Retrieve and Screen of Literatures

Table 10.4.2.7 Report of Retrieve and Screen of Literatures

Table 10.4.2.8 Content and Format of Clinical Evaluation Report based on Clinical Data of Medical Devices of Same Varieties

List Of Figures

LIST OF FIGURES

Figure 4.2.1 CFDA's Organizational Structure

Figure 10.4.2.5. Proposed Screening Process of Literatures

I would like to order

Product name: Latest Guidebook for Conducting Medical Device Clinical Evaluation and Clinical Trial in China: From Regulations to Practices (2014 Edition)

Product link: <https://marketpublishers.com/r/LC13DEED5CEEN.html>

Price: US\$ 1,495.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/LC13DEED5CEEN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

****All fields are required**

Customer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970

