



Jack Wong
Raymond Tong

HANDBOOK OF
Medical Device
Regulatory
Affairs in Asia



Handbook Of Medical Device Regulatory Affairs In Asia

Jack Wong, Raymond Tong



Handbook Of Medical Device Regulatory Affairs In Asia:

Medical Regulatory Affairs Jack Wong,Raymond Tong,2022-01-26 This handbook covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application It is the first to cover the medical device regulatory affairs in Asia Experts from influential international regulatory bodies including the US Food and Drug Administration FDA UK Medicines and Healthcare Products Regulatory Agency Japan Pharmaceuticals and Medical Devices Agency Saudi Food and Drug Authority Korea Testing Laboratory Taiwan FDA World Health Organization Asian Harmonization Working Party Regulatory Affairs Professionals Society and British Standards Institution have contributed to the book Government bodies the medical device industry academics students and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects Handbook of Medical Device Regulatory Affairs in Asia Jack Wong,Raymond Tong Kaiyu,2013-03-27 Medical device regulation in Asia has gained more importance than ever Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones A registered product requires a lot of technical documentation to prove its efficacy safety and quality A smooth and successful registration process dem Handbook of Medical Device Regulatory Affairs in Asia Jack Wong,Raymond Tong,2018-03-28 Medical device regulation in Asia has gained more importance than ever Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones A registered product requires a lot of technical documentation to prove its efficacy safety and quality A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government testing centers and hospitals and among doctors This handbook covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application It is the first to cover the medical device regulatory affairs in Asia Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs **Handbook of Medical Device Regulatory Affairs in Asia** Jack Wong,Raymond Tong Kaiyu,2013-03-27 Medical device regulation in Asia has gained more importance than ever Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones A registered product requires a lot of technical documentation to prove its efficacy safety and quality A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government testing centers and hospitals and among doctors Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application Government bodies the medical device industry and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects **Medical Regulatory**

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Framing Asian Studies Albert Tzeng, 2018-05-24 This book explores the interconnection between geopolitical context and the ways this context frames our knowledge about Asia highlighting previously neglected cause effect relations It also examines how various knowledge institutions promote and shape Asian Studies The authors seek to explain why Asian Studies and its subfields developed in the way they did and what the implications of these transformations might be on intellectual and political understandings of Asia The book not only builds on the current debates on the decolonization and de imperialization of knowledge about Asia it also proposes a more multifaceted view rather than just examining the impact of the West on the framing of Asian Studies

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