

Handbook of Medical Device Regulatory Affairs in Asia

Handbook of Medical Device Regulatory Affairs in Asia

Second Edition

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Published by

Pan Stanford Publishing Pte. Ltd. Penthouse Level, Suntec Tower 3 8 Temasek Boulevard Singapore 038988

Email: editorial@panstanford.com Web: www.panstanford.com

British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

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ISBN 978-981-4774-31-4 (Hardcover) ISBN 978-0-429-50439-6 (eBook)

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Preface

Medical device regulation in Asian markets has become important. Governments and regulatory bodies of countries across the region have placed new regulatory systems or refined the existing ones. Regulatory affairs (RA) is a science of how to get a medical product registered with different countries' health authorities. A registered product would demand a lot of technical documentation to prove its efficacy, safety, and quality. To successfully and smoothly register a product, many soft skills are required for dealing with various key stakeholders in governments, testing centers, hospitals, and medical doctors.

The handbook is the first to cover medical device regulatory affairs in Asia. It is enriched by contributions by authors working with several regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Saudi Food and Drug Authority (SFDA), Taiwan FDA). Each chapter provides substantial background materials relevant to a particular area to provide the reader a better understanding of regulatory affairs. The text also presents in-depth discussion on requirements for medical device registration in China and India.

Government bodies will find this book useful to understand the global regulatory environment to help enhance their regulatory systems. The medical device industry can use it to better understand and access the Asian market. Academics and students will find this book very important for their careers in biomedical engineering and medical device—related fields. In research and development, with the help of this book, companies can plan their projects and ensure that the developed medical devices adhere to the global regulatory environment.

The chapters have been grouped into four main parts as follows:

- Part 1 explains what RA is, how to be a good RA professional, how a RA professional works with other team members, and some associated soft skills.
- Part 2 focuses on medical device fundamentals, such as history, labeling requirement, clinical trial requirement, how to do classification, and two important standards for medical device regulatory (ISO 13485 and ISO 14971).
- Part 3 discusses the US and EU regulatory systems in detail. We also invite experts from the US FDA. European Union, Saudi Arabia, and Latin America to share their experience on combinational product regulatory. Their experience will be very helpful for Asia.
- Part 4 is the core of this book. It describes the regulatory system in the Asian market, with contributions from regulatory authorities, testing laboratories, and industries.

This book would not have been possible without contributions from outstanding experts in various topics discussed in it. We wish to express our gratitude to all of them for their precious efforts and strong support.

Fifty percent of the revenue from this book will be donated to the Asia Regulatory Professional Association and the remaining 50% to the Department of Biomedical Engineering, the Chinese University of Hong Kong—both are for the development of medical device regulatory affairs in Asia.

Finally, many thanks to our families (Jack Wong's mother, Cheung Shim Kuen, wife, Sherry Kwan Suet Sum, and son, Jay Wong Yat; Raymond Tong's parents, Wai-chuen Tong and Lai-lin Tsui, wife, Wai-nga Lam, and daughter and sons, Lok-ching, Lok-tin, and Lok-ting), for their support, encouragement, and patience. They have been our driving forces.

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