



EUROPEAN HANDBOOK OF MEDICAL DEVICES REGULATORY AFFAIRS 2022

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.

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 be 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.

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