

Latest Guidebook for Chinese Medical Device GMP Regulations

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Abstracts

China is one of the fastest growing global economies with a 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. Among them, medical devices represented dynamical growth since 2000s. By 2014, total value of medical devices on Chinese healthcare market has reached 255.6 billion RMB (about 40.25 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 overseas 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 (MRI) equipments, computed tomography (CT) equipments 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 53.15 billion US dollars) by 2015, and will surpass Japan to become the second largest medical device market behind the United States. Undoubtedly, China has an indispensable medical device market for overseas and multinational medical device companies. It's definitely a field worth playing on.

However, since October 2014, Chinese regulatory authorities have significantly changed the regulations on medical devices. China Food and Drug Administration (CFDA) issued the latest Chinese Good Manufacturing Practice (GMP) Regulations for Medical Devices on December 29, 2014, which has come into force as March 1, 2015. On July 10, 2015, China Food and Drug Administration (CFDA) further issued the latest Implementation Regulations of Good Manufacturing Practice (GMP) for Sterile Medical Devices, Implementation Regulations of Good Manufacturing Practice (GMP) for

Implantable Medical Devices as the appendices of the latest Chinese Good Manufacturing Practice (GMP) Regulations for Medical Devices respectively. They have come into force as October 1, 2015. Furthermore, on September 25, 2015, China Food and Drug Administration (CFDA) issued the latest On-site Inspection Guideline of Good Manufacturing Practice (GMP) for Medical Devices, On-site Inspection Guideline for Sterile Medical Device GMP Implementation Regulations, and On-site Inspection Guideline for Implantable Medical Device GMP Implementation Regulations. Everything changed.

China Food and Drug Administration (CFDA) requests that all the newly established medical device manufacturers, the existing medical device manufacturers to increase production of Class III medical devices, the relocated medical device manufacturers or the medical device manufacturers to expand manufacturing sites should follow the requirements of the latest Good Manufacturing Practice (GMP) Regulations for Medical Devices and the relevant assorted GMP implementation regulations. Since January 1, 2016, the medical devices manufacturers to manufacture Class III medical devices must comply with the the requirements of the latest Good Manufacturing Practice (GMP) Regulations for Medical Devices and the relevant assorted GMP implementation regulations. Since January 1, 2018, all the medical devices manufacturers must comply with the requirements of the latest Good Manufacturing Practice (GMP) Regulations for Medical Devices and the relevant assorted GMP implementation regulations.Those manufacturers that do not meet those deadlines may face enforcement actions by the food and drug regulatory authorities.

At present, overseas and multinational medical device manufacturers, as well as domestic medical device manufacturers are confronting with multiple inspection and verification of GMP rules and the relevant assorted GMP implementation regulations. The overseas medical device manufacturers exporting Class II and Class III overseas medical devices into Chinese medical device market, they must be subject to examination and approval of registration license, as well as the inspection and verification of GMP rules by the CFDA directly under the State Council. The multinational medical device manufacturers have penetrated into the Chinese medical device market, their affiliated manufacturers within territory of China must be subject to not only the examination and approval of registration license and production license, as well as on-site inspection and verification of GMP rules, but also on-site inspections of GMP rules for various supervisions and enforcements, (such as the routine supervision and enforcement, the follow-up supervision and enforcement, the surprise spot-check for “special issues”, etc.). The on-site inspection of GMP rules and the relevant assorted GMP implementation regulations is an extremely stringent inspection and

verification process of GMP rules and the relevant assorted GMP implementation regulations for medical device manufacturing enterprise. The regulatory authorities will dispatch the inspection team to conduct the on-site inspection by the manner of article to article, clause to clause in accordance with the GMP rules and the relevant assorted GMP implementation regulations to verify whether the medical device manufacturing enterprise is compliance with the GMP rules and the relevant assorted GMP implementation regulations.

How do you in compliance with the latest Chinese medical device GMP regulations? How do you operate business smoothly in China? The overseas and multinational medical device manufacturers and their senior executive officers engaging in regulatory affairs must have a comprehensive and thorough knowledge of the latest Chinese medical device GMP regulations. Otherwise, the restrictive legal requirements and approval delays will 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 Guidebook for Chinese Medical Device GMP Regulations is an essential resource for overseas and multinational medical device manufacturers to achieve a successful entry into the Chinese medical device market, and to operate business smoothly in China, which provides not only a comprehensive and thorough knowledge of the latest Chinese Medical Device GMP Regulations, but also the practical operation how to comply with the latest Chinese Medical Device GMP Regulations, how to smoothly pass through the extremely stringent on-site inspection and verification process of GMP rules and the relevant assorted GMP implementation regulations.

The organizations of this guidebook are arranged as follows. Chapter 2 provides the organizational structure of Chinese regulatory authorities for medical device GMP regulations. Chapter 3 provides an overview of Good Manufacturing Practice (GMP) for Medical Devices, which are comprehensive regulations to regulate a manufacturer's quality management system throughout the process from design, development and manufacturing to sales and after-sales service. Chapter 4 introduces the detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Sterile Medical Devices. Chapter 5 introduces the detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Implantable Medical Devices. Chapter 6 elaborates the on-site inspection of Good Manufacturing Practice (GMP) for medical devices to smoothly navigate complex regulatory requirements step by step. Chapter 7 elaborates the on-site inspection items and contents of Good Manufacturing Practice (GMP) for medical devices to help overseas and multinational medical device companies to

understand complex inspection requirements by article to article and clause to clause. Chapter 8 introduces the detailed on-site inspection items and contents for Sterile Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extremely complex inspection requirements by article to article and clause to clause. Chapter 9 elaborates the on-site inspection items and contents for Implantable Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extraordinarily complex inspection requirements by article to article and clause to clause.

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 license or production license of their medical device products in China, how to comply with the latest Chinese medical device GMP regulations, how to smoothly pass through the extremely stringent on-site inspection and verification process of GMP rules and the relevant assorted GMP implementation regulations.

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

Report Highlights

An overview of organizational structure of Chinese regulatory authorities for medical device GMP regulations.

An overview of Good Manufacturing Practice (GMP) for Medical Devices, which are comprehensive regulations to regulate a manufacturer's quality management system covering the entire process from design, development and manufacturing to sales and after-sales service.

The detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Sterile Medical Devices

The detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Implantable Medical Devices.

The overall provisions of on-site inspection and verification of Good Manufacturing Practice (GMP) for medical devices to smoothly navigate complex regulatory requirements step by step.

The overall on-site inspection items and contents of Good Manufacturing Practice (GMP) for Medical Devices to help overseas and multinational medical device companies to understand complex inspection requirements by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents of Good Manufacturing Practice (GMP) for Medical Devices to help overseas and multinational medical device companies to understand complex inspection requirements article by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents for Sterile Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extremely complex inspection requirements by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents for Implantable Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extraordinarily complex inspection requirements by article to article and clause to clause.

China's medical device market is indispensable for overseas and multinational medical device manufacturers. It's definitely a field worth playing on, but Chinese regulatory framework for medical devices has undergone significantly changed. Since October 2014, China Food and Drug Administration (CFDA) issued the latest Chinese Good Manufacturing Practice (GMP) Regulations for Medical Devices, the latest Implementation Regulations of Good Manufacturing Practice (GMP) for Sterile Medical Devices and the Implementation Regulations of Good Manufacturing Practice (GMP) for Implantable Medical Devices as the appendices of the latest Chinese Good Manufacturing Practice (GMP) Regulations for Medical Devices, as well as the latest On-site Inspection Guideline of Good Manufacturing Practice (GMP) for Medical Devices,

On-site Inspection Guideline for Sterile Medical Device GMP Implementation Regulations, and On-site Inspection Guideline for Implantable Medical Device GMP Implementation Regulations. Everything changed.

Facing sharp changes of medical devices GMP regulations, how do you in compliance with the latest Chinese medical device GMP regulations, how do you operate business smoothly in China? The overseas and multinational medical device manufacturers and their senior executive officers engaging in regulatory affairs must have a comprehensive and thorough knowledge of the latest Chinese medical device GMP regulations. Otherwise, the restrictive legal requirements and approval delays will 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 Guidebook for Chinese Medical Device GMP Regulations is an essential resource for overseas and multinational medical device manufacturers to achieve a successful entry into the Chinese medical device market, and to operate business smoothly in China, which provides not only a comprehensive and thorough knowledge of the latest Chinese Medical Device GMP Regulations, but also the practical operation how to comply with the latest Chinese Medical Device GMP Regulations, how to smoothly pass through the extremely stringent on-site inspection and verification process of GMP rules and the relevant assorted GMP implementation regulations. It is worth for overseas and multinational medical device manufacturers and their senior executive officers engaging in regulatory affairs reading on.

Report Highlights

An overview of organizational structure of Chinese regulatory authorities for medical device GMP regulations.

An overview of Good Manufacturing Practice (GMP) for Medical Devices, which are comprehensive regulations to regulate a manufacturer's quality management system covering the entire process from design, development and manufacturing to sales and after-sales service.

The detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Sterile Medical Devices

The detailed Implementation Regulations of Good Manufacturing Practice (GMP) for Implantable Medical Devices.

The overall provisions of on-site inspection and verification of Good Manufacturing Practice (GMP) for medical devices to smoothly navigate complex regulatory requirements step by step.

The overall on-site inspection items and contents of Good Manufacturing Practice (GMP) for Medical Devices to help overseas and multinational medical device companies to understand complex inspection requirements by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents of Good Manufacturing Practice (GMP) for Medical Devices to help overseas and multinational medical device companies to understand complex inspection requirements article by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents for Sterile Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extremely complex inspection requirements by article to article and clause to clause.

The comprehensive and detailed on-site inspection items and contents for Implantable Medical Device GMP Implementation Regulations to help overseas and multinational medical device companies to understand extraordinarily complex inspection requirements by article to article and clause to clause.

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