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"Handbook of Medical Device Regulatory Affairs in Asia"

Jack Wong and Raymond Tong Kaiyu, 2013, 581 pages, Pan Stanford Publishing, $149.95

Review by Norman M. Goldfarb

"Handbook of Medical Device Regulatory Affairs in Asia" provides extensive information about the medical device regulatory environment in Asia and the Middle East. In addition to overviews of 16 countries, it discusses medical device classification, ISO 13485 and ISO 14971 quality standards, affordable access, medical device harmonization inititiatives in Asia, and other topics of both regional and global interest.

The second half of the book reviews the regulatory systems for the folllowing countries: Australia, China, Hong Kong, India, Indoniesia, Japan, Jordan, Republic of Korea, Malaysia, Philippines, Saudi Arabia, Singapore, Taiwan, Thailand, UAE and Vietnam.

The book includes 39 chapters in four sections:

- Introduction (7)
- Medical Device Safety and Related ISO Standards (6)
- Harmonization of Medical Devices in Asia (6)
- Medical Device Regulatory System in the United States and the European Union (4)
- Medical Device Regulatory System in Asia-Pacific Region (16)

The book is available in bookstores.

Reviewer

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