Innovative Medical Device Solutions

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Outlook for Medical Technology Innovation National Academies Press
Understanding Medical Devices: An introduction to the medical device industry throws light on the meaning of medical devices and the effects that the global trends have on their usage and demand. It informs about the research that is aimed at improving the medical devices and the various solutions to overcome the barriers in the choosing of medical devices. The book makes the readers understand the various guidelines for medical device donations and throws light on the importance of public health in this sector. Also discussed in the book are the examples of various medical devices, the essential principles of safety and performance, the use of standards by the regulatory bodies, the various phases of medical device development, the responsible entity for the medical devices and the way the medical device industry has globalized.

The Changing Economics of Medical Technology National Academies Press
A short handbook for the medical device innovator who wishes to understand the innovation process for new medical devices.

Engineering Open-Source Medical Devices Arcler Press
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.

Understanding Medical Devices: an Introduction to the Medical Device Industry National Academies Press
Updated third edition of the authoritative textbook on business models and trends in the tech sectors of the healthcare industry.

Medical Device Design and Regulation CRC 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

Innovation and Invention in Medical Devices Academic Press
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.

The Innovation and Evolution of Medical Devices CRC 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
Contextual Inquiry for Medical Device Design IOS Press
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 Device Innovation Handbook National Academies Press
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.
Medical 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
Technological Innovation Academic 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
Clinical Evaluation of Medical Devices Springer Nature
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.
Development of Medical Device Policies National Academies Press
Exploring the practical, entrepreneurial, and historical aspects of medical device development, this second edition of The Medical Device R&D Handbook provides a how-to guide for medical device product development. The book offers knowledge of practical skills such as prototyping, plastics selection, and catheter construction, allowing designers to apply these specialized techniques for greater innovation and time saving. The author discusses the historical background of various technologies, helping readers understand how and why certain devices were developed. The text also contains interviews with leaders in the industry who offer their vast experience and insights on how to start and grow successful companies—both what works and what doesn’t work. This updated and expanded edition adds new information to help meet the challenges of the medical device industry, including strategic intellectual property management, operating room observation protocol, and the use of new technologies and new materials in device development.
Biodesign Notion 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.
Public Health Effectiveness of the FDA 510(k) Clearance Process World Health Organization
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. Needs assessment is a complex process, incorporating a number of variables, that provides decision-makers with the information necessary to prioritize and select appropriate

medical devices at a national, regional or hospital level. This document describes and illustrates the objective, the general approach and the process of such a needs assessment. The main section, Specific Approach (Section 4), demonstrates in seven steps how to identify related needs, consider the requirements of baseline information, analyze the gathered information, appraise the options, and prioritize the specific requirements. Tools are being continuously developed to support this decision-making process, and this document also includes information on useful tools that will help in the execution of these steps.

Medical Device Technologies Springer
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

Medical Devices and EHealth Solutions Academic 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.

Inventing Medical Devices Lulu.com
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

The Medical Device R&D Handbook, Second Edition World Health Organization
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. Once established, the inventory serves as the foundation for moving forward within the HTM system and ensuring safe and effective medical equipment. The inventory may be used to develop budgets for capital purchases, maintenance and running costs; to build and support an effective clinical engineering department, by allowing for workshop planning, hiring and training of technical support staff, and establishing and maintaining service contracts; to support an effective medical equipment management program, such as planning preventive maintenance activities and tracking work orders; and to plan the stock of spare parts and consumables. The inventory may also be used to support equipment needs assessment within the health-care facility and to record the purchase, receipt, retirement and discarding of equipment. Facility risk analysis and mitigation, and emergency and disaster planning, are also supported by an inventory.

Medical Device Safety 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.