Medical Device Regulatory Practices: An International Perspective

Val Theisz
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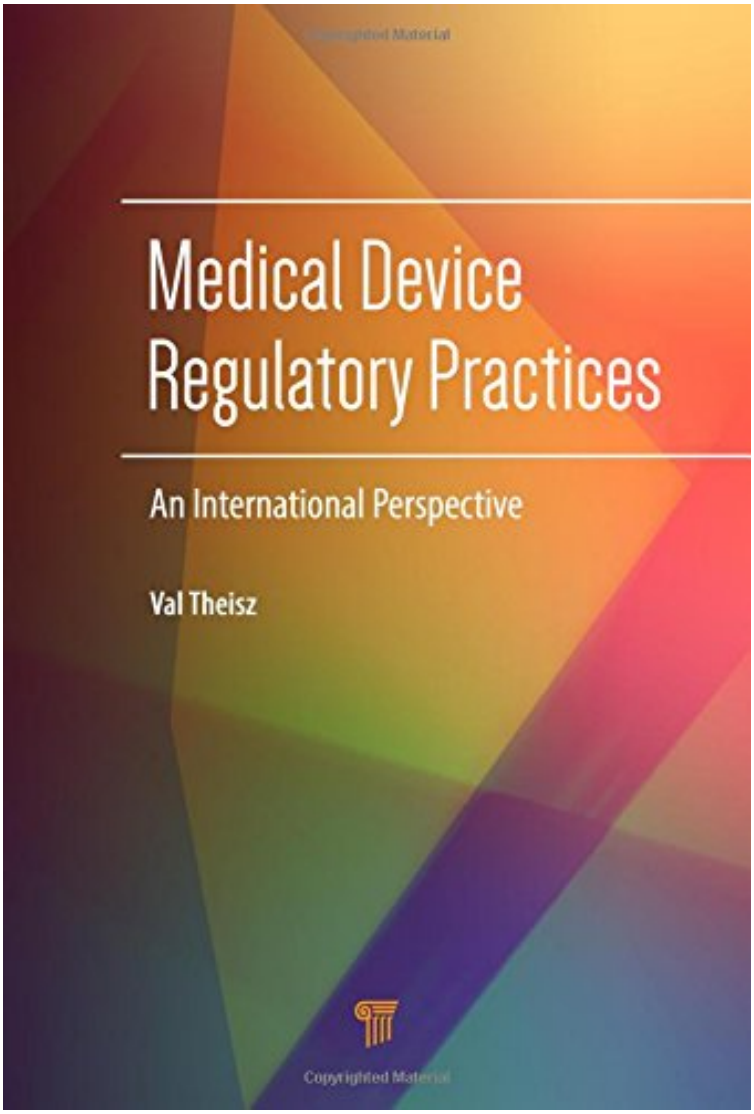

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Val Theisz : Medical Device Regulatory Practices: An International Perspective before purchasing it in order to gage whether or not it would be worth my time, and all praised Medical Device Regulatory Practices: An International Perspective:

0 of 0 people found the following review helpful. Five StarsBy George Gary CalafactorGreat product seller!

This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case studies. Medical devices, like pharmaceuticals, are highly regulated,

and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in their pursuit of commercial success. Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes practical solutions for a coherent, one-size-fits-all (or most) set of systems and processes in compliance with regulations in all key markets, throughout the life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets; important terminology needed to understand the regulators language; and examples, case studies, and practical recommendations that bridge the gap between regulatory theory and practice.

"I can only commend Val's book to all newcomers in the regulatory profession, be it in industry or in a regulatory agency. It explains the basics very well also for a start-up or an inventor who has to start dealing with regulations if he or she ever wants to market a product. I'm sure it could also be used as a valuable tool for those departments or ministries of health that want to set up a new national medical device regulatory agency in their jurisdictions. As it gives a global overview of how regulatory systems are applied in different legal settings and how industry should deal with these requirements, it is a unique guidance reference book for medical device regulations. Using the information contained in this book will make life easier for regulatory affairs professionals." Rainer Voelksen, Project Manager, Swiss Federal Office of Public Health, Chairman 2015, Regulatory Affairs Professionals Society (RAPS)About the AuthorVal Theisz is a regulatory professional with over 15 years experience in medical device regulations, of which she spent 8 in leadership roles in regulatory affairs, regulatory operations, and quality assurance. She holds a masters degree in electrical engineering from the Polytechnic University of Timioara, Romania, and a Regulatory Affairs Certification (RAC) for European and US regulations from the Regulatory Affairs Professionals Society (RAPS). Val has been a RAPS fellow since 2010. Working on both sides of the regulatory divideas a reviewer and quality systems auditor (7 years) and in roles with responsibility for obtaining regulatory approvals and maintaining regulatory compliance (10 years)enabled Val to gain an in-depth understanding of the typical challenges facing medical device companies. One of her achievements was obtaining the CE marking approval for a life-sustaining active implantable medical device within six months from the date of submission. During a five-year stint as regulatory operations manager with one of the largest pharmaceutical companies, Val implemented electronic data management systems for a large product portfolio and learned about process improvement techniques.