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Usability, Accessibility and Ambient Assisted Living - Alexandra Queirós 2019-01-21 Worldwide, the population ageing is a reality. The concept of Active Ageing, adopted by the World Health Organization, aims to guarantee quality ageing and appears as a strategy to solve this demographic challenge. The technological solutions might have a key role in the promotion of human functioning and in the mitigation of disabilities, particularly those resulting from the natural ageing process. This perspective is evident in the development of Ambient Assisted Living (AAL) solutions. In this context, it is relevant to know about the recent developments in AAL and discuss future trends and challenges in this area. One of the objectives of this book is to do a systematic literature review on AAL, not only considering the technology used, but also the health condition that is intended to improve. For this purpose, we consider the human functioning, in particular the conceptual model of International Classification of Functioning, Disability and Health (ICF). Considering that the ICF conceptual framework is accepted within the healthcare domain, the use of its concepts and terminologies to promote multidisciplinary approaches for AAL solutions development processes can help to overcome difficulties of communication between users, careers and technological developers. AAL solutions must consider in their development the needs of the person that will use AAL solutions. The development must be user-centred and usability questions cannot be forgotten. In addition, the acceptance of the AAL solutions is closely related to the quality of the systems, so it is necessary to appropriately assess these solutions.

Nanostructured Biomaterials for Regenerative Medicine - Vincenzo Guarino 2019-10-05 Nanostructured Biomaterials for Regenerative Medicine focuses on the definition of new trends for the design of biomaterials for biomedical applications. It includes the ex novo synthesis as well as technological strategies to manipulate them into appropriate two-dimensional (2D) and three-dimensional (3D) forms, in order to impart all the main physical, chemical, structural and biological properties requested to achieve desired clinical efficacy. This book aims at offering a concise overview of innovative platforms based on nanostructured biomaterials as a function of their chemical nature - established by a consolidated material classification i.e., polymer, ceramics and metals. For each class, emerging bioinspired systems with rapid expansion in the biomedical research area and fabricated via new enabling technologies will be proposed for the use in tissue repair/regeneration and nanomedicine. This book is an essential resource for researchers, academics and professionals interested in the potential of nanostructured biomaterials for regenerative medicine. Classifies materials into three classes for comprehensive discussion Discusses design techniques to create innovative nanostructured biomaterials Looks at enabling technologies and strategies for emerging applications

Electrospun Materials for Tissue Engineering and Biomedical Applications - Tamer Uyar 2017-05-31 Electrospinning, an electro-hydrodynamic process, is a versatile and promising platform technology for the production of nanofibrous materials for tissue engineering and biomedical applications. Electrospun Materials for Tissue Engineering and Biomedical Applications,

examines the rapid development of electrospun materials for use in tissue engineering and biomedical applications. With a strong focus on fundamental materials science and engineering, this book also looks at successful technology transfers to the biomedical industry, highlighting biomedical products already on the market as well as the requirements to successfully commercialize electrospun materials for potential use in tissue engineering and biomedical areas. This book is a valuable resource for materials and biomedical scientists and engineers wishing to broaden their knowledge on the tissue engineering and biomedical applications of electrospun fibrous materials. Provides all-encompassing coverage of fundamental science, technology and industrial case studies Presents guidance on industrial scalability of electrospun biomaterials Written by a multidisciplinary team or researchers from academia and industry, offering a balanced viewpoint on the subject

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.

Diradicaloids - Taylor & Francis Group 2022-04

Personal Hygiene and Health Care Appliances, UL 1431 - Underwriters' Laboratories 1996-11-01

Polymer-Based Additive Manufacturing - Declan M. Devine 2019-09-16

This book aims to give readers a basic understanding of commonly used additive manufacturing techniques as well as the tools to fully utilise the strengths of additive manufacturing through the modelling and design phase all the way through to post processing. Guidelines for 3D-printed biomedical implants are also provided. Current biomedical applications of 3D printing are discussed, including indirect applications in the rapid manufacture of prototype tooling and direct applications in the orthopaedics, cardiovascular, drug delivery, ear-nose-throat, and tissue engineering fields. Polymer-Based Additive Manufacturing: Biomedical Applications is an ideal resource for students, researchers, and those working in industry seeking to better understand the medical applications of additive manufacturing.

Biocompatibility of Dental Materials - Gottfried Schmalz 2008-10-10

This book provides a comprehensive and scientifically based overview of the biocompatibility of dental materials. Up-to-date concepts of biocompatibility assessment are presented, as well as information on almost all material groups used in daily dentistry practice. Furthermore, special topics of clinical relevance (e.g,, environmental and occupational hazards and the diagnosis of adverse effects) are covered. The book will: improve the reader’s ability to critically analyze information provided by manufacturers supply a better understanding of the biocompatibility of single material groups, which will help the reader choose the most appropriate materials for any given patient and thus prevent adverse effects from developing provide insights on how to conduct objective, matter-of-fact discussions with patients about the materials to be used in dental procedures advise readers, through the use of well-documented concepts, on how to treat patients who claim adverse effects from dental materials feature clinical photographs that will serve as a reference when analyzing clinical symptoms, such as oral mucosa reactions.

Computer Safety, Reliability, and Security - Alexander Romanovsky 2019-09-02

This book constitutes the proceedings of the Workshops held in conjunction with SAFECOMP 2019, 38th International Conference on Computer Safety, Reliability and Security, in September 2019 in Turku, Finland. The 32 regular papers included in this volume were carefully reviewed and selected from 43 submissions; the book also contains two invited papers. The workshops included in this volume are: ASSURE 2019: 7th International Workshop on Assurance Cases for Software-Intensive Systems DECSoS 2019: 14th ERCIM/EWICS/ARTEMIS Workshop on Dependable Smart Embedded and Cyber-Physical Systems and Systems-of-Systems SASSUR 2019: 8th

International Workshop on Next Generation of System Assurance Approaches for Safety-Critical Systems STRIVE 2019: Second International Workshop on Safety, securiTy, and pRivacy In automotiVe systEms WAISE 2019: Second International Workshop on Artificial Intelligence Safety Engineering

Endocannabinoids - Roger G. Pertwee 2015-09-25

There is currently considerable interest in the development of medicines that would enhance endocannabinoid-induced “autoprotection”, for example through inhibition of endocannabinoid metabolizing enzymes or cellular uptake processes or that would oppose endocannabinoid-induced “autoimpairment”. This volume describes the physiology, pathophysiology and pharmacology of the endocannabinoid system and potential strategies for targeting this system in the clinic.

Guidelines for the blood transfusion services in the United Kingdom - United Kingdom Blood Transfusion Services 2005-10-12

This is the seventh edition of a book that provides best practice guidelines and detailed technical procedures for blood transfusion services. It takes account of the European Directives on blood and tissues and resulting UK regulations and indicates which of the guidelines that are now legal requirements.

ANSI/AAMI St79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities - Aami 2013-10-01

The AAMI recommended practice, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, is a breakthrough standard in terms of its scope. AAMI has updated ST79 with the release of ST79:2010/A4:2013. Of particular importance, A4:2013 provides four new figures demonstrating the wrapping of items for steam sterilization and adds an annex focused on Moisture assessment. As of Oct. 25, 2013, purchasers of ST79 will receive ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012 and A4:2014 as a single consolidated document. Among other changes from the 2006 edition of ST79, this revised and expanded second edition of ST79 includes guidance on the use and application of Class 6 emulating indicators, a chemical monitoring device fairly new to the United States. Because ST79 essentially consolidates five AAMI steam sterilization standards (whose content was reviewed and updated to reflect current good practice prior to being incorporated into ST79), it truly is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization.

Systems Engineering for Aerospace - Richard Sheng 2019-02-23

Systems Engineering for Aerospace: A Practical Approach applies insights gained from systems engineering to real-world industry problems. The book describes how to measure and manage an aircraft program from start to finish. It helps readers determine input, process and output requirements, from planning to testing. Readers will learn how to simplify design through production and acquire a lifecycle strategy using Integrated Master Plan/Schedule (IMP/IMS). The book directly addresses improved aircraft system design tools and processes which, when implemented, contribute to simpler, lower cost and safer airplanes. The book helps the reader understand how a product should be designed, identifying the customer’s requirements, considering all possible components of an integrated master plan, and executing according to the plan with an integrated master schedule. The author demonstrates that systems engineering offers a means for aircraft companies to become more effective and profitable. Describes how to measure and manage an aircraft program Instructs on how to determine essential input, process and output requirements Teaches how to simplify the design process, thus allowing for increased profit Provides a lifecycle strategy using Integrated Master Plan/Schedule (IMP/IMS) Identifies cost driver influences on people, products and processes

Development of Biopharmaceutical Drug-Device Products - Feroz Jameel 2020-03-13

The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used

as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.

Adverse Reactions to Biomaterials: State of the Art in Biomaterial Risk Assessment, Immunomodulation and In Vitro Models for Biomaterial Testing - Nihal Engin Vrana 2019-05-15

Adverse immune reactions to biomaterials are important bottlenecks for translation of novel biomaterials for clinical use. Moreover, recent advances in highthrough-put biomaterial discovery and synthetic biology, while providing exciting new veues, also significantly increases potential risks related to the in vivo reactions to these new materials. For example, the novel materials might have unintended biological activities due to their natural building blocks. In this perspective, biomaterial field needs i) better understanding of cell/biomaterial interactions at systems level; ii) development of new analysis and testing tools for advanced risk assessment iii) tools and technologies for modulating reactions to biomaterials and iv) advanced in vitro models for understanding and testing of reactions to biomaterials. In the following collection of articles you will find examples of such systems,together with comprehensive reviews of current developments in in vitro model systems. The collection also contains articles that elucidate the immune reaction to biomaterials in vitro and in vitro.

Support for the conceptual design stage of effective and resource-efficient offerings - Sergio Brambila 2020-10-20

Human activities in the form of production and consumption have increased to an all-time high. In many cases, this increase has resulted in environmental problems such as waste and pollution that, in turn, affect our health and way of living. Societies have proposed different measures to address such environmental problems. These range from different waste treatment technologies to alternative business models, policy measures, and lifecycle thinking in the design of products, to mention but a few. In this research, the focus is on supporting early

design activities of what is often called the conceptual design stage with the objective to provide effective and resource-efficient offerings. The early design activities considered here are planning, analysis, and evaluation. Design researchers have largely supported these three activities with a variety of methods and tools. However, previous research has shown that design support coming from academia has had a low uptake in industry. In this regard, the aim of this research is to propose not only useful but also usable support for design practitioners during the conceptual design stage. This research is carried out in the manufacturing sector in Sweden, where selected companies expressed an interest in collaborating with academia to address more thoroughly effective and resource-efficient offerings. To better match company needs and research from academia, this research took a pragmatic and cross-disciplinary approach. This research approach, along with literature reviews, semi-structured interviews, workshops, and questionnaires, shows different ways in which support can be made more useful and usable. The main gap addressed here is that the knowledge and the related skills of the user of the support have not been sufficiently explored. The results include requirements of the user of the support, proposed methods and tools derived from the requirements identified, and, most importantly, the knowledge and skills needed by the user of the support. The main message of this research is that support could be expanded from methods and tools to include knowledge and skills needed by design practitioners, the users of support. The flow of support from academia to industry could also be reinforced in a two-way flow through a pragmatic and cross-disciplinary approach to first and foremost address design practitioners' needs. Mänskliga aktiviteter i form av produktion och konsumtion har aldrig varit högre. Denna ökning över tid har i många fall lett till miljöproblem som avfall och föroreningar, vilka i sin tur påverkar vår hälsa och levnadssätt. För att möta dessa miljöproblem har olika åtgärder föreslagits, som tekniker för avfallshantering, alternativa affärsmodeller, policy och livscykeldesign, för att nämna några. Fokus i forskningen som presenteras i denna avhandling är på tidiga designaktiviteter, vilka ofta kallas det konceptuella designstadiet och som syftar till att ta fram resurseffektiva erbjudanden. Detta steg behandlas här genom att närmare undersöka designaktiviteterna planering, analys och utvärdering. Designforskare har till stor del stöttat dessa tre aktiviteter med en mängd olika metoder och verktyg. Emellertid visar tidigare forskning att designstöd från akademin har ett lågt upptag i industrin. Syftet med denna forskning är därför att föreslå ett användbart stöd som också är användarvänlig för utövare under det konceptuella designstadiet. För att uppnå detta genomförs forskningen inom tillverkningssektorn i Sverige där deltagande företag uttryckt ett intresse av att samarbeta med akademin avseende resurseffektiva erbjudanden. För att bättre matcha företagens behov med forskning från akademin antas en pragmatisk och tvärvetenskaplig strategi. Denna strategi, tillsammans med litteraturöversikter, semistrukturerade intervjuer, workshops och enkäter visar hur stödet i det konceptuella designstadiet kan bli mer användbart och användarvänlig. Den huvudsakliga forskningsluckan som tas upp här är att kunskap och relaterade färdigheter hos användaren av stödet inte har undersökts tillräckligt. Resultatet ger en beskrivning av kraven på de stöd som användaren behöver, föreslag på metoder och verktyg som baseras på de identifierade kraven och, viktigast av allt, den kunskap och de färdigheter som användaren av stödet behöver ha. Huvudbudskapet är att stöd kan utvidgas från att omfatta metoder och verktyg till att även inkludera behovet av kunskap och färdigheter hos designutövare, det vill säga användarna av supporten. Stödet från den akademiska världen till industrin kan också förstärkas genom att bli ett tvåvägsflöde som med en pragmatisk och tvärvetenskaplig strategi först och främst adresserar användarens behov.

Evidence - George M. Cleland 2012

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.

Five Millennium Catalog of Lunar Eclipses: -1999 To +3000 - Fred Espenak 2021-08-07

During the 5,000-year period from -1999 to +3000 (2000 BCE to 3000 CE), Earth will experience 12,064 eclipses of the Moon. The eclipses are distributed as follows: 4,378 penumbral eclipses, 4,207 partial eclipses, and 3,479 total eclipses.The "Five Millennium Catalog of Lunar Eclipses: -1999 to +3000" contains an individual figures and maps for each eclipse showing the geographic regions of visibility for each phase (penumbral, partial, and total). The uncertainty in Earth's rotational period expressed in DT and its impact on the geographic visibility of eclipses in the past and future is discussed.The statistics of the lunar eclipse distribution over 5,000 years are examined in detail. This includes eclipse types by month and by century, eclipse frequency in the calendar year, extremes in eclipse magnitude for all eclipse types, maximum durations of penumbral, partial, and total eclipses, and eclipse duos (two eclipses within 30 days of each other).Finally, the periodicity of lunar eclipses is investigated with particular attention to the Saros cycle. Tables list the start and end dates, number, and type of eclipses of every Saros series in progress during the 5,000-year period covered by the Five Millennium Catalog.The Catalog serves as a supplement to the 2-volume "Five Millennium Canon of Solar Eclipses" which contains a map of every eclipse. The Catalog and the Canon both use the same solar and lunar ephemerides as well as the same value of ?T. This 1-to-1 correspondence between them enhances the value of each.

Precision Medicine and Artificial Intelligence - Michael Mahler 2021-03-12

Precision Medicine and Artificial Intelligence: The Perfect Fit for Autoimmunity covers background on artificial intelligence (AI), its link to precision medicine (PM), and examples of AI in healthcare, especially autoimmunity. The book highlights future perspectives and potential directions as AI has gained significant attention during the past decade. Autoimmune diseases are complex and heterogeneous conditions, but exciting new developments and implementation tactics surrounding automated systems have enabled the generation of large datasets, making autoimmunity an ideal target for AI and precision medicine. More and more diagnostic products utilize AI, which is also starting to be supported by regulatory agencies such as the Food and Drug Administration (FDA). Knowledge generation by leveraging large datasets including demographic, environmental, clinical and biomarker data has the potential to not only impact the diagnosis of patients, but also disease prediction, prognosis and treatment options. Allows the readers to gain an overview on precision medicine for autoimmune diseases leveraging AI solutions Provides background, milestone and examples of precision medicine Outlines the paradigm shift towards precision medicine driven by value-based systems Discusses future applications of precision medicine research using AI Other aspects covered in the book include regulatory insights, data analytics and visualization, types of biomarkers as well as the role of the patient in precision medicine

Handbook of Vitamins - Janos Zempleni 2013-07-29

Within the last few years, knowledge about vitamins has increased dramatically, resulting in improved understanding of human requirements for many vitamins. This new edition of a bestseller presents comprehensive summaries that analyze the chemical, physiological, and nutritional relationships, as well as highlight newly identified functions, for a

Proceedings of the 2nd International Conference on Microplastic Pollution in the Mediterranean Sea - Mariacristina Cocca 2021-04-25

This book addresses a broad range of issues concerning microplastic pollution, including microplastic pollution in various environments

(freshwater, marine, air and soil); the sources, fate and effects of microplastics; detection systems for microplastic pollution monitoring; green approaches for the synthesis of environmentally friendly polymers; recovery and recycling of marine plastics; wastewater treatment plants as a microplastic entrance route; nanoplastics as emerging pollutants; degradation of plastics in the marine environment; impacts of microplastics on marine life; microplastics: from marine pollution to the human food chain; mitigation of microplastic impacts and innovative solutions; sampling, extraction, purification and identification approaches for microplastics; adsorption and transport of pollutants on and in microplastics; and lastly, the socio-economic and environmental impacts: assessment and risk analysis. In addition to presenting cutting-edge information and highlighting current trends and issues, the book proposes concrete solutions to help face this significant environmental threat. It is chiefly intended for researchers and industry decision-makers; international, national and local institutions; and NGOs, providing them with comprehensive information on the origin of the problem; its effects on marine environments, with a particular focus on the Mediterranean Sea and coasts; and recent and ongoing research activities and projects aimed at finding technical solutions to mitigate the phenomenon.

Systems, Software and Services Process Improvement - Xabier Larrucea 2018-08-22

This volume constitutes the refereed proceedings of the 25th European Conference on Systems, Software and Services Process Improvement, EuroSPI conference, held in Bilbao, Spain, in September 2018. The 56 revised full papers presented were carefully reviewed and selected from 95 submissions. They are organized in topical sections on SPI context and agility, SPI and safety testing, SPI and management issues, SPI and assessment, SPI and safety critical, gamifySPI, SPI in industry 4.0, best practices in implementing traceability, good and bad practices in improvement, safety and security, experiences with agile and lean, standards and assessment models,team skills and diversity strategies, SPI in medical device industry, empowering the future infrastructure.

A Quick Guide to Welding and Weld Inspection - S E Hughes 2009-10-20

A concise and accessible guide to the knowledge required to fulfil the role of a welding inspector. In covering both European and US-based codes, the book gives those wishing to gain certification in welding inspection a basic all-round understanding of the main subject matter. A concise and accessible guide to the knowledge required to fulfil the role of a welding inspector Covers both European and US-based codes Gives those wishing to gain certification in welding inspection a basic all-round understanding of the main subject matter

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices - World Health Organization 2017-05-09

The Model recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient regulation to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. It foresees that such countries will progress from basic regulatory controls towards an expanded level to the extent that their resources allow. The Model is written for the legislative, executive, and regulatory branches of government as they develop and establish a system of medical devices regulation. It describes the role and responsibilities of a country's regulatory authority for implementing and enforcing the regulations. Also, it describes circumstances in which a regulatory authority may either "rely on" or "recognize" the work products from trusted regulatory sources (such as scientific assessments, audit, and inspection reports) or from the WHO Prequalification Team. Section 2 of this document recommends definitions of the terms "medical devices" and IVDs. It describes how they may be grouped according to their potential for harm to the patient or user and specifies principles of safety and performance that the device manufacturer must adhere to. It explains how the manufacturer

must demonstrate to a regulatory authority that its medical device has been designed and manufactured to be safe and to perform as intended during its lifetime. Section 3 presents the principles of good regulatory practice and enabling conditions for effectively regulating medical devices. It then introduces essential tools for regulation, explaining the function of the regulatory entity and the resources required. Section 4 presents a stepwise approach to implementing and enforcing regulatory controls for medical devices as the regulation progresses from a basic to an expanded level. It describes elements from which a country may choose according to national priorities and challenges. Also, it provides information on when the techniques of reliance and recognition may be considered and on the importance of international convergence of regulatory practice.Section 5 provides a list of additional topics to be considered when developing and implementing regulations for medical devices. It explains the relevance of these topics and provides guidance for regulatory authorities to ensure that they are addressed appropriately. The Model outlines a general approach but cannot provide country-specific guidance on implementation. While it does not offer detailed guidance on regulatory topics, it contains references to relevant documents where further information may be found. It does not detail the responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies, and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of medical devices.

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.

Biocompatibility and Performance of Medical Devices - Jean-Pierre Boutrand 2019-11-21

Biocompatibility and Performance of Medical Devices, Second Edition, provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment. Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices, discuss the evaluation and characterization of biocompatibility in medical devices, describe preclinical performance studies for bone, dental and soft tissue implants, and provide information on the regulation of medical devices in the European Union, Japan and China. The book concludes with a review of histopathology principles for biocompatibility and performance studies. Presents diverse insights from experts in government, industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information, including sections on managing extractables, accelerating and simplifying medical device development through screening and alternative biocompatibility methods, and quality strategies which fasten device access to market

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.

Usability Testing of Medical Devices - Michael E. Wiklund P.E. 2015-12-23

Usability Testing of Medical Devices covers the nitty-gritty of usability test planning, conducting, and results reporting. The book also discusses the government regulations and industry standards that motivate many medical device manufacturers to conduct usability tests.Since publication of the first edition, the FDA and other regulatory groups h

Materials for Medical Application - Robert B. Heimann 2020-08-24

This book gives an introduction to the highly interdisciplinary field of biomaterials. It concisely summarizes properties, synthesis and modification of materials such as metals, ceramics, polymers or composites. Characterization, in vitro and in vivo testing as well as a selection of various applications are also part of this inevitable guide.

Handbook of Life Course Health Development - Neal Halfon 2017-11-20

This book is open access under a CC BY 4.0 license. This handbook synthesizes and analyzes the growing knowledge base on life course health development (LCHD) from the prenatal period through emerging adulthood, with implications for clinical practice and public health. It presents LCHD as an innovative field with a sound theoretical framework for understanding wellness and disease from a lifespan perspective, replacing previous medical, biopsychosocial, and early genomic models of health. Interdisciplinary chapters discuss major health concerns (diabetes, obesity), important less-studied conditions (hearing, kidney health), and large-scale issues (nutrition, adversity) from a lifespan viewpoint. In addition, chapters address methodological approaches and challenges by analyzing existing measures, studies, and surveys. The book concludes with the editors' research agenda that proposes priorities for future LCHD research and its application to health care practice and health policy. Topics featured in the Handbook include: The prenatal period and its effect on child obesity and metabolic outcomes. Pregnancy complications and their effect on women's cardiovascular health. A multi-level approach for obesity prevention in children. Application of the LCHD framework to autism spectrum disorder. Socioeconomic disadvantage and its influence on health development across the lifespan. The importance of nutrition to optimal health development across the lifespan. The Handbook of Life Course Health Development is a must-have resource for researchers, clinicians/professionals, and graduate students in developmental psychology/science; maternal and child health; social work; health economics; educational policy and politics; and medical law as well as many interrelated subdisciplines in psychology, medicine, public health, mental health, education, social welfare, economics, sociology, and law.

Advanced Textiles for Wound Care - S. Rajendran 2009-04-30

An important and growing area of the textile industry is the medical sector. The extent of this growth is due to constant improvements in both textile technology and medical procedures. This collection provides a detailed review of how

textiles are incorporated into wound care applications, explaining the importance and suitability of using textiles on different wound types. Part one of the book provides an overview of the use of textiles in particular aspects of wound care, providing details of wound management and the importance of laboratory testing in relation to wound care. Further chapters cover minor wounds, moist wound management and bioactive dressings to promote healing. Given their increasing importance, part two describes how advanced textiles, such as smart temperature controlled textiles and composites, can be used for wound care products. The final chapter gives an interesting insight into the use of fibrous scaffolds for tissue engineering. Advanced textiles for wound care is essential reading for any manufacturers, designers, scientists and producers of wound care materials. It is a valuable resource for professionals within the medical sector, as well as those in academia. Provides a comprehensive introduction to wound care from types of wound and wound healing mechanisms to the importance of testing in relation to wound care Analyses the application of textiles to wound healing covering minor wounds, burns, ulcers and other deep skin wounds Reviews the current use of smart textiles for wound care including drug delivery dressings and textile-based scaffolds for tissue engineering as well as future trends

Regulatory Affairs for Biomaterials and Medical Devices - Stephen F. Amato 2014-10-27

All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance. This book provides readers with information on the systems in place in the USA and the rest of the world. Chapters focus on a series of procedures and policies including topics such as commercialization, clinical development, general good practise manufacturing and post market surveillance. Addresses global regulations and regulatory issues surrounding biomaterials and medical devices Especially useful for smaller companies who may not employ a full time vigilance professional Focuses on procedures and policies including risk management, intellectual protection, marketing authorisation, university patent licenses and general good practise manufacturing

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.

Medical Devices - Seeram Ramakrishna 2015-08-18

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 Quality Management Systems - Susanne Manz 2018-10-02

Medical Devices Quality Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness is written for the needs of quality, compliance, and regulatory professionals

in medical device companies. It includes secrets for developing an effective, yet efficient, Quality Management System (QMS) and explains how to create a vision, strategy, and tactical plans. Author Manz shares lessons on leadership, key roles and responsibilities within a medical device company, while also exploring the concepts of process ownership, individual accountability, and how to cultivate a culture of quality and compliance. This book is useful for all executive, functional leaders, and organizations in the highly regulated medical device industry.

GAMP 5 - Sion Wyn 2008

GAMP 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

Fundamentals of EU Regulatory Affairs - Raps 2002-06-30

Wearable Robotics: Challenges and Trends - Juan C. Moreno 2021-07-01

This book reports on advanced topics in the areas of wearable robotics research and practice. It focuses on new technologies, including neural interfaces, soft wearable robots, sensors and actuators technologies, discussing industrially and medically-relevant issues, as well as legal and ethical aspects. It covers exemplary case studies highlighting challenges related to the implementation of wearable robots for different purposes, and describing advanced solutions. Based on the 5th International Symposium on Wearable Robotics, WeRob2020, and on WearRacon Europe 2020, which were both held online on October 13-16, 2020, the book addresses a large audience of academics and professionals working in for the government, in the industry, and in medical centers, as well as end-users alike. By merging together engineering, medical, ethical and industrial perspectives, it offers a multidisciplinary, timely snapshot of the field of wearable technologies.

Internet of Things (IoT) - BK Tripathy 2017-10-10

The term IoT, which was first proposed by Kevin Ashton, a British technologist, in 1999 has the potential to impact everything from new product opportunities to shop floor optimization to factory worker efficiency gains, that will power top-line and bottom-line gains. As IoT technology is being put to diversified use, the current technology needs to be improved to enhance privacy and built secure devices by adopting a security-focused approach, reducing the amount of data collected, increasing transparency and providing consumers with a choice to opt out. Therefore, the current volume has been compiled, in an effort to draw the various issues in IoT, challenges faced and existing solutions so far. Key Points: • Provides an overview of basic concepts and technologies of IoT with communication technologies ranging from 4G to 5G and its architecture. • Discusses recent security and privacy studies and social behavior of human beings over IoT. • Covers the issues related to sensors, business model, principles, paradigms, green IoT and solutions to handle relevant challenges. • Presents the readers with practical ideas of using IoT, how it deals with human dynamics, the ecosystem, the social objects and their relation. • Deals with the challenges involved in surpassing diversified architecture, protocol, communications, integrity and security.