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Latest Chinese Guidebook for Application and Approval of Imported In-Vitro Diagnostic Reagent Registration: From Regulations to Practices (2014 Edition)

https://marketpublishers.com/r/C040C07090DEN.html
Date: September 2014
Pages: 208
Price: US$ 1,495.00 (Single User License)
ID: C040C07090DEN

Abstracts

China’s regulatory framework for in-vitro diagnostic reagents is undergoing earthshaking changes. The country’s new leaders have recognized that the regulations for supervision and administration of in-vitro diagnostic reagents 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 June 1, 2014. Before long, China Food and Drug Administration issued a series of the latest regulations on in-vitro diagnostic reagents on July 30, 2014 respectively, and they will come into force as October 1, 2014. The overseas in-vitro diagnostic reagents exporting into China market will be subject to administration of overall new regulations on in-vitro diagnostic reagent registration since October 1, 2014.

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, in-vitro diagnostic reagents represented dynamical growth since 2007. By 2013, total value of in-vitro diagnostic reagents on Chinese healthcare market has reached 3.5 billion US dollars, an increase of 22.9% over 2012 level. It is estimated that Chinese in-vitro diagnostic reagent market is likely to be more than 5.5 billion US dollars until 2015, and it is one of segment market of the most growth potentiality. The Chinese in-vitro diagnostic reagent market is attracting more and more in-vitro diagnostic reagents produced by overseas and multinational manufacturers to penetrate such market.

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However, China’s radical change of regulatory framework for in-vitro diagnostic reagents will bring overseas and multinational in-vitro diagnostic reagent manufacturers the maximum challenges and opportunities. How do you in compliance with the latest Chinese regulations on in-vitro diagnostic reagents? How do you operate business smoothly in China? To enter such a lucrative in-vitro diagnostic reagent market, overseas and multinational in-vitro diagnostic reagent manufacturers must have a comprehensive and thorough knowledge of the latest Chinese regulations on in-vitro diagnostic reagent registration. Otherwise, the restrictive legal requirements and approval delays eat up your time and energy to achieve a successful entry into such a lucrative in-vitro diagnostic reagent market, and cause trouble for your business smoothly in China.

Latest Chinese Guidebook for Application and Approval of Imported In-vitro Diagnostic Reagent Registration: From Regulations to Practices (2014 Edition) not only provided a comprehensive and thorough knowledge of the latest Chinese regulations for imported in-vitro diagnostic reagent 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 in-vitro diagnostic reagent market.

Report Highlights

An analysis and research for radical change of Chinese regulations on in-vitro diagnostic reagents.

An overview of the latest Chinese applicable regulations for for in-vitro diagnostic reagent registration.

An overview of organizational structure of Chinese regulatory authorities for imported overseas in-vitro diagnostic reagent registration and recordation to give the direction of gateway for imported overseas in-vitro diagnostic reagent registration.

The Chinese general regulations for imported overseas in-vitro diagnostic reagent registration to let overseas in-vitro diagnostic reagent manufacturer understand the unique Chinese approach for in-vitro diagnostic reagent registration and lay the knowledge foundation for the practical operation.

The detailed Chinese classification and naming principles for in-vitro diagnostic

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reagents.

The Chinese unique requirements for clinical trials of in-vitro diagnostic reagents, from the basic principles of clinical trials, the clinical trial design, scheme and methods, the sample size of clinical trial, to the clinical trial report and protocol.

The requirements for compilation of instruction of in--vitro diagnostic reagent registration in China.

The practical guidance for application of imported overseas in-vitro diagnostic reagent recordation, from how to compile recordation documents, how to apply for recordation to how to handle alteration recordation to smoothly navigate complex regulatory requirements step by step.

The practical guidance for application and approval of imported overseas in-vitro diagnostic reagent registration, also from how to compile application documents, how to compile the product technical requirements, how to apply for approval of imported overseas in-vitro diagnostic reagent registration to how to submit application documents to smoothly navigate complex regulatory requirements step by step.

The practical guidance for alteration registration and renewal registration of imported overseas in-vitro diagnostic reagents, also from how to compile application documents to how to submit application documents step by step.

A complete set of full text in English of the latest Chinese regulations for imported overseas in-vitro diagnostic reagent registration, which cover “Regulations for the Supervision and Administration of Medical Devices”, “Measures for the Administration of In Vitro Diagnostic Reagent Registration”, “Rules for Medical Device Classification”, “Technical Guidance Principles for Clinical Trials of In--vitro Diagnostic Reagents” and “Guidance Principles for Compilation of Instruction of In--vitro Diagnostic Reagents ”.

The audiences of this guidebook are overseas in-vitro diagnostic reagent manufacturers wishing to enter into the Chinese in-vitro diagnostic reagent market, and multinational in-vitro diagnostic reagent companies have penetrated into the Chinese in-vitro diagnostic reagent market, and their senior executive officers engaging in regulatory affairs

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expecting to understand how to apply for registration of their in-vitro diagnostic reagent products in China, how to comply with the latest Chinese regulations for in-vitro diagnostic reagent 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 in-vitro diagnostic reagent 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 in-vitro diagnostic reagent manufacturers and producers to achieve a successful entry into the Chinese medical device market, and smoothly operate their products in China.

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