EUROPEAN HANDBOOK OF MEDICAL DEVICES REGULATORY AFFAIRS 2021

You're Guide to European Medical Devices Regulations

As medical device quality assurance and regulatory affairs professionals, it can be challenging to stay on top of changes happening in our industry. Few people have the time to read lengthy articles these days and although many online newsletters exist, they are often packed with PR releases, ads or unrelated information. That is why we started **this Handbook** for QA/RA professionals in the medical device and IVD industry.

Medical device regulation around the world 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 centres, and hospitals and among doctors.

This Handbook 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 begins by providing a solid background to concepts such as device classification, clinical trials, and labelling. Detailed information is then provi-ded for each country. It is a useful tool as companies and innovators are increasingly looking worldwide to market existing products but also provide a launching pad for new technologies.

This comprehensive Handbook is essential for researchers in medical devices 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. The contacts listed in the chapters are valuable and will lead readers to have their first approach in understanding the dynamic process involved in regulatory affairs.

Features:

Covers medical device regulatory system in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application.
Provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs. Presents contributions from authors working in regulatory organizations.

Market Coverage (Including updated contact information for all countries):

European Union: All 28 countries
Europe (Non-EU): Norway Russia, Serbia, Switzerland, Ukraine

The European Handbook of Medical Devices Regulatory Affairs is a trusted and increasingly valuable resource. The medical device industry will find this book immensely useful to understand the regulatory environment. Additionally it can used to better understand and access the European market. Industry professionals will find it very useful for their research and development projects, and it will ensure that the product developed by them adheres to the regulatory environment.

Book, PDF or CD-Rom Price: US$250.00 including delivery. ISBN: 978-1-925598-36-0

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