Innovative Medical Device Solutions

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The Business of Healthcare Innovation CRC Press
Americans praise medical technology for saving lives and improving health. Yet, new technology is often cited as a key factor in skyrocketing medical costs. This volume, second in the Medical Innovation at the Crossroads series, examines how economic incentives for innovation are changing and what that means for the future of health care. Up-to-date with a wide variety of examples and case studies, this book explores how payment, patent, and regulatory policiesâ€"as well as the involvement of numerous government agenciesâ€"affect the introduction and use of new pharmaceuticals, medical devices, and surgical procedures. The volume also includes detailed comparisons of policies and patterns of technological innovation in Western Europe and Japan. This fact-filled and practical book will be of interest to economists, policymakers, health administrators, health care practitioners, and the concerned public.

New Medical Devices National Academies
This book explains all of the stages involved in developing medical devices; from concept to medical approval including system engineering, bioinstrumentation design, signal processing, electronics, software and ICT with Cloud and e-Health development. Medical Instrument Design and Development offers a comprehensive theoretical background with extensive use of diagrams, graphics and tables (around 400 throughout the book). The book explains how the theory is translated into industrial medical products using a market-sold Electrocardiograph disclosed in its design by the Gamma Cardio Soft manufacturer. The sequence of the chapters reflects the product development lifecycle. Each chapter is focused on a specific University course and is divided into two sections: theory and implementation. The theory sections explain the main concepts and principles which remain valid across technological evolutions of medical instrumentation. The Implementation sections show how the theory is translated into a medical product. The Electrocardiograph (ECG or EKG) is used as an example as it is a suitable device to explore to fully understand medical instrumentation since it is sufficiently simple but encompasses all the main areas involved in developing medical electronic equipment. Key Features: Introduces a system-level approach to product design Covers topics such as bioinstrumentation, signal processing, information theory, electronics, software, firmware, telemedicine, e-Health and medical device certification Explains how to use theory to implement a market product (using ECG as an example) Examines the design and applications of main medical instruments Details the additional know-how required for product implementation: business context, system design, project management, intellectual property rights, product life cycle, etc. Includes an accompanying website with the design of the certified ECG product (www.gammacardiosoft.it/book) Discloses the details of a marketed ECG Product (from Gamma Cardio Soft) compliant with the ANSI standard AAMI EC 11 under open licenses (GNU GPL, Creative Common) This book is written for biomedical engineering courses (upper-level undergraduate and graduate students) and for engineers interested in medical instrumentation/device design with a comprehensive and interdisciplinary system perspective.

Class 1 Devices National Academies Press
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

Engineering Open-Source Medical Devices National Academies Press
Contextual Inquiry for Medical Device Design helps users understand the everyday use of medical devices and the way their usage supports the development of better products and increased market acceptance. The text explains the concept of contextual inquiry using real-life examples to illustrate its application. Case studies provide a frame of reference on how contextual inquiry is successfully used during product design, ultimately producing safer, improved medical devices. Presents the ways contextual inquiry can be used to inform the evaluation and business case of technology Helps users understand the everyday use of medical devices and the way their usage supports the development of better products Includes case studies that provide a frame of reference on how contextual inquiry is successfully used during the product design process

Compendium of Innovative Health Technologies for Low-Resource Settings (PDF) Notion Press
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.

Clinical Evaluation of Medical Devices CRC Press
Evidence suggests that medical innovation is becoming increasingly dependent on interdisciplinary research and on the crossing of institutional boundaries. This volume focuses on the conditions governing the supply of new medical technologies and suggest that the boundaries between disciplines, institutions, and the private and public sectors have been redrawn and reshaped. Individual essays explore the nature, organization, and management of interdisciplinary R&D in medicine; the introduction into clinical practice of the laser, endoscopic innovations, cochlear implantation, cardiovascular imaging technologies, and synthetic insulin; the division of innovating labor in biotechnology; the government- industry-university interface; perspectives on industrial R&D management; and the growing intertwining of the public and proprietary in medical technology.

Medical Innovation Springer Science & Business Media
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

Medical Devices World Health Organization
The Case Studies in Medical Devices Design series consists of practical, applied case studies relating to medical device design in industry. These titles complement Ogrodnik's Medical Device Design and will assist engineers with applying the theory in practice. The case studies presented directly relate to Class I, Class IIa, Class IIb and Class III medical devices. Designers and companies who wish to extend their knowledge in a specific discipline related to their respective class of operation will find any or all of these titles a great addition to their library. Class 1 Devices is a companion text to Medical Devices Design: Innovation from Concept to Market. The intention of this book, and its sister books in the series, is to support the concepts presented in Medical Devices Design through case studies. In the context of this book the case studies consider Class I (EU) and 510(k) exempt (FDA) . This book covers classifications, the conceptual and embodiment phase, plus design from idea to PDS. These titles will assist anyone who is working in the medical devices industry or who is studying biomedical subject areas to design a successful medical device and avoid repeating past mistakes. Written by an experienced medical device engineer and entrepreneur, with real world experience of developing and commercializing medical products. Joins up theory and practice in an accessible style.

Public Health Effectiveness of the FDA 510(k) Clearance Process Springer Nature
Medical devices and eHealth solutions have the potential to save lives. However, too many worldwide suffer because they do not 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. 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.

New Medical Devices National Academies Press
Medical Innovation: Concept to Commercialization is a practical, step-by-step approach on how to move a novel concept through development to realize a commercially successful product. Real-world experience cases and knowledgeable contributors provide lessons that cover the practices of diverse organizations and multiple products. This important reference will help improve success and avoid innovation failure for translational researchers, entrepreneurs, medical school educators, biomedical engineering students and faculty, and aspiring physicians. Provides multiple considerations and comprehensive lessons from varied organizations, researchers and products Designed to help address topics that improve success and avoid the high cost of innovation failure Recommends the practical steps needed to move a novel, non-developed concept into a tangible, realistic and commercially successful product

MED-CHAINS & COVID – 19: Innovative Solutions for Pandemics Academic Press
The first wide-ranging analysis of business trends in the manufacturing segment of the health care industry.

Purchasing Medical Innovation OECD Publishing
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.

Energy Efficiency of Medical Devices and Healthcare Applications National Academies Press

As in other areas of technological advance, the benefits of new medical devices are not without cost and raise many issues for study. We know that certain medical devices, such as the computed tomographic scanner, have reduced the net cost of treating som diseases. But how are other new technologies related to the rising cost of health care, and how can we ensure the most cost-effective use of new equipment? How can we promote innovation in medical technologies when the trends in the judical application of tort law have made industries hesitant to develop products for which profits may be modest and liabilities severe? The symposium considered topics in three general areas, which make up the three major devisions of this volume. These topics are 1) innovation and use of new medical devices; 2) current trends in federal and private support of technological innovation, medical device regulation, product liability, and health care reimbursement; and 3) several perspectives on how these trends interact to influence the availability and appropriate use of new medical devices.

The Innovation and Evolution of Medical Devices Cambridge University 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

Biodesign Univ of California Press

Medical Device Technologies introduces undergraduate engineering students to commonly manufactured medical devices. It is the first textbook that discusses both electrical and mechanical medical devices. The first 20 chapters are medical device technology chapters; the remaining eight chapters focus on medical device laboratory experiments. Each medical device chapter begins with an exposition of appropriate physiology, mathematical modeling or biocompatibility issues, and clinical need. A device system description and system diagram provide details on technology function and administration of diagnosis and/or therapy. The systems approach lets students quickly identify the relationships between devices. Device key features are based on five applicable consensus standard requirements from organizations such as ISO and the Association for the Advancement of Medical Instrumentation (AAMI). The medical devices discussed are Nobel Prize or Lasker Clinical Prize winners, vital signs devices, and devices in high industry growth areas Three significant Food and Drug Administration (FDA) recall case studies which have impacted FDA medical device regulation are included in appropriate device chapters Exercises at the end of each chapter include traditional homework problems, analysis exercises, and four questions from assigned primary literature Eight laboratory experiments are detailed that provide hands-on reinforcement of device concepts

The Role of Human Factors in Home Health Care Cambridge University 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 Springer

One of the cornerstones of the Universal Health Coverage (UHC) initiative is access to essential medicines andhealth technologies. Medical devices assistive devices and eHealth solutions are important components ofhealth 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 technologywith 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 solutionsis to provide a neutral platform for technologies which are likely to be suitable for use in less resourcedsettings. It presents a snapshot of several health technologies which might have the potential to improvehealth 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 pressingneed 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 greaterinvestment 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 anevaluation process; technologies were assessed by an expert panel based on the material and evidenceprovided by the applicant as well as publicly available information. in 2013 unlike previous years inclusion inthe 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 forfitness of the technology for a particular purpose. All innovative solutions in the compendium are presented in one page summarizing the health problemaddressed the proposed solution and product specifications based on data information and images providedby the developers of the technologies concerned.

Outlook for Medical Technology Innovation National Academies Press

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.

Design Innovation for Health and Medicine John Wiley & Sons

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.

Sources of Medical Technology Lulu.com

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.