



# 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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About the Author

Ming Q. Lu, M.D., Ph.D, is a senior medical director at Helsinn Therapeutics, Inc. He received his M.D in P.R. China and his Ph. D from the University of Connecticut, and completed a fellowship at Johns Hopkins Medical Schools under academician Peter Agre, M.D, who in 2003 received the Nobel Prize. Dr. Lu has expansive experience in both academia and pharmaceutical industry, particularly in research and development (R&D) of new medications. Since 1998, he has been heavily involved in the conduct and management of various aspects of clinical drug research and development, running the gamut from project initiation, to drug candidate discovery, and from pre-clinical pharmacology to all the clinical phases in both the US and overseas, especially in mainland China. He has also chaired the regulatory filing and defense processes with China Food and Drug Administration (CFDA), leading to the success of marketing approval in both China and Hong Kong.

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