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.

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.

A Comparative Analysis of Medical Device Regulations in the EU and the USA
This third edition provides a substantial comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure a company's design control program evolves in accordance with current industry practice. It assists in the development of an effective design control program that not only satisfies the US FDA Quality Systems Regulation (QSR) and 13485:2016 standards, but also meets today's Notified Body Auditors' and FDA Investigators' expectations. The book includes a review of the design control elements such as design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations and classes in the US, Canada, and Europe. Practical advice, methods and appendixes are provided to assist with implementation of a compliant design control program and extensive references are provided for further study. This third edition: Examines new coverage of ISO 13485-2016 design control requirements Explores proven techniques and methods for compliance Contributes fresh templates for practical implementation Provides updated chapters with additional details for greater understanding and compliance Offers an easy to understand breakdown of design control requirements Reference to MDSAP design control requirements

**Perspectives in the Development of Mobile Medical Information Systems**

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.

**Healthcare Technology Management Systems**

Perspectives in the Development of Mobile Medical Information Systems: Life Cycle, Management, Methodological Approach and Application discusses System Development Life Cycle (SDLC) thoroughly, focusing on Mobile Healthcare Information Systems (M-HIS). Covering all aspect of M-HIS development, the book moves from modeling, assessment, and design phases towards prototype phase. Topics such as mobile healthcare information system requirements, model identification, user behavior, system analysis and design are all discussed. Additionally, it covers the construction, coding and testing of a new system, and encompasses a discussion on future directions of the field. Based on an existing mobile cardiac emergency system used as a real case throughout the chapters, and unifying and clarifying the various processes and concepts of SDLC for M-HIS, this book is a valuable source for medical informaticians, graduate students and several members of biomedical and medical fields interested in medical information systems. Presents a system development life cycle that can be used for developing different kinds of systems other than health related and also can be used for educational purposes Includes behavioral studies in the system development life cycle to assist in the design of systems with consideration of users' behavior, which is even more important for medical systems Uses a real mobile cardiac emergency system as an example for systems development

**Medical Device Design and Regulation**

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. HTA is the systematic evaluation of properties, effects, and/or impacts of health technology. Its main purpose is to inform technology-related policy-making in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system. It is one of three complementary functions to ensure the appropriate introduction and use of health technology. The other two components are regulation, which is concerned with safety and efficacy, and assessment of all significant intended as well as unintended consequences of technology use; and management, which is concerned with the procurement and maintenance of the technology during its life-cycle. The performance of health systems is strengthened when the linkages and exchange among these elements are clearly differentiated but mutually supportive. This document integrates health technology assessment into the WHO
framework for evidence-informed policy-making. Health systems are strengthened when HTA is integrated into the human and material resources, data, transparent decision-and policy-making, and linked to the overall vision of equity and accountability. Good governance can rely on health technology assessment to provide a policy approach that is accountable for its decisions to the population.

**Medical Devices for Pharmacy and Other Healthcare Professions**

A step-by-step, full-color guide to successful medical technology innovation with a new focus on value-based innovation and global opportunities.

**New Medical Devices**

The goal of this textbook is to provide undergraduate engineering students with an introduction 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 8 chapters are medical device laboratory experiment chapters. 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 enables students to 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). Key Features: 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 Equipment Maintenance Programme Overview**

Practical information about the complexities of biomedical technology and regulation, and their implications for manufacturers and marketers of health care devices. Written primarily for those in the industry concerned about staying competitive in light of complex and fluctuating regulatory approach

**The Medical Device Industry**

First published in 2001: This handbook has been written to give those professionals working in the development and use of medical devices practical knowledge about biomedical technology, regulations, and their relationship to quality health care.

**Weapon Systems**

**Design Controls for the Medical Device Industry, Second Edition**

**Safety Risk Management for Medical Devices**

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 Devices**

This unique and comprehensive outcomes-based Code of Practice is the essential guide needed to plan, commission and provide good quality and effective Technology Enabled Care Services. The Code acts as a quality framework for procurement and provision of services, worldwide.

**Biodesign**

**Handbook of Medical Device Design**

This volume gathers the proceedings of the International Conference on Medical and Biological Engineering, which was held from 16 to 18 May 2019 in Banja Luka, Bosnia and Herzegovina. Focusing on the goal to ‘Share the Vision’, it highlights the latest findings, innovative solutions and emerging challenges in the field of Biomedical Engineering. The book covers a wide range of topics, including: biomedical signal processing, medical physics, biomedical imaging and radiation protection, biosensors and bioinstrumentation, bio-micro/nano technologies, biomaterials, biomechanics, robotics and minimally invasive surgery, and cardiovascular, respiratory and endocrine systems engineering. Further topics include bioinformatics and computational biology, clinical engineering and health technology assessment, health informatics, e-health and telemedicine, artificial intelligence and machine learning in healthcare, as well as pharmaceutical and genetic engineering. Given its scope, the book provides academic researchers, clinical researchers and professionals alike with a timely reference guide to measures for improving the quality of life and healthcare.

**Handbook of Research on Biomedical Engineering Education and Advanced Bioengineering Learning: Interdisciplinary Concepts**

Addressing the exploding interest in bioengineering for healthcare applications, this book provides readers with detailed yet easy-to-understand guidance on biomedical device engineering. Written by prominent physicians and engineers, Medical Devices: Surgical and Image-Guided Technologies is organized into stand-alone chapters covering devices and systems in diagnostic, surgical, and implant procedures. Assuming only basic background in math and science, the authors clearly explain the fundamentals for different systems along with such topics as engineering considerations, therapeutic techniques and applications, future trends, and more. After describing how to manage a design project for medical devices, the book examines the following: Instruments for laparoscopic and ophthalmic surgery, plus surgical robotics Catheters in vascular therapy and energy-based hemostatic surgical devices Tissue ablation systems and the varied uses of lasers in medicine Vascular and cardiovascular devices, plus circulatory support devices Ultrasound transducers, X-ray imaging, and neuronavigation An absolute must for biomedical engineers, Medical Devices: Surgical and Image-Guided Technologies is also an invaluable guide for students in all engineering majors and pre-med programs interested in exploring this fascinating field.

**Medical Devices**

This book offers comprehensive, easy to understand guidance for medical device technology innovators on how to work through the United States FDA regulatory review process, while also providing insight on the various intellectual property concerns that many medical device innovators face. In the first portion of this book, readers are
Introduces important concepts concerning FDA compliance for medical devices, as well as strategies for successfully navigating the FDA regulatory review process. Specifically, the first portion discusses the expansive range of medical devices and then walks through the most common routes to market: the PMA and 510(k) application processes. In the second portion of this book, readers are introduced to the various types of intellectual property rights that are available for medical device technology inventions and innovations, and can explore ways to overcome unique intellectual property challenges faced by many medical device technology innovators. In the third portion of the book, specific strategies are discussed to navigate the interface between the FDA regulatory process and the process of obtaining intellectual property protection. This book also includes a number of descriptive examples, case studies and scenarios to illustrate the topics discussed, and is intended for use by medical device designers, developers and innovators.

Medical Device Approval and Certification System Of East Asia

Healthcare Technology Management Systems provides a model for implementing an effective healthcare technology management (HTM) system in hospitals and healthcare provider settings, as well as promoting a new analysis of hospital organization for decision-making regarding technology. Despite healthcare complexity and challenges, current models of management and organization of technology in hospitals still has evolved over those established 40-50 years ago, according to totally different circumstances and technologies available now. The current health context based on new technologies demands working with an updated model of management and organization, which requires a re-engineering perspective to achieve appropriate levels of clinical effectiveness, efficiency, safety and quality. Healthcare Technology Management Systems presents best practices for implementing procedures for effective technology management focused on human resources, as well as aspects related to liability, and the appropriate procedures for implementation. Presents a new model for hospital organization for Clinical Engineers and administrators to implement Healthcare Technology Management (HTM) Understand how to implement Healthcare Technology Management (HTM) and Health Technology Assessment (HTA) within all types of organizations, including Human Resource Impact, Technology Policy and Regulations, Health Technology Planning (HTP) and Acquisition, as well as Asset and Risk Management. Transfer of knowledge from applied research in CE, HTM, HTP and HTA, from award-winning authors who are active in international health organizations such as the World Health Organization (WHO), Pan American Health Organization (PAHO), American College of Clinical Engineering (ACCE) and International Federation for Medical and Biological Engineering (IFMBE)

Development of Medical Device Policies

Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

Medical Device Technologies

This book highlights recent advances in soft and stretchable biointegrated electronics. A renowned group of authors address key ideas in the materials, processes, mechanics, and devices of soft and stretchable electronics; the wearable electronics systems; and bioinspired and implantable biomedical electronics. Among the topics discussed are liquid metals, stretchable and flexible energy sources, skin-like devices, in vitro neural recording, and more. Special focus is given to recent advances in extremely soft and stretchable bio-inspired electronics with real-world clinical studies that validate the technology. Foundational theoretical and experimental aspects are also covered in relation to the design and application of these biointegrated electronics systems. This is an ideal book for researchers, engineers, and industry professionals involved in developing healthcare devices, medical tools and related instruments relevant to various clinical practices.

International Code of Practice for Planning, Commissioning and Providing Technology Enabled Care Services

A collaboration between leading scientists, practitioners, and researchers at Carnegie-Mellon University and the University of Pittsburgh, this book is a comprehensive resource.
The Learning Healthcare System

In recent years, even though a medical device industry has been grown rapidly as a next generation global industry, most of markets are dominated by some of major countries. A medical device is distinct from general goods; it requires not only ordinary medical engineering R&D knowledge, but also it involves with each phases of specific market knowledge, experience, and expertise from development to commercialization according to complicated regulatory affairs. Moreover, since the purpose of manufactured medical device is usually not only for domestic market but for overseas expansion, expertise of global medical device industry knowledge are needed, such as each country’s medical device law, data of medical device usage and etc..... The book provides comprehensive, yet practical knowledge of product planning, research, development, manufacturing, certification and approval, and distribution of medical device in order to enable readers to conduct business easily through general R&D education as well as essential subject, medical device approval and certification system. The main purpose of book is to foster practical medical device experts through understanding of medical device approval and certification system of East Asia including Korea, Japan, and China. Since the author has had an experienced working in Ministry of Food and Drug Safety (MFDS), especially in medical device certification department as well as an educator in Universities for a long time, the author contains practical-knowledge-oriented information such as problems and corresponding strategies of each country in an aspect of regulatory affairs based on global certification and approval for medical device, which are distinct from a regular textbook: engineering-education-oriented information for medical device manufacturing. This book describes information of regulatory affairs easily for various class of readers: from a undergraduate and graduate student who are interested in medical device industry to personnel who are performing medical device regulation related work. The contained information is based on public announced material from each country’s regulatory authority. However, the contained information may change in the future due to characteristics of regulatory affairs. Therefore, the author will continuously publish revised edition and respectfully accept requests for revision and improvement. 2016 December Gyu Ha Ryu, Ph.D

Needs Assessment for Medical Devices

Wearable and Implantable Medical Devices: Applications and Challenges, Fourth Edition highlights the new aspects of wearable and implanted sensors technology in the healthcare sector and monitoring systems. The book's contributions include several interdisciplinary domains, such as wearable sensors, implanted devices, Internet-of-Things (IoT), security, real-time medical healthcare monitoring, WIBSN design and data management, encryption, and decision-support systems. Contributions emphasize several topics, including real-world applications and the design and implementation of wearable devices. This book demonstrates that this new field has a brilliant future in applied healthcare research and in healthcare monitoring systems. Includes comprehensive information on wearable and implanted device technology, wearable and implanted sensors design, WIBSN requirements, WIBSN in monitoring systems and security concepts Highlights machine learning and computing in healthcare monitoring systems based on WIBSN Includes a multidisciplinary approach to different healthcare applications and their associated challenges based on wearable and implanted technologies

Healthcare Technology Management - A Systematic Approach

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.

**Health Devices Sourcebook**

The second edition of a bestseller, Design Controls for the Medical Device Industry provides a comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure your company’s design control program evolves in accordance with current industry practice. The text assists in the development of an effective design control program that not only satisfies the US FDA Quality System Regulation (QSR) and ISO 9001 and 13485 standards, but also meets today’s third-party auditor/investigator expectations and saves you valuable time and money. The author’s continual participation in FDA QSR inspections and Notified Body ISO audits is reflected in updates to all chapters and appendices of the book, now bursting at the seams with: New coverage of ISO 9001 and 13485 design control requirements More real-world examples from the medical device industry Additional detail for greater understanding and clarity Fresh templates for practical implementation Extensive references for further study The book addresses design control elements such as design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations and classes in the US, Canada, and Europe.

**CMBEBIH 2019**

**Medical Devices**

As our nation enters a new era of medical science that offers the real prospect of personalized health care, we will be confronted by an increasingly complex array of health care options and decisions. The Learning Healthcare System considers how health care is structured to develop and to apply evidence—from health profession training and infrastructure development to advances in research methodology, patient engagement, payment schemes, and measurement—and highlights opportunities for the creation of a sustainable learning health care system that gets the right care to people when they need it and then captures the results for improvement. This book will be of primary interest to hospital and insurance industry administrators, health care providers, those who train and educate health workers, researchers, and policymakers. The Learning Healthcare System is the first in a series that will focus on issues important to improving the development and application of evidence in health care decision making. The Roundtable on Evidence-Based Medicine serves as a neutral venue for cooperative work among key stakeholders on several dimensions: to help transform the availability and use of the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and, ultimately, to ensure innovation, quality, safety, and value in health care.

**New Frontiers in Medical Device Technology**

Global Health Watch, now in its fourth edition, is widely perceived as the definitive voice for an alternative discourse on health and healthcare. It covers a range of issues that currently impact on health, including the present political and economic architecture in a fast-changing and globalized world; a political assessment of the drive towards Universal Health Coverage; broader determinants of health, such as gender-based violence and access to water; stories of struggles, actions and change; and a scrutiny of a range of global institutions and processes. It integrates rigorous analysis, alternative proposals and stories of struggle and change to present a compelling case for a radical transformation of the way we approach actions and policies on health.

**Design Controls for the Medical Device Industry, Third Edition**

This book provides a comprehensive approach to studying the principles and design of biomedical devices as well as their applications in medicine. It is written for engineers
and technologies who are interested in understanding the principles, design and applications of medical device technology. The book is also intended to be used as a textbook or reference for biomedical device technology courses in universities and colleges. It focuses on the functions and principles of medical devices (which are the invariant components) and uses specific designs and constructions to illustrate the concepts where appropriate. This book selectively covers diagnostic and therapeutic devices that are either commonly used or that their principles and design represent typical applications of the technology. In this second edition, almost every chapter has been revised—some with minor updates and some with significant changes and additions. For those who would like to know more, a collection of relevant published papers and book references is added at the end of each chapter. Based on feedback, a section on “Common Problems and Hazards” has been included for each medical device. In addition, more information is provided on the indications of use and clinical applications. Two new areas of medical device technology have been added in the two new chapters on “Cardiopulmonary Bypass Units” and “Audiology Equipment.”

Stretchable Bioelectronics for Medical Devices and Systems

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

Medical Device Technologies

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.

Global Health Watch 4

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. An effective medical equipment maintenance program consists of adequate planning, management and implementation. Planning considers the financial, physical and human resources required to adequately implement the maintenance activities. Once the program has been defined, financial, personnel and operational aspects are continually examined and managed to ensure the program continues uninterrupted and improves as necessary.
Ultimately, proper implementation of the program is key to ensuring optimal equipment functionality.

BIOMEDICAL DEVICE TECHNOLOGY

Today, more than ever, the pharmacist is a full-member of the health team and many of the pharmacist’s patients are using a host of other devices from various specialty areas of medicine and surgery. Medical Devices for Pharmacy and Other Healthcare Professions presents a comprehensive review of most devices that pharmacists and pharmacy personnel encounter during practice. The devices covered are relevant to pharmacists working in various work settings from hospitals, community pharmacies, and health insurance sectors, to regulatory bodies, academia, and research institutes. Even if a pharmacist does not come across each of these devices on a regular basis, the book is a valuable reference source for those occasions when information is needed by a practitioner, and for instructing interns and residents. The book discusses devices needed for special pharmaceutical services and purposes such as residential care homes and primary care based with GPs, pharmacy-based smoking cessation services, pharmacy-based anticoagulant services, pain management and terminal care, medication adherence and automation in hospital pharmacy. Additional features include: Provides information on devices regarding theory, indications, and procedures concerning use, cautions, and place, in therapy. Assists pharmacists in understanding medical devices and instructing patients with the use of these devices. Focuses on providing the available evidence on effectiveness and cost-effectiveness of devices and the latest information in the particular field. Other healthcare providers interested in medical devices or involved in patients care where medical devices represent part of the provided care would benefit from the book.

Health Technology Assessment of Medical Devices

From bandage to the bioreactor, this book looks at five different device technologies from inception to healthcare practice, drawing on medical sociology, science and technology studies and political science. It examines ‘evidence’, regulation and governance processes, and diverse stakeholders in innovating the technologies that shape health care.

Quality of Life Technology Handbook

This cutting-edge volume is the first book that provides you with practical guidance on the use of medical device data for bioinformatics modeling purposes. You learn how to develop original methods for communicating with medical devices within healthcare enterprises and assisting with bedside clinical decision making. The book guides in the implementation and use of clinical decision support methods within the context of electronic health records in the hospital environment. This highly valuable reference also teaches budding biomedical engineers and bioinformaticists the practical benefits of using medical device data. Supported with over 100 illustrations, this all-in-one resource discusses key concepts in detail and then presents clear implementation examples to give you a complete understanding of how to use this knowledge in the field.

Medical Device Data and Modeling for Clinical Decision Making

Safety Risk Management for Medical Devices, Second Edition teaches the essential safety risk management methodologies for medical devices compliant with the requirements of ISO 14971:2019. Focusing exclusively on safety risk assessment practices required in the MedTech sector, the book outlines sensible, easily comprehensible, state-of-the-art methodologies that are rooted in current industry best practices, addressing safety risk management of medical devices, thus making it useful for those in the MedTech sector who are responsible for safety risk management or need to understand risk management, including design engineers, product engineers, development engineers, software engineers, Quality assurance and regulatory affairs. Graduate-level engineering students with an interest in medical devices will also benefit from this book. The new edition has been fully updated to reflect the state-of-the-art in this fast changing field. It offers guidance on developing and commercializing medical devices in line with the most current international standards and regulations. Includes new coverage of ISO 14971:2019, ISO/TR 24971. Presents the latest information on the history of risk management, lifetime of a medical device, risk management review, production and post production activities, post market risk management Provides practical, easy-to-understand and state-of-the-art methodologies that meet the requirements of international regulation.
Managing Medical Devices within a Regulatory Framework

Healthcare Technology Management: A Systematic Approach offers a comprehensive description of a method for providing safe and cost-effective healthcare technology management (HTM). The approach is directed to enhancing the value (benefit in relation to cost) of the medical equipment assets of healthcare organizations to best support patients, clinicians and other care providers, as well as financial stakeholders. The authors propose a management model based on interlinked strategic and operational quality cycles which, when fully realized, delivers a comprehensive and transparent methodology for implementing a HTM programme throughout a healthcare organization. The approach proposes that HTM extends beyond managing the technology in isolation to include advancing patient care through supporting the application of the technology. The book shows how to cost effectively manage medical equipment through its full life cycle, from acquisition through operational use to disposal, and to advance care, adding value to the medical equipment assets for the benefit of patients and stakeholders. This book will be of interest to practicing clinical engineers and to students and lecturers, and includes self-directed learning questions and case studies. Clinicians, Chief Executive Officers, Directors of Finance and other hospital managers with responsibility for the governance of medical equipment will also find this book of interest and value. For more information about the book, please visit: www.htmbook.com

Medical Technology into Healthcare and Society

Bachelor Thesis from the year 2012 in the subject Economy - Health Economics, grade: First, Berlin School of Economics and Law, language: English, abstract: Innovations in the medical device industry have improved the health of the world population with the ability to better diagnose, prevent, predict and cure illnesses. The number of medical devices on the market is increasing exponentially, together with the complexity, diversity and technical variation of such products. In light of its impact on patient health, regulation of medical devices is necessary to ensure that safe and effective products enter the marketplace, and that the product’s benefit to the patient population outweighs its potential risks. Although there has been increasing public scrutiny of health care reform, medical devices and their global regulation has been a minor field of health economic studies. This study examines the medical device regulatory systems and its impact on health care economics, exemplarily on the legislative programs of two major markets - the United States (U.S.) and European Union (EU). Modern medical device technology dates its origin to the early 19th century, but has grown most significantly in the last 50 years (Banta, p. 15). Today, 10,000 different families of medical device types exist with more than 400,000 different individual products on the market (Eucomed 2011). Outstanding developments have included heart-lung machines, artificial joints, as well as radiographic imaging and the means to perform advanced brain surgery. The medical device technology sector is extremely innovative, with seven out of ten major medical innovations in the last 40 years coming from this field (Fuchs, Sox, JR. 2001). Despite these technological advances, medical devices sometimes fail during use and can actually result in patient harm. The purpose of regulating medical equipment is to minimize the risk of harm to the end user and to prevent potentially unsafe products from entering the marketplace. The main obstacle in developing and implementing effective regulation is the term safety itself, as it can hardly be measured and there is no formula that can be consistently applied. Guidelines have been established that measure product risk, mitigate risks where possible, and then evaluate the residual risks to determine which are acceptable. This means by implication that acceptance of risk is part of the regulation process in order to bring life-saving technologies with unknown long-term effects to the market.

Wearable and Implantable Medical Devices

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