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Peter Ogrodnik

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This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements—some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. * The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how.* Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand.* Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products.



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