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Respiratory Infections - Mieczyslaw Pokorski 2014-11-22
The successful prophylaxis and treatment of ubiquitous respiratory infections is essential for the enhancement of public health. The chapters provide new insights into the biology of causative pathogens, tackle the epidemiological aspects, and present an update on diagnostics, prevention and therapy of infections. The emerging new pathogens and antibiotic resistance of the old ones are discussed. Novel markers of the severity of community acquired pneumonia, which bears high morbidity and mortality, also are presented.
Medical Devices and IVDs - Wolfgang Ecker 2021-03-31
Are you fit for the new rules in Europe? The new EU regulations on medical devices and in vitro diagnostic medical devices (IVDs) are changing the rules of the game in this important area of health care. It is now necessary to adapt quickly to the new and more demanding rules on market access in Europe. This requires a thorough knowledge of the new rules for all those responsible and employed in the sector. A sound knowledge of the new EU regulations is also indispensable for the education, training and further education of students, and for staff in research and development, in regulatory affairs and quality management. For all those who are active and responsible in the field of medical technology, biomedical and clinical engineering, e-health and related fields. The new 3rd edition gives the latest stage of regulatory corrigenda, amendments and EU-target dates and reflects the latest Guidance documents of EU on this. Don't be late: those that fail to prepare - prepare to fail! 336 pages; 38 Fig., 23 Tab.
Medical Devices - Carlo Boccato 2022
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.
MEDINFO 2017: Precision Healthcare Through Informatics - A.V. Gundlapalli 2018-01-31

Medical informatics is a field which continues to evolve with developments and improvements in foundational methods, applications, and technology, constantly offering opportunities for supporting the customization of healthcare to individual patients. This book presents the proceedings of the 16th World Congress of Medical and Health Informatics (MedInfo2017), held in Hangzhou, China, in August 2017, which also marked the 50th anniversary of the International Medical Informatics Association (IMIA). The central theme of MedInfo2017 was "Precision Healthcare through Informatics", and the scientific program was divided into five tracks: connected and digital health; human data science; human, organizational, and social aspects; knowledge management and quality; and safety and patient outcomes. The 249 accepted papers and 168 posters included here span the breadth and depth of sub-disciplines in biomedical and health informatics, such as clinical informatics; nursing informatics; consumer health informatics; public health informatics; human factors in healthcare; bioinformatics; translational informatics; quality and safety; research at the intersection of biomedical and health informatics; and precision medicine. The book will be of interest to all those who wish to keep pace with advances in the science, education, and practice of biomedical and health informatics worldwide.

Medical Devices - United States. Congress. Senate. Committee on Health, Education, Labor, and Pensions 2014

Medical Devices - Christa Altenstetter 2017-09-08

Medical devices are the bread and butter from which health care and clinical research are derived. Such devices are used for patient care, genetic testing, clinical trials, and experimental clinical investigations. Without medical devices, there is no clinical research or patient care. Without life-adjusting devices, there are no medical procedures or surgery. Without life-saving and life-maintaining devices, there is no improvement in well-being and quality of life. Without innovative medical devices and experimentation, there can be no medical progress or patient safety. Medical devices and medical technology are used to create or support many different products and medical-surgical procedures. This volume on the regulation of medical devices in the European Union, with a focus on France, tackles a topic of interdisciplinary interest and significance for policymakers in countries around the globe. The EU regulatory regime is one of three global regional regimes, and medical products manufactured in EU countries are sold worldwide. As countries confront an aging population on a global scale, with associated increases in chronic diseases, physical handicaps, and multi-morbidity, there will inevitably be an increase in the demand for health services and, concomitantly, the use of medical devices in medical and surgical procedures. This will be the case regardless of whether services are delivered in hospitals, doctors' offices, or at home. The associated risks of a particular device will be the same whatever the country of origin for the device, or where the need occurs. Revolutionary medical advances increase diagnostic capabilities, but they increase the potential of harm and risks to patients. Medical technologies and devices are used ethically most of the time; yet they have the potential for unethical use when scientific medicine is elevated over human life and death. Assumptions that are taken for granted can be dangerous to a patient's health. That is why our understanding of appropriate and effective regulation of medical devices is significant to all people on all continents.

Personalized Medicine in Healthcare Systems - Nada Bodiroga-Vukobrat 2019-08-02

This book gathers scientific contributions on comprehensive approaches to personalized medicine. In a systematic and clear manner, it provides extensive information on the methodological, technological, and clinical aspects of high-throughput analytics, nanotechnology approaches, microbiota/human interactions, in-vitro fertilization and preimplantation, and various diseases like cancer.Moreover, the book analyzes the social and legal aspects of social security systems, healthcare systems and EU law – e.g. the role of solidarity, regulatory possibilities and obstacles, justice and equality, privacy/disclosure of data, and the right to know – from an interdisciplinary perspective. Lastly, it explores the economical

and ethical context in the fields of business models, intellectual property issues, the patient/physician relationship, and price discrimination.

Biomedical Hydrogels - Steve Rimmer 2011-02-26

Hydrogels are very important for biomedical applications because they can be chemically manipulated to alter and control the hydrogel's interaction with cells and tissues. Their flexibility and high water content is similar to that of natural tissue, making them extremely suitable for biomaterials applications. Biomedical hydrogels explores the diverse range and use of hydrogels, focusing on processing methods and novel applications in the field of implants and prostheses. Part one of this book concentrates on the processing of hydrogels, covering hydrogel swelling behaviour, superabsorbent cellulose-based hydrogels and regulation of novel hydrogel products, as well as chapters focusing on the structure and properties of hydrogels and different fabrication technologies. Part two covers existing and novel applications of hydrogels, including chapters on spinal disc and cartilage replacement implants, hydrogels for ophthalmic prostheses and hydrogels for wound healing applications. The role of hydrogels in imaging implants in situ is also discussed. With its distinguished editor and international team of contributors, Biomedical hydrogels is an excellent reference for biomedical research scientists and engineers in industry and academia, as well as others involved in research in this area, such as research clinicians. Examines the diverse range and use of hydrogels, focusing on processing methods and novel applications Comprehensive book explores the structure and properties of hydrogels and different fabrication technologies Covers important areas such as processing of hydrogels, covering hydrogel swelling behaviour, superabsorbent cellulose-based hydrogels and regulation of novel hydrogel products

Respiratory Health - Mieczyslaw Pokorski 2015-07-29

The tracheobronchial tree is open to the environment surrounding the body. Respiration has thus the essential bearing on general morbidity, vulnerability to disease and immunity. Further, respiratory function shapes the neuropsychological responses to succumbing to disease, controls the mind-to-body interaction and sets the perception of quality of life. The chapters of this book deal with the preventable drivers of poor respiratory health, the role of health information technology, the improvement in health care delivery and the integration of respiratory health and behavioral health services. Innovative strategies to promote prevention, care coordination and care integration as well as to align disease acceptance and quality of life measures also are tackled. Maintaining respiratory health is of rising research interest as a way of preventing a disease or a non pharmacological therapeutic succor. The book will be of interest to clinicians, family practitioners and medical researchers.

Nano-Bio- Electronic, Photonic and MEMS Packaging - C. P.(Ching-Ping) Wong 2021-03-17

This book shows how nanofabrication techniques and nanomaterials can be used to customize packaging for nano devices with applications to electronics, photonics, biological and biomedical research and products. It covers topics such as bio sensing electronics, bio device packaging, MEMS for bio devices and much more, including: Offers a comprehensive overview of nano and bio packaging and their materials based on their chemical and physical sciences and mechanical, electrical and material engineering perspectives; Discusses nano materials as power energy sources, computational analyses of nano materials including molecular dynamic (MD) simulations and DFT calculations; Analyzes nanotubes, superhydrophobic self-clean Lotus surfaces; Covers nano chemistry for bio sensor/bio material device packaging. This second edition includes new chapters on soft materials-enabled packaging for stretchable and wearable electronics, state of the art miniaturization for active implantable medical devices, recent LED packaging and progress, nanomaterials for recent energy storage devices such as lithium ion batteries and supercapacitors and their packaging. Nano- Bio-Electronic, Photonic and MEMS Packaging is the ideal book for all biomedical engineers, industrial electronics packaging engineers, and those engaged in bio nanotechnology applications research.

Drug Discovery and Evaluation: Methods in Clinical Pharmacology - H.Gerhard Vogel 2010-12-15

Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

m_Health Current and Future Applications - Giuseppe Andreoni 2019-02-25

This book describes current trends in m_Health technology, systems, and applications. The book proposes a multifaceted view on m-Health opportunities and requirements starting from four aspects: patient, technology, design and innovation. The analysis is completed by a market segmentation overview and by the most recent research experiences to offer a complete benchmark and vision of m_Health for today and tomorrow. The contributions are based on the outcomes of initiatives on the future of healthcare, funded by the EU in the frame of FP7 and Horizon 2020 and their deployment into real clinical practice. Throughout the book, clinicians, technicians, researchers, and end-users debate their experience, needs, risks, opportunities, and available solutions in this fast moving field.

Medical Regulatory Affairs - Jack Wong 2022-01-27

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

Software Process Improvement and Capability Determination - Tanja Woronowicz 2013-05-21

This book constitutes the refereed proceedings of the 13th International Conference on Software Process Improvement and Capability Determination, SPICE 2013, held in Bremen, Germany, in June 2013. The 21 revised full papers presented and 7 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on process quality; medical device software processes; design and use of process models; studies of software development; agile development; IT service management; assessment for diagnosis.

Medical Device Safety - G.R Higson 2001-10-29

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, engineering, and medical regulatory affairs.

Advanced Technologies and Polymer Materials for Surgical Sutures - Sabu Thomas 2022-09-29

Polymeric materials offer a high level of versatility due to the range of applications possible within the biomedical and clinical fields – including wound closure - particularly in comparison to metals or ceramics. These specialised materials also allow for a diverse array of therapeutic effects. Although there have been advances in improving polymeric materials for surgical sutures, there is little information available regarding improving the therapeutic value of sutures, and advanced technologies used to implement this improvement. Advanced Technologies and Polymer Materials for Surgical Sutures provides thorough coverage on suture materials with improved mechanical and therapeutic properties that can improve quality of life; chapter topics include drug-releasing kinetics of sutures, shape memory polymer sutures and future trends. This book is a useful resource for academics and researchers in the materials science and biomedical engineering fields, as well as professionals in biomaterials and biotextiles development and clinicians looking to learn more about suture material properties and suture/body interactions. Depicts recent advances in both the therapeutic effects of polymer-based sutures, as well as the various manufacturing techniques employed in the production of sutures Offers an interdisciplinary approach, covering material properties and engineering technologies, as well as an understanding of the biological properties of sutures, such as suture/body interactions Comprehensive coverage allows both experienced researchers in the area and new entrants (such as clinicians) to learn more about this important topic

Pharmacoepidemiology - Brian L. Strom 2019-12-16

This classic, field-defining textbook, now in its sixth edition, provides the most comprehensive guidance available for anyone needing up-to-date information in pharmacoepidemiology. This edition has been fully revised and updated throughout and continues to provide a rounded view on all perspectives from academia, industry and regulatory bodies, addressing data sources, applications and methodologies with great clarity.

Biological Performance of Materials - Jonathan Black 2005-12-20

Bioengineers need a thorough grounding in biocompatibility - the biological performance of materials. Until now, there were no publications suitable for a neophyte in the field; prior publications were either not comprehensive or focused on rather narrow interests. Drawing on the author's 35 years of experience as a teacher, researcher, and consult

Clinical Evaluation and Investigation of Medical Devices under the new EU-Regulation - Wolfgang Ecker 2020-06-04

The concept of clinical evaluation and the framework for clinical investigations have been significantly enforced within the new EU-Medical Device Regulation (MDR). This book provides in-depth and practice-oriented guidance on the systematic identification and generation of clinical data through clinical investigations and other relevant sources. It addresses the needs of all stakeholders, be it manufacturers, notified bodies or competent authorities, when they have to plan, perform or assess clinical evaluations and investigations for medical devices on the way to conformity assessment and CE marking. It is a valuable tool of qualification for clinicians and related experts when preparing for a role of a clinical evaluator in the field, either when serving any of the stakeholders or when trying to make their own involvement stand out in start-ups. spin-offs or other development projects or in counselling services.

Clinical Evaluation of Medical Devices - Karen M. Becker 2007-11-05

The original edition of this text, Clinical Evaluation of Medical Devices: Principles and Case Studies, provided the first overview of key pr- ciples and approaches to medical device clinical trials, illustrated with a series of detailed, real-world case studies. The book is designed as a resource for clinical professionals and regulatory specialists working in the field of new medical device development and marketing. Since the first edition of this text was published in 1997, the rapid pace of inno- tion in health care technologies continues to yield exciting and important new products. The regulatory landscape has also evolved, reflecting some of the changes and needs within the medical device industry. The purpose of Clinical Evaluation of Medical Devices: Principles and Case Studies, Second Edition is to provide an updated and expanded presentation of the scientific methods and regulatory requirements applied to the study

of new significant risk medical devices. The text now includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this p- pose as well as health care technology assessment methods; (2) infor- tion on new statistical methodologies applied to medical device trials; and (3) all new case studies, including examples of combination pr- ucts, three-phase development models (i. e. , feasibility, FDA approval, Medicare reimbursement), and novel study designs.

Guide to EU Pharmaceutical Regulatory Law - Sally Shorthose 2017-02-17

In the European Union (EU) and its Member States, as elsewhere, the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of fifteen incisive chapters examines a particular process or subject. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - stages and standards for creating a product dossier; - clinical trials; - how and when an abridged procedure can be used; - criteria for conditional marketing authorisations; - generic products and 'essential similarity'; - paediatric use and the requisite additional trials; - biologicals and 'biosimilars'; - homeopathic and herbal medicines; - reporting procedures; - pharmacovigilance; - parallel trade; - relevant competition law and intellectual property rights; and - advertising. In addition, national variation charts in many of the chapters illustrate eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK). Sample forms and URLs for the most important Directives are included. Pharmaceutical lawyers and regulatory advisers, both in-house and in private practice, will welcome this unique book. It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations.

Neurorehabilitation Technology - David J. Reinkensmeyer 2016-08-03

This revised, updated second edition provides an accessible, practical overview of major areas of technical development and clinical application in the field of neurorehabilitation movement therapy. The initial section provides a rationale for technology application in movement therapy by summarizing recent findings in neuroplasticity and motor learning. The following section then explains the state of the art in human-machine interaction requirements for clinical rehabilitation practice. Subsequent sections describe the ongoing revolution in robotic therapy for upper extremity movement and for walking, and then describe other emerging technologies including electrical stimulation, virtual reality, wearable sensors, and brain-computer interfaces. The promises and limitations of these technologies in neurorehabilitation are discussed. Throughout the book the chapters provide detailed practical information on state-of-the-art clinical applications of these devices following stroke, spinal cord injury, and other neurologic disorders. The text is illustrated throughout with photographs and schematic diagrams which serve to clarify the information for the reader. Neurorehabilitation Technology, Second Edition is a valuable resource for neurologists, biomedical engineers, roboticists, rehabilitation specialists, physiotherapists, occupational therapists and those training in these fields.

Image-Based Computational Modeling of the Human Circulatory and Pulmonary Systems - Krishnan B. Chandran 2010-11-18

Image-Based Computational Modeling of the Human Circulatory and Pulmonary Systems provides an overview of the current modeling

methods and applications enhancing interventional treatments and computer-aided surgery. A detailed description of the techniques behind image acquisition, processing and three-dimensional reconstruction are included. Techniques for the computational simulation of solid and fluid mechanics and structure interaction are also discussed, in addition to various cardiovascular and pulmonary applications. Engineers and researchers involved with image processing and computational modeling of human organ systems will find this a valuable reference.

The Handbook of Cuffless Blood Pressure Monitoring - Josep Solà 2019-08-21

This book is the first comprehensive overview of the emerging field of cuffless blood pressure monitoring. Increasing clinical evidence proves that longitudinal measurements of blood pressure allow for earlier detection and better management of multiple medical conditions and for superior prediction of cardiovascular events. Unfortunately, today's clinical and industry standards for blood pressure monitoring still require the inflation of a pneumatic cuff around a limb each time a measurement is taken. Over the last decades clinicians, scientists and device manufacturers have explored the feasibility of technologies that reduce or even completely eliminate the need of cuffs, initiating the era of cuffless blood pressure monitoring. Among the existing literature, this book is intended to be a practical guide to navigate across this emerging field. The chapters of the handbook have been elaborated by experts and key opinion leaders in the domain, and will guide the reader along the clinical, scientific, technical, and regulatory aspects of cuffless blood pressure monitoring.

Handbook of Medical Device Regulatory Affairs in Asia - Jack Wong 2013-03-27

Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the medical device industry, and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects.

Certification – Trust, Accountability, Liability - Peter Rott 2019-03-12

This book offers an in-depth analysis of the function of certification in general and of certification systems in a range of different sectors. The authors examine certification from both a theoretical and a practical standpoint and from the perspectives of different disciplines, including law, economics, management, and the social sciences. They also discuss instruments that help ensure the quality of certification, which can range from public law measures such as accreditation, to private law incentives, to deterrents, such as liability towards victims. Further, they assess the role of competition between certification bodies. Readers will learn the commonalities as well as the necessary distinctions between certification bodies in various fields, which may stem from the different functions they serve. These similarities and differences may also be the result of different types of damage that the certified producer or service provider could potentially cause to individuals or to the public at large. Often, companies use certification bodies as an argument to assure the general public, e.g. regarding the safety of medical products. Closer inspection reveals, however, that sometimes certification bodies themselves lack credibility. The book offers essential information on the benefits and pitfalls associated with certification.

Guide to Clinical Preventive Services - U.S. Preventive Services Task Force 1989

A report on recommended clinical preventive services that should be provided to patients in the course of routine clinical care, including screening for vascular, neoplastic and infectious diseases, and metabolic,

hematologic, ophthalmologic and ontologic, prenatal, and musculoskeletal disorders. Also, mental disorders and substance abuse, counseling, and immunizations/chemoprophylaxis. Tables.

Design Controls for the Medical Device Industry - Marie B. Teixeira 2013-11-12

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 effectiv

Bioactive Glasses - Heimo Ylänen 2011-07-26

Due to their biocompatibility and bioactivity, bioactive glasses are used as highly effective implant materials throughout the human body to replace or repair damaged tissue. As a result, they have been in continuous use since shortly after their invention in the late 1960s and are the subject of extensive research worldwide. Bioactive glasses provides readers with a detailed review of the current status of this unique material, its properties, technologies and applications. Chapters in part one deal with the materials and mechanical properties of bioactive glass, examining topics such as surface modification and cell interaction. Part two is focussed on the applications of bioactive glasses, covering their uses in wound healing, maxillofacial surgery and bone tissue engineering, among other topics. With its distinguished editor and expert team of contributors, Bioactive glasses is an invaluable reference for researchers and scientists in the field of biomaterials, both in academia and in industry. Provides a detailed review of bioactive glasses, its properties, technologies and applications An invaluable reference for researchers and scientists in the field of biomaterials, both in academia and in industry Comprehensively covers materials and mechanical properties of bioactive glass and its applications, including wound healing, maxillofacial surgery and bone tissue engineering

Design Controls for the Medical Device Industry, Third Edition - Marie B. Teixeira 2019-08-02

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

Managing Medical Devices within a Regulatory Framework - Beth Ann Fiedler 2016-09-10

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

Extracellular Matrix-derived Implants in Clinical Medicine - Daniel L Mooradian 2016-05-18

Extracellular Matrix-Derived Implants in Clinical Medicine comprehensively covers the emergence of tissue engineering and regenerative medicine over the past few decades, along with discussions of continuous funding and research. The book provides a state-of-the-art review of this increasingly important technology and how it is translating from bench to bedside. Part One of the book looks at the historical use of human and animal tissues, focusing on the main application areas, including cardiovascular, hard and soft tissue engineering, and neurological, while Part Two examines the challenges in harvesting, processing, and manufacturing of extracellular matrices, with a final section reviewing the international regulatory environment and economics of tissue-based products. Addresses issues of tissue engineering and regenerative medicine from a biomaterials industry perspective Looks at the historical use of human and animal tissues, focusing on the main application areas, including cardiovascular, hard and soft tissue engineering, and neurological Examines the challenges in harvesting, processing, and manufacturing of extracellular matrices Reviews the international regulatory environment and economics of tissue-based products

Pharmacovigilance: A Practical Approach - Thao Doan 2018-07-31

Written by experts in the field of pharmacovigilance and patient safety, this concise resource provides a succinct, easy-to-digest overview of an increasingly critical area of medical safety. Drs. Thao Doan, Fabio Lievano, Mondira Bhattacharya, and Linda Scarazzini provide essential information for health care professionals, clinical researchers, and regulators who need a comprehensive, up-to-date source of information on the principles and practice of pharmacovigilance.

Textbook of Neuromodulation - Helena Knotkova 2014-11-15

Until recently, it was thought that the adult brain is modifiable only during early stages of ontogenesis. However, neurophysiological and neuroimaging studies now indicate that the mature human brain is, under certain conditions, capable of substantial neuroplastic changes. Neuroplasticity reflects the ability of the human brain to alter the pattern of neural activation in response to previous experience, and recent findings indicate that the effects of experience can lead to both structural as well as functional reorganization. It has been shown that pathological neuroplastic changes can be reverted/normalized and that the modulation of the neuroplastic changes can be paralleled by improvement of the patient's status. However, there is a gap between the potential of neuromodulation, technical progress and actual preparedness of medical personnel to provide this type of treatment. A prevalent opinion among medical professionals indicates that training programs and educational materials in neuromodulatory techniques are well needed and appreciated. Neuromodulation will focus on the description and discussion of methods currently available for invasive and non-invasive neuromodulation, their clinical potential, significance and practical applications. In order to facilitate understanding of the topic, the initial part of the textbook will review neurophysiological systems involved in neuromodulation and will provide readers with basic principles of neuroplasticity that constitutes the rationale for

neuromodulation in human medicine. Additionally, the clinical use of these techniques will be described with special regard to safety and avoidance of complications.

Fundamentals of Biomaterials - Vasif Hasirci 2018-11-26

This text for advanced undergraduate and graduate students covers the fundamental relationships between the structure and properties of materials and biological tissues. The successful integration of material and biological properties, shape, and architecture to engineer a wide range of optimized designs for specific functions is the ultimate aim of a biomaterials scientist. Relevant examples illustrate the intrinsic and tailored properties of metal, ceramic, polymeric, carbon-derived, composite, and naturally derived biomaterials. Fundamentals of Biomaterials is written in a single voice, ensuring clarity and continuity of the text and content. As a result, the reader will be gradually familiarized with the field, starting with materials and their properties and eventually leading to critical interactions with the host environment. Classical and novel examples illuminate topics from basic material properties to tissue engineering, nanobiomaterials, and guided tissue regeneration. This comprehensive and engaging text: integrates materials and biological properties to understand biomaterials function and design provides the basics of biological tissue components and hierarchy includes recent topics from tissue engineering and guided tissue regeneration to nanoarchitecture of biomaterials and their surfaces contains perspectives/case studies from widely-recognized experts in the field features chapter-ending summaries to help readers to identify the key, take-home messages.

Combination Drug Delivery Approach as an Effective Therapy for Various Diseases - Prashant Kesharwani 2022-04-08

Combination Drug Delivery Approach as an Effective Therapy for Various Diseases explores the use of bioengineering tools in combination drug delivery approaches to control various diseases at different clinical stages of synergistic action, varying mechanisms of action, and during the suppression of drug resistance. The book presents fundamental knowledge on the experiential and experimental aspects of drug combination approaches in order to equip rational applications in preventing the emergence of resistance during the treatment of various diseases. It provides a holistic understanding of the principles behind formation, characterization, applications, regulations, toxicity, challenges and future perspectives of combination drug delivery approaches. It will be of interest to researchers and advanced graduate students in pharmaceutical science, chemistry, biology and medicine, as well as pharmaceutical companies and scientific organizations. Provides an accounting of vital aspects on various combination drug delivery approaches, presenting next generation diagnostics and therapeutics Discusses the perspectives of current technologies in highly organized tables, illustrative figures and flow charts Defines major gaps in knowledge that can lead to significant scientific discoveries

Assembling the Pieces of a Systematic Review - Margaret J. Foster 2017-03-03

Here is a complete guide for librarians seeking to launch or refine their systematic review services. Conducting searches for systematic reviews goes beyond expert searching and requires an understanding of the entire process of the systematic review. Just as expert searching is not fully mastered by the end of a library degree, mastering the systematic review process takes a great deal of time and practice. Attending workshops and webinars can introduce the topic, but application of the knowledge through practice is required. Running a systematic review service is complicated and requires constant updating and evaluation with new standards, more efficient methods, and improved reporting guidelines. After a brief introduction to systematic reviews, the book guides librarians in defining and marketing their services, covering topics such as when it is appropriate to ask for co-authorship and how to reach out to stakeholders. Next, it addresses developing documentation and conducting the reference interview. Standards specific to systematic reviews, including PRISMA, Institute of Medicine, and Cochrane Collaboration, are discussed. Search strategy techniques, including choosing databases, harvesting search terms, selecting filters, and searching for grey literature are detailed. Data management and critical

appraisal are covered in detail. Finally, the best practices for reporting the findings of systematic reviews are highlighted. Experts with experience in both systematic reviews and librarianship, including the editors of the book, contributed to the chapters. Each step (or piece) of the review process (Planning the review, Identifying the studies, Evaluating studies, Collecting and combining data, Explaining the results, and Summarizing the review into a report), are covered with emphasis on information roles. The book is for any librarian interested in conducting reviews or assisting others with reviews. It has several applications: for training librarians new to systematic reviews, for those developing a new systematic review service, for those wanting to establish protocols for a current service, and as a reference for those conducting reviews or running a service. Participating in systematic reviews is a new frontier of librarianship, in which librarians can truly become research partners with our patrons, instead of merely providing access to resources and services.

Medical Device Design - Peter J Ogrodnik 2012-12-17

This book 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. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelsstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

Reauthorization of MDUFA - United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Health 2012

Ventilatory Disorders - Mieczyslaw Pokorski 2015-12-07

Respiratory function is a major determinant of the overall quality of health and well-being of an individual. This book runs the gamut of chapters devoted to chronic cough-related conditions in children and adults, health care quality and safety, environmental pollution health effects, efficiency of therapeutic approaches and a mutual dependence of respiratory and non-respiratory illnesses. An integrated approach to the investigation and treatment of sleep disordered breathing as well as the use of new and more efficient diagnostic strategies for pleural tuberculosis are presented. Chapters focus on translating science into practice, with an eye on presymptomatic identification of serious ailments for which there could be more effective therapy, leading to improved general health outcomes. This book includes chapters about disorders which will be of interest to clinicians, family practitioners and medical researchers.