

Innovative Medical Device Solutions

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Medical Devices and Ehealth Solutions Lulu.com
This step-by-step guide to medical technology innovation, now in full color, has been rewritten to reflect recent trends of industry globalization and value-conscious healthcare. Written by a team of medical, engineering, and business experts, the authors provide a comprehensive resource that leads students, researchers, and entrepreneurs through a proven process for the identification, invention, and implementation of new solutions. Case studies on innovative products from around the world, successes and failures, practical advice, and end-of-chapter 'Getting Started' sections encourage readers to learn from real projects and apply important lessons to their own work. A wealth of additional material supports the book, including a collection of nearly one hundred videos created for the second edition, active links to external websites, supplementary appendices, and timely updates on the companion website at ebiodesign.org. Readers can access this material quickly, easily, and at the most relevant point in the text from within the ebook.

Innovation in the Polish health sector: A quality assessment
Cambridge University Press
This book provides caregivers and administrators with high-quality support for strategic decision making in the selection and use of medical devices so as to ensure value optimization. Medical treatment is increasingly complex, with wide application of medical devices and corresponding involvement of physics and engineering. A multidisciplinary methodology that brings together expertise from key disciplines in a holistic, system-oriented approach is essential in controlling this complexity and further improving health care. This

book will help readers to understand the design, validation, and application of medical devices and the standards and regulations that apply to them across the world. In addition, it provides technical, operational, and economic perspectives on their use. The relevance of concepts such as expenditure optimization and sustainability to medical device technology is explained and healthcare reimbursement systems are discussed from different points of view. Readers will gain a clear appreciation of the managerial and economic implications of the use of medical devices and how to get the most out of them. Academic research, industrial experiences, and case studies are presented as appropriate.

Key Supply Chain Integration Factors for Success of Medical Device Startups Lippincott Williams & Wilkins
Assurance of Sterility for Sensitive Combination Products and Materials: New Paradigms for the Next Generation of Medical Devices and Pharmaceuticals discusses the medical device industry and existing challenges regarding the exciting new world of sensitive combination products (SCPs) and their terminal sterilization. This book reassesses the current assumptions to assure the patient's best interests are met in the development of increasingly rigorous sterilization methods used to counteract MRSA and other 'super-bugs'. In addition, the book discusses the special challenges faced with implantable medical devices, sterilization requirements and further methods needed for material selection and the design process. This book is unique in taking a holistic, end-to-end approach to sterilization, with a particular focus on materials selection and product design. Introduces sterilization principles at the material selection and design stages Addresses the industry need for new sterilization processes for new medical devices and biomaterials Provides guidance to select the appropriate sterilization technique for newly developed sensitive combination

products Examines forward thinking tactics for matching new developments in material compatibility with possible regulatory and QSR strategies
Engineering Open-Source Medical Devices Routledge
Updated third edition of the authoritative textbook on business models and trends in the tech sectors of the healthcare industry.
Medical Devices Cambridge University Press
One of the cornerstones of the Universal Health Coverage (UHC) initiative is access to essential medicines and health technologies. Medical devices, assistive devices and eHealth solutions are important components of health technology which have the potential to save lives and improve quality of life and well-being. However, too many people worldwide suffer because they don't have access to high quality, affordable health technology with the problem being more acute in low- and middle-income countries. 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 encourages 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. All submissions to the "Call for

innovative health technologies for low-resource settings" underwent an evaluation process; technologies were assessed by an expert panel based on the material and evidence provided by the applicant as well as publicly available information. In 2013, unlike previous years, inclusion in the Compendium for medical devices was restricted to commercialized products with regulatory approval. Note that for a selected technology, the inclusion in the compendium does not constitute a warranty for fitness of the technology for a particular purpose. All innovative solutions in the compendium are presented in one page summarizing the health problem addressed, the proposed solution and product specifications, based on data, information, and images provided by the developers of the technologies concerned.

Biodesign wil keesee

Provides a comprehensive review of all types of medical therapeutic delivery solutions from traditional pharmaceutical therapy development to innovative medical device therapy treatment to therecent advances in cellular and stem cell therapy development • Provides information to potentially allow future development of treatments with greater therapeutic potential and creativity • Includes associated regulatory requirements for the development of these therapies • Provides a comprehensive developmental overview on therapeutic delivery solutions • Provides overview information for both the general reader as well as more detailed references for professionals and specialists in the field

Modern Methods of Clinical Investigation

IGI Global

Digital Innovation for Healthcare in COVID-19 Pandemic: Strategies and Solutions provides comprehensive knowledge and insights on the application of information technologies in the healthcare sector, sharing experiences from leading researchers and academics from around the world. The book presents innovative ideas, solutions and examples to deal with one of

the major challenges of the world, a global problem with health, economic and political dimensions. Advanced information technologies can play a key role in solving problems generated by the COVID-19 outbreak. The book addresses how science, technology and innovation can provide advances and solutions to new global health challenges. This is a valuable resource for researchers, clinicians, healthcare workers, policymakers and members of the biomedical field who are interested in learning how digital technologies can help us avoid and solve global disease dissemination. Presents real-world cases with experiences of applications of healthcare solutions during the pandemic of COVID-19 Discusses new approaches, theories and tools developed during an unprecedented health situation and how they can be used afterwards Encompasses information on preparedness for future outbreaks to make less costly and more effective healthcare responses to crises

Engineering in Medicine E&E Medicals

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

International Trade and Pharmaceuticals John Wiley & Sons

Engineering in Medicine: Advances and Challenges documents the historical development, cutting-edge research and future perspectives on applying engineering technology to medical and healthcare challenges. The book has 22 chapters under 5 sections: cardiovascular engineering, neuroengineering, cellular and molecular bioengineering, medical and biological imaging, and medical devices. The challenges and future perspectives of engineering in medicine are discussed, with novel methodologies that have been implemented in

innovative medical device development being described. This is an ideal general resource for biomedical engineering researchers at both universities and in industry as well as for undergraduate and graduate students. Presents a broad perspective on the state-of-the-art research in applying engineering technology to medical and healthcare challenges that cover cardiovascular engineering, neuroengineering, cellular and molecular bioengineering, medical and biological imaging, and medical devices Presents the challenges and future perspectives of engineering in medicine Written by members of the University of Minnesota's prestigious Institute of Engineering in Medicine (IEM), in collaboration with other experts around the world

Medical Technology in Japan Academic Press

Japan is suffering from a "device gap." Compared to its American and European counterparts, Japan lags in adopting innovative medical devices and making new treatments and procedures available to its patients. Many blame its government and bureaucracy for Japan's delayed access to modern medicine and new medical devices. Christa Altenstetter examines the contextual social, historical, and political conditions of Japan's medical field to make sense of the state of the country's medical profession and its regulatory framework. She explores the development of regulatory frameworks and considers possibilities for eventual reform and modernization. More specifically, Altenstetter looks into how physicians and device companies connect to the government and bureaucracy, the relationships connecting Japanese patients to their medical system and governmental bureaucracy, and how the relationships between policymakers and the medical profession are changing. The issues addressed here are becoming increasingly relevant as numerous countries in Asia, Latin America, and Central and Eastern Europe are

only now beginning to regulate medical technology, following the lead of the US and the European Union. Those interested in global medicine and Asian studies will find this book both informative and compelling.

Managing Medical Technological Innovations:

Exploring Multiple Perspectives Elsevier
Prior research has shown that some patients and caregivers such as relatives are innovating in relation to their unmet medical needs. However, there is little evidence whether and how these ideas are later implemented into market-ready solutions and subsequently commercialized. We analyze cases of patients and their caregivers becoming user entrepreneurs - persons who develop and market medical devices according to their own and/or their relatives' needs. We apply the framework of opportunity recognition and exploitation and conduct 14 case studies with medical device developers who have successfully brought their product to market. Our findings show that these innovation opportunities were mostly recognized during time-consuming and exhausting daily routines when no suitable medical device or other solutions were present. In 12 cases, the inventor founded a company to commercialize a product; in the remaining two cases, the idea was licensed after IP was secured. In all cases, the innovation had significant impacts on the quality of lives of the patients and, in case of caregivers, on both the patients and relatives. Since technical knowledge was not present in most cases, knowledgeable friends and relatives were consulted and often integrated into the product development. The most prevalent motivation for further development and diffusion turned out to be the aspiration to validate the product idea and to deliver the benefits to others with the same ailment. This finding on innovation's social component complements current research on lead-users, as the solution of one's own problem was previously regarded as the key motivation.

One major constraint to diffusing a medical device are regulations in the healthcare sector. Ten of 14 products in our sample were approved medical devices, with five classified as a higher-risk products and five as lower-risk products. We observe that patients and caregivers who recognize and exploit their ideas in the medical devices market did so despite particularly high market entry barriers in this sector. Few patients and caregivers were capable to bring even higher-risk medical devices to the market. This is unsurprising, because neither patients nor caregivers are experienced or trained to go through these time-consuming, demanding, and sometimes costly procedures. Healthcare companies should establish measures to support innovative patients and to systematically integrate them into their innovation processes.

Medical Device Companies Directory Book 2015 Academic Press

This review highlights achievements of the Mexican Institute of Social Security (Instituto Mexicano del Seguro Social, IMSS) in a number of areas - human resources, technological capacities and relations with suppliers - previously identified by the OECD as pivotal for the successful reform of IMSS
Compendium of Innovative Health Technologies for Low-Resource Settings National Academies Press

This book focuses on the challenges and potentials of open source and collaborative design approaches and strategies in the biomedical field. It provides a comprehensive set of good practices and methods for making these safe, innovative and certifiable biomedical devices reach patients and provide successful solutions to healthcare issues. The chapters are sequenced to follow the complete lifecycle of open source medical technologies. The information provided is eminently practical, as it is supported by real cases of study, in which collaboration among medical

professionals, engineers and technicians, patients and patient associations, policy makers, regulatory bodies, and citizens has proven beneficial. The book is also supported by an online infrastructure, UBORA, through which open-source medical devices can be collaboratively developed and shared for the democratization of medical technology and for promoting accessible biomedical engineering education.

Medical Device Design for Six Sigma IOS Press
Handbook of the Management of Creativity and Innovation: Theory and Practice is a collection of theories and practices for the effective management of creativity and innovation, contributed by a group of European experts from the fields of psychology, education, business, engineering, and law. Adopting an interdisciplinary and intercultural approach, this book offers rich perspectives – both theoretical and practical – on how to manage creativity and innovation effectively in different domains and across cultures. This book appeals to students, teachers, researchers, and managers who are interested in creative and innovative behavior, and its management. Although the authors are from the fields of psychology education, business, engineering, and law, readers from all disciplines will find the coverage of this book beneficial in deepening their understanding of creativity and innovation, and helping them to identify the right approaches for managing creativity and innovation in an intercultural context.

Securities Law & Practice AuthorHouse
Innovate The Way You Were Designed To is an eye-opening look into the world of design and innovation from the perspective of first understanding how our human cognitive powers work when it comes to creative thought. Filled with anecdotes from 30 years of past experience, this book gives concrete examples of experiences from the

design and development world. Learning about the author's path from art to medical device design puts a perspective around the basis for the book, and creates a strong connection between the intentional use of both sides of our brains and successful innovative outcomes in our design engineering innovation attempts. Utilizing our brain's inherent ability to create by understanding how it operates is the key thesis to the practical, step by step, process laid out in the book. The process is broken down into practical phases that act as a simple framework for any development project, with safeguards, best practices, and tested methodologies that will set the readers up for successful innovation projects of their own. The encouragement from this book is to get out there and use your inherent abilities to innovate and contribute to making this world a better place in your own unique way.

WHO Compendium of Innovative Health Technologies for Low-Resource Settings 2011-2014 Academic Press
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

Energy Efficiency of Medical Devices and Healthcare Applications Medical Devices and Ehealth Solutions Medical devices and eHealth solutions have the potential to save lives. However too many worldwide suffer because they don't have access to appropriate health care technology. The compendium series of innovative medical devices and eHealth solutions has been created as a neutral platform for technologies which are likely to be suitable for use in low-resource settings. It presents a snapshot of several health technologies which might have the potential to improve health outcomes or to offer a solution to an unmet medical need in low-resource settings. The compendium specifically focuses on showcasing innovative technologies that are not yet widely available in developing countries. It is released to encourage the dialogue between ministries of health procurement officers donors technology developers manufacturers clinicians academics and the general public. In doing so WHO aims at raising awareness of the pressing need for appropriate and affordable design solutions and for further development and technology dissemination. All submissions to the Call for innovative health technologies for low-resource settings underwent an evaluation process; technologies were assessed by an expert panel

based on the material and evidence provided by the applicant as well as publicly available information. Note that for a selected technology the inclusion in the compendium does not constitute a warranty for fitness of the technology for a particular purpose. Technologies in the compendium are presented in one page summarizing the health problem addressed the proposed solution and product specifications based on data and information provided by the developers of the technologies concerned. Compendium of Innovative Health Technologies for Low-Resource Settings One of the cornerstones of the Universal Health Coverage (UHC) initiative is access to essential medicines and health technologies. Medical devices, assistive devices and eHealth solutions are important components of health technology which have the potential to save lives and improve quality of life and well-being. However, too many people worldwide suffer because they don't have access to high quality, affordable health technology with the problem being more acute in low- and middle-income countries. 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 encourages 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. All submissions to the "Call for innovative health technologies for low-resource settings" underwent an evaluation process; technologies were assessed by an expert panel based on the material and evidence provided by the applicant as well as publicly available

information. In 2013, unlike previous years, inclusion in the Compendium for medical devices was restricted to commercialized products with regulatory approval. Note that for a selected technology, the inclusion in the compendium does not constitute a warranty for fitness of the technology for a particular purpose. All innovative solutions in the compendium are presented in one page summarizing the health problem addressed, the proposed solution and product specifications, based on data, information, and images provided by the developers of the technologies concerned. The Business of Healthcare Innovation

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.

German Medical Data Sciences: Shaping Change - Creative Solutions for Innovative Medicine SAGE
This brochure illustrates a project promoted by Korean medical device companies wanting to develop

a presence in global market with support from Korean government. Inside you will find how Korean medical device companies are reliable partners for global collaboration.

Springer

Managing Medical Devices within a Regulatory Framework helps administrators, designers, manufacturers, clinical engineers, and biomedical support staff to navigate worldwide regulation, carefully consider the parameters for medical equipment patient safety, anticipate problems with equipment, and efficiently manage medical device acquisition budgets throughout the total product life cycle. This contributed book contains perspectives from industry professionals and academics providing a comprehensive look at health technology management (HTM) best practices for medical records management, interoperability between and among devices outside of healthcare, and the dynamics of implementation of new devices. Various chapters advise on how to achieve patient confidentiality compliance for medical devices and their software, discuss legal issues surrounding device use in the hospital environment of care, the impact of device failures on patient safety, methods to advance skillsets for HTM professionals, and resources to assess digital technology. The authors bring forth relevant challenges and demonstrate how management can foster increased clinical and non-clinical collaboration to enhance patient outcomes and the bottom line by translating the regulatory impact on operational requirements. Covers compliance with FDA and CE regulations, plus EU directives for service and maintenance of medical devices Provides operational and clinical practice recommendations in regard to regulatory changes for risk management Discusses best

practices for equipment procurement and maintenance Provides guidance on dealing with the challenge of medical records management and compliance with patient confidentiality using information from medical devices

Handbook Of The Management Of Creativity And Innovation: Theory And Practice WIPO

This working paper aims to present the specifics of innovation in the Polish health industry through the prism of the experiences and opinions of a representative group of 42 companies from both the pharmaceutical and medtech sectors. Through analysis of in-depth interviews, it aims to illuminate the legal, economic and social mechanisms and phenomena that determine innovation in this sector. The survey examines which areas of the Polish health sector are most innovative, the understanding of innovation that prevails in the sector, and the characteristics of R&D activities carried out there. Subsequently, the study explores the general impact of intellectual property, and particularly of patent law on innovation, in the Polish health sector. Finally, it surveys the other economic and legal instruments currently stimulating innovation and how legal regulations and governmental policy could be modified to create an optimal pro-innovation environment. The conclusions include short legal and factual background of innovation in the Polish health sector, the summarized results of the conducted analysis and final comments concerning the level and culture of innovation within the examined industry.