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Biodesign Cambridge University Press
Hearing on technological advances in the field of medical devices from the perspective of the Food & Drug Admin. (FDA), as well as from patients & providers. Witnesses: Michael Friedman, Bruce Burlington, & Susan Alpert, FDA; John F. Hansbrough, Dir. of the Regional Burn Center, UCSD Medical Center; C. Warren Olanow, Chairman, Dept. of Neurology, Mount Sinai Medical Center; Robert A. Schmidt, Dir. of Mammography, Univ. of Chicago Hospitals; Joseph M. Smith, Asst. Prof. of Medicine, Washington University School of Medicine; & Joy Vaas. Also includes prepared statement submitted by Nonprescription Drug Manufacturers Assoc .

Medical Device Design Lulu.com
The objective of the workshop that is the subject of this summary report was to present the challenges and opportunities for medical devices as perceived by the key stakeholders in the field. The agenda, and hence the summaries of the presentations that were made in the workshop and which are presented in this summary report, was organized to first examine the nature of innovation in the field and the social and economic infrastructure that supports such innovation. The next objective was to identify and discuss the greatest unmet clinical needs, with a futuristic view of technologies that might meet those needs. And finally, consideration was given to the barriers to the application of new technologies to meet clinical needs.

Innovations in Healthcare Management
National Academies 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
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.

Medical Devices **Notion Press**
Background papers 1 to 9 published as technical documents. Available in separate records from WHO/HSS/EHT/DIM/10.1 to WHO/HSS/EHT/DIM/10.9

Innovation and Invention in Medical Devices
World Health Organization
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

Outlook for Medical Technology Innovation Academic Press
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 in this convenient handbook for the first time. The Medical Device R&D Ha

Design Innovation for Health and Medicine **E&E Medicals**

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.

New Medical Devices CRC 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.

Case Studies of Innovative Medical Device Companies from India Academic 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.

Energy Efficiency of Medical Devices and Healthcare Applications Springer Nature

Given that medical devices in India tend to be imported (75%), it is important to understand local attempts at innovation in this space. Based largely on interviews, we have prepared case studies of six local innovative device companies. The innovators' efforts have been enabled by close linkages with doctors, with awareness of scientific and technological advances internationally and with trying to meet the regulatory requirements of Western nations. Some of the challenges they face include the lack of product specification guidance by the Indian regulators or institutional health care payers and the absence of Health Technology Assessment. Some of the steps that would help include a larger and better equipped national regulatory body, medical guidelines that facilitate market assess of innovative products, continuous medical education, institutionalized health care payers and so on. The firms are pioneering, and have brought out (or will bring out) products that are relevant to the sometimes difficult conditions that prevail in the country.

Public Health Effectiveness of the FDA 510(k) Clearance Process 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.

The Business of Healthcare Innovation CRC Press

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

MED-CHAINS & COVID – 19: Innovative Solutions for Pandemics Createspace Independent Publishing Platform

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

Six Sigma for Medical Device Design 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 the same for the medical devices field. Six Sigma for Medical Device Design is the first book to approach the subject for use in the medical device field. Authored by experienced professionals, it provides a how-to guide to implementing such a program while dispelling commonly held myths regarding deployment and adoption. This volume also links the philosophy with the FDA's Design Control regulation, useful for companies that must be compliant as well as for those in the process of implementing a quality system for design control. For management wishing to launch innovative medical devices as quickly as possible, this text establishes a way to align all levels of the organization to produce a high level of development that is both timely and compliant. It is also an excellent tool for technical and scientific personnel to understand the realities of business and markets and to optimize the product realization process.

Medical Device Safety Cambridge University Press

Medical Device Design: Innovation from Concept to Market, Second Edition 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; this book fills that need. It addresses medical devices' regulatory (FDA and EU) requirements, shows the essential methodologies medical designers must understand to ensure their products meet requirements, and brings together proven

design protocols, thus enabling engineers and medical device manufacturers to rapidly bring new products to the marketplace. This book is unique because it takes the reader through the process of medical device development, from very early stages of conceptualization, to commercialization on the global market. This rare resource can be used by both professionals and newcomers to device design. Provides a reference to standards and regulations that have been updated, including ISO 13485:2016, FDA regulations and the European Medical Device Regulation Includes new case studies in the areas of classifying medical devices, the design process, quality, labeling, instructions for use, and more Presents additional content around software and biocompatibility concerns

Inspection 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

Clinical Evaluation of Medical Devices CRC 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 Devices and the Public's Health National Academies 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.

Engineering Open-Source Medical Devices CRC Press

MED-CHAINS & COVID – 19: Innovative Solutions for Pandemics is the groundbreaking new book by Dr. Eyong, offering the medical community new insight into COVID-19 and previous pandemics. Rather than quarreling over the inadequacies and inconsistencies of current pandemic practices, Dr. Eyong ' s new book offers his tangible and innovative solutions on how to approach, analyze and handle a pandemic crisis. His thoroughly researched approach to pandemics employs the expertise of respected medical researchers, acclaimed scientists, and innovative medical device developers across the industry. By employing their combined medical wisdom, Dr. Eyong provides feasible solutions for preparing, managing, and the ultimate goal of preventing a pandemic, such as COVID-19, from occurring in the future. This book will be available in ten languages: English, French, Spanish, German, Portuguese, Chinese, Russian, Arabic, Latin, and Japanese.