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"*This is an excellent and comprehensive book for researchers in medical devices, for students who want to get early exposure to safety and efficacy issues, and for marketing/sales personnel who need to know the various institutions that approve regulatory matters for market accessibility.*"

Prof. Swee-Hin Teoh
Nanyang Technology University, Singapore

"*While much has been written about US and European medical device regulations, the Asian regulatory picture has remained clouded for most people. This book is an excellent reference for understanding what is required to bring medical devices to market under the many different regulatory systems in this important region. It is a useful tool as companies and innovators are increasingly looking to Asia as not only a new market for existing products but a launching pad for new technologies.*"

Mark Holmes
Terumo BCT, Inc., USA

"*This is a very interesting book for biomedical engineering students and medical engineers and an important reference for regulatory affairs professionals.*"

Dr. Kwok-kwan Chan
Hospital Authority, Hong Kong
Chairman in Biomedical Division (2012–13), Hong Kong Institution of Engineers

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 (SFDA), 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, and academics and students will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

Jack Wong is the founder of the Asia Regulatory Professional Association (ARPA). He has more than 20 years of experience in regulatory affairs, clinical trials, and pharmacovigilance in Asia and possesses good knowledge in the field of medical devices, pharmaceuticals, and nutritional, consumer healthcare, and biological products. Prof. Wong developed the First Asia Regulatory Affairs Certificate course in 2007 and has been teaching at more than 10 universities.

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