



Approaching China's Pharmaceutical Market: A Fundamental Guide to Clinical Drug Development

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This authoritative volume examines the major laws, regulations and guidelines related to pharmaceutical product development in China. With a focus on patent, clinical and registration strategies, the book helps Western companies introduce their clinical drugs to the Chinese market, determine a strategic path and bridge the gap for regulatory and legal differences between China and the Western world. For a better understanding of the drug registration process, it explores the differences between the China Food and Drug Administration (CFDA) including its regulations and registration procedures and those of the Western world. The volume discusses disparities between China's application requirements compared to Western standards to make it easier for companies to prepare their application packages. It also provides detailed commentary on CFDA guidelines in reference to clinical trial (IND) and market application (NDA) requirements. Overall, this book offers guidance for Western companies aspiring to expand into China's pharmaceutical market in hopes that they may gain a fundamental understanding of its rules and complexities in order to ensure a smooth transition and prevent future issues.

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