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Special Issue Reprint

Regulatory Data Science for Medical Devices

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Regulations that cover the legal obligations that manufacturers are bound to are essential for keeping the general public safe. Companies need to follow the regulations in order to bring their products to market. A good understanding of the regulations and the regulatory pathway defines how fast and at what cost the manufacturer can introduce innovations to the market. Regulatory technology and data science can lead to new regulatory processes and evidence in the medical field. It can equip stakeholders with unique tools that can make regulatory decisions more objective, efficient, and accurate. This book describes the latest research within the broader domain of Medical Regulatory Technology (MedRegTech). It covers concepts such as the complexity and user-friendliness of medical device regulations, novel algorithms for regulatory navigation, descriptive datasets from a health service provider, regulatory data science techniques, and considerations of the environmental impacts within a national health service. This book brings all these aspects together to offer an introduction into MedRegTech research. In the long term, these technologies and methods will help optimize the regulatory strategy for individual healthcare innovations and revolutionize the way we engage with regulatory services.

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