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The Medical Device R&D Handbook presents a wealth of information for the hands-on design and building of medical devices. Detailed information on such diverse topics as catheter building, prototyping, materials, processes, regulatory issues, and much more are available

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First published in 2001: This handbook has been written to give those professionals working in the development and use of medical devices practical knowledge about biomedical technology, regulations, and their relationship to quality health care.

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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

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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 scalpelsstents 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

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US

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Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

Medical device regulation in Asia 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 centers, and hospitals and among doctors. This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Each chapter provides substantial background materials relevant

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to the particular area to have a better understanding of regulatory affairs.

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Medical device regulation in Asia 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 centers, and hospitals and among doctors. Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the medical device industry, and academics and students will find this

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2018 Handbook coverage of new topics, such as Health Technology Assessment (HTA), Decision Support Systems (DSS), Mobile Apps, Success Stories in Clinical Engineering, and Human Factors Engineering

Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process, integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact, when it's ideal to use, and related challenges. Also discussed are other barriers, such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing and regulation. Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU) Explains technology development and the application of human factors throughout the development process Covers FDA and MHRA regulations Includes case examples with each method

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