Innovative Medical Device Solutions

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The Role of Human Factors in Home Health Care Univ of California Press

Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.

Development of Medical Device Policies Academic Press

"This book comprehensively captures the essence of inventing medical devices through anecdotes, case studies and real life examples. A recommended must read for any aspiring entrepreneur who wishes to invent new medical devices in India." - Dr. Balram Bhargava,Padmashri, Professor of Cardiology, Cardiothoracic Sciences Centre, Executive Director, Stanford India Biodesign Centre, School of International Biodesign (SIB), All India Institute of Medical Sciences, New Delhi. "A timely resource- This is a remarkably readable and useful primer on medical device innovation in India, written by one of the emerging leaders in the field. The realistic perspective and practical suggestions in this book have arrived just in time for a health technology ecosystem that is in a substantial stage of growth." - Dr. Paul Yock, Founder and Director, Stanford Biodesign "Despite the stated focus as a book for doctors looking to engage with the MedTech ecosystem in India, this book has several teachings for engineers, product designers, business strategists, marketing folks and investors as well." - The Hans India In this book, the author shares his experiences, anecdotes, insights and failures while inventing medical devices in India over the last six years. The idea is to give entrepreneurs (clinicians, engineers, designers, business professionals) a realistic expectation of the time, money, co-ordination and teamwork required to develop a medical device in India. This book includes case studies, anecdotes, caricatures and a special “how I do it” section at the end of the book that gives step-by-step guidelines on how to identify a need, make clinical observations, create need statements, perform needs filtering, develop criteria, conceptualize a solution and take it to a proof of concept. This book is recommended for all Indian healthcare professionals, engineers and product designers who seek to solve unmet clinical challenges with new medical devices, but are unsure of how to go about taking their idea from the concept stage to an actual product. This book illustrates ways for engineers and designers to formally engage with doctors, and gives a comprehensive perspective of the path from ideation to commercialization.

New Medical Devices World Health Organization

For designers of medical devices, the FDA and ISO requirements are extremely stringent. Designers and researchers feel pressure from management to quickly develop new devices, while they are simultaneously hampered by strict guidelines. The Six Sigma philosophy has solved this dichotomous paradigm for organizations in other fields, and seeks to do

Inventing Medical Devices Springer

Energy Efficiency of Medical Devices and Healthcare Facilities provides comprehensive coverage of cutting-edge, interdisciplinary research, and commercial solutions in this field. The authors discuss energy-related challenges, such as energy-efficient design, including renewable energy, of different medical devices from a hardware and mechanical perspectives, as well as energy management solutions and techniques in healthcare networks and facilities. They also discuss energy-related trade-offs to maximize the medical devices availability, especially battery-operated ones, while providing immediate response and low latency communication in emergency situations, sustainability and robustness for chronic disease treatment, in addition to high

protection against cyber-attacks that may threaten patients ' lives. Finally, the book examines technologies and future trends of next generation healthcare from an energy efficiency and management point of view, such as personalized or smart health and the Internet of Medical Things — IoMT, where patients can participate in their own treatment through innovative medical devices and software applications and tools. The books applied approach makes it a useful resource for engineering researchers and practitioners of all levels involved in medical devices development, healthcare systems, and energy management of healthcare facilities. Graduate students in mechanical and electric engineering, and computer science students and professionals also benefit. Provides in-depth knowledge and understanding of the benefits of energy efficiency in the design of medical devices and healthcare networks and facilities Presents best practices and state-of-art techniques and commercial solutions in energy management of healthcare networks and systems Explores key energy tradeoffs to provide scalable, robust, and effective healthcare systems and networks

Contextual Inquiry for Medical Device Design National Academies Press

The intent of this book (MDDR, for short) is to present an introduction to, and overview of, the world of medical device regulation by the United States Food and Drug Administration (FDA), and the relationship of this regulatory scheme to the design and development of medical devices. In providing this information, the book covers the broad range of requirements, which are presented within eight major topics: background and regulatory environment, device design control, nonclinical testing, clinical testing, marketing applications, post-market requirements, quality systems/GMPs, and compliance/enforcement. This book provides students and professionals in the medical device industry with a road map to the regulation of medical devices. It provides a broad understanding of the breadth and depth of medical device regulation by collecting in one textbook coverage of the regulatory scheme for medical devices in terms that are suitable for engineers, scientists, and healthcare providers. The vast amount of information available on the subject is distilled into a concise and coherent presentation. There also are problems and projects at the end of each chapter. In addition to the usual questions requiring specific answers, the projects include the drafting of a device control plan, the development of a nonclinical test procedure, the resolution of a recall, the response to a Warning Letter, and the creation of a CAPA for a device deficiency. A solutions manual for these exercises is available to teachers who adopt the textbook for classroom use or for employee training. Medical Device Design and Regulation (MDDR) also makes available over 100 complimentary live hyperlinks to web pages with additional relevant information, and offers users the opportunity to join and participate in the " MDDR Users Group " on LinkedIn.

Technological Innovation Academic Press

New Frontiers in Medical Device Technology offers the engineering, medical, and business communities an up-to-date report on current and emerging medical technologies. This timely and authoritative book brings together a core of experts who provide comprehensive coverage of new medical device technologies and focuses on the link between the engineering and medical aspects. Relevant engineering principles are reviewed before focusing on the state-of-the-art technologies and their applications. For engineers, this book will provide knowledge of the needs, applications, and biological effects of medical devices and thus point the way

toward new opportunities for engineering solutions. Members of the medical community will gain an understanding of the engineering concepts applied to medical devices and their most recent applications. Business and legal professionals will acquire a better understanding of medical technology and its enormous market potential.

Medical Device Innovation Handbook CRC Press

The first wide-ranging analysis of business trends in the manufacturing segment of the health care industry.

The Innovation and Evolution of Medical Devices Springer Nature

The objective of the compendium series of innovative medical devices, assistive devices and eHealth solutions is to provide a neutral platform for technologies which are likely to be suitable for use in less resourced settings. It presents a snapshot of several health technologies which might have the potential to improve health outcomes and the quality of life, or to offer a solution to an unmet medical/health technology need. It is released to acknowledge some success stories and at the same time, to raise awareness of the pressing need for appropriate and affordable design solutions and to encourage more innovative efforts in the field. This effort also aims to encourage greater interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics and the general public to ensure greater investment in health technology and to move towards universal access to essential health technologies. This volume now includes 127 technologies from 36 countries on the following areas: assistive devices, basic equipment for health facilities, devices for infectious diseases and for infection prevention, healthcare management, medical imaging, laboratory, monitoring, non-communicable diseases, reproductive, maternal, neonatal and child health, respiratory support and surgery.

New Medical Devices CRC Press

A short handbook for the medical device innovator who wishes to understand the innovation process for new medical devices.

Purchasing Medical Innovation Academic Press

This text provides a central resource for physicians, entrepreneurs, and the MBA students about how innovation occurs in medical device industry. The book uses the rise and fall of vaginal mesh kits to highlight the evolution of responses by the physicians, patients and the regulatory bodies. There are specific chapters reviewing the US regulatory issues and business practices that were consequential to withdrawal of most vaginal mesh kits from the US market. The book is meant to be concise, evidence-based, and practical for the first time readers to understand the innovation forces. Concise textual information from acknowledged experts is complemented by high-quality diagrams and images to provide a thorough update of this rapidly evolving medical device industry. The case study chapters fully elucidate the anatomical basis that led to conceptualization of vaginal mesh kits, their introduction into the market, medicolegal and business implications followed with innovation that occurred by the surgeons to utilize ultrasound for and innovative surgeries to overcome device complications. With a luxurious number of well-marked pictures, readers will gain a clear understanding of the medical device innovation and evolution. Innovation

and Evolution of Medical Devices: The vaginal Mesh Kits provides a rich practical resource written in a simple a step-by- step approach for all readers in their approach to new medical devices and technologies.

Class 1 Devices National Academies Press

The rapid growth of home health care has raised many unsolved issues and will have consequences that are far too broad for any one group to analyze in their entirety. Yet a major influence on the safety, quality, and effectiveness of home health care will be the set of issues encompassed by the field of human factors research-the discipline of applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments. To address these challenges, the National Research Council began a multidisciplinary study to examine a diverse range of behavioral and human factors issues resulting from the increasing migration of medical devices, technologies, and care practices into the home. Its goal is to lay the groundwork for a thorough integration of human factors research with the design and implementation of home health care devices, technologies, and practices. On October 1 and 2, 2009, a group of human factors and other experts met to consider a diverse range of behavioral and human factors issues associated with the increasing migration of medical devices, technologies, and care practices into the home. This book is a summary of that workshop, representing the culmination of the first phase of the study.

Medical Devices CRC Press

Medical Device Safety: The Regulation of Medical Devices for Public Health and Safety examines the prospects for achieving global harmonization in medical device regulation and describes a possible future global system. Unresolved difficulties are discussed while solutions are proposed. An essential book for all those involved in health physics, en

Design Innovation for Health and Medicine Springer Science & Business Media

In the past 50 years the development of a wide range of medical devices has improved the quality of people's lives and revolutionized the prevention and treatment of disease, but it also has contributed to the high cost of health care. Issues that shape the invention of new medical devices and affect their introduction and use are explored in this volume. The authors examine the role of federal support, the decision-making process behind private funding, the need for reforms in regulation and product liability, the effects of the medical payment system, and other critical topics relevant to the development of new devices.

MED-CHAINS & COVID – 19: Innovative Solutions for Pandemics E&E Medicals

As developed economies enter a period of slower growth, emerging economies such as India have become prime examples of how more can be achieved with less. Bringing together experience and expertise from across the healthcare industry, this book examines innovations that can bring about real advances in the healthcare industry. Innovations in H

Medical Device Design and Regulation Academic Press

WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas: * policy framework for health technology * medical device regulations * health technology assessment * health technology management * needs assessment of medical devices * medical device procurement * medical equipment donations * medical equipment inventory management * medical equipment maintenance * computerized maintenance management systems * medical device data * medical device nomenclature * medical devices by health-care setting * medical devices by clinical procedures * medical device innovation, research and development. These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. The number of countries with existing health technology policies and with units to implement those policies shows that there is forward movement in the development and implementation of health technology policies. However, because medical devices are complex to select, manage and use, it is important to ensure that new policies are developed appropriately and existing ones are modified as necessary to make them as effective as possible. Proper integration of health technology policies and strategies within the framework of a national health plan has the potential to harness the political support to ensure improved access, quality and use of medical devices, enhance the best use of the resources in a framework of universal coverage, respond to the needs of the population, and ultimately achieve better health outcomes.

Medical Device Design Notion Press

Design Innovation for Health and Medicine offers an innovative approach for solving complex healthcare issues. In this book, three design experts examine a range of case studies to explain how design is used in health and medicine—exploring issues such as diverse patient needs, an ageing population and the impact of globalisation on disease. These case studies, along with high-profile industry projects conducted by the authors over the past decade, inform a novel framework for designing and implementing innovative solutions in this context. The book aims to assist designers, medical engineers, clinicians and researchers to shape the next era of healthcare.

Biodesign Academic Press

This book offers all countries a guide to implementing verification systems for medical devices to ensure they satisfy their regulations. It describes the processes, procedures and need for integrating medical devices into the legal metrology framework, addresses their independent safety and performance verification, and highlights the associated

savings for national healthcare systems, all with the ultimate goal of increasing the efficacy and reliability of patient diagnoses and treatment. The book primarily focuses on diagnostic and therapeutic medical devices, and reflects the latest international directives and regulations. Above all, the book demonstrates that integrating medical devices into the legal metrology system and establishing a fully operational national laboratory for the inspection of medical devices could significantly improve the reliability of medical devices in diagnosis and patient care, while also reducing costs for the healthcare system in the respective country.

Managed Care and the Evaluation and Adoption of Emerging Medical Technologies National Academies

Recognize market opportunities, master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. Outlining a systematic, proven approach for innovation - identify, invent, implement - and integrating medical, engineering, and business challenges with real-world case studies, this book provides a practical guide for students and professionals.

Energy Efficiency of Medical Devices and Healthcare Applications Cambridge University Press

The Food and Drug Administration (FDA) is responsible for assuring that medical devices are safe and effective before they go on the market. As part of its assessment of FDA's premarket clearance process for medical devices, the IOM held a workshop June 14-15 to discuss how to best balance patient safety and technological innovation. This document summarizes the workshop.

Medical Device Safety World Health Organization

Updated third edition of the authoritative textbook on business models and trends in the tech sectors of the healthcare industry.