Iso 14971 2012

This book constitutes the thoroughly refereed conference proceedings of the Third International Workshop on Risk Assessment and Risk-driven Testing, RISK 2015, held in conjunction with the OMG Technical Meeting in Berlin, Germany, in June 2015. The revised 8 full papers were carefully reviewed and selected from 12 submissions. This workshop addresses systematic approaches that combine risk assessment and testing. Also, the workshop was structured into the three sessions namely Risk Assessment, Risk and Development and Security Testing.

Increasing demand for and awareness of the applications of nanotechnology in medicine has resulted in the emergence of a new fast-growing multidisciplinary area - nanomedicine. This book offers comprehensive knowledge of and diverse perspectives on nanomedicine through two independent volumes. It aims to bridge the gap between nanotechnology and medicine through contributions by world-renowned experts from wide range of backgrounds including academia, industry, professional consultancy, and government agencies. Each contribution integrates knowledge from a wide range of areas to present the fundamentals of new applications and products of nanomedicine, as well as an outlook for the future. This book can well serve as a reference and guide for students, academics, researchers, scientists, engineers, clinicians, government researchers, and healthcare professionals.

Medical Device Use Error: Root Cause Analysis offers practical guidance on how to methodically discover and explain the root cause of a use error-a mistake-that occurs when someone uses a medical device. Covering medical devices used in the home and those used in clinical environments, the book presents informative case studies about the use errors

Risk is everywhere. It does not matter where we are or what we do. It affects us on a personal level, but it also affects us in our world of commerce and our business. This indispensable summary guide is for everyone who wants some fast information regarding failures and how to deal with them. It explores the evaluation process of risk by utilizing one of the core methodologies available: failure modes and effects analysis (FMEA). The intent is to make the concepts easy to understand and explain why FMEA is used in many industries with positive results to either eliminate or mitigate risk.

Third International Symposium, FHIES 2013, Macau, China, August 21-23, 2013. Revised Selected Papers

A Problem-Solving Approach

Product Lifecycle Management

The Road to Success

Decontamination in Hospitals and Healthcare

An International Handbook for Medical Devices and Healthcare Products

Software Process Improvement and Capability Determination

Usability Professionals Workshop deals with the practical applications of human-machine interaction research. It is organized by the German ACM specialty section of the UPA (Usability Professionals Association). The volume presents the latest research findings through case studies and practice reports along with in-depth discussions.

The use of nanotechnologies continues to grow, as nanomaterials have proven their versatility and use in many different fields and industries within the scientific profession. Using nanotechnology, materials can be made lighter, more durable, more reactive, and more efficient leading nanoscale materials to enhance many everyday products and processes. With many different sizes, shapes, and internal structures, the applications are endless. These uses range from pharmaceutics to materials such as cement or cloth, electronics, environmental sustainability, and more. Therefore, there has been a recent surge of research focused on the synthesis and characterizations of these nanomaterials to better understand how they can be used, their applications, and the many different types. The Research Anthology on Synthesis, Characterization, and Applications of Nanomaterials seeks to address not only how nanomaterials are created, used, or characterized, but also to apply this knowledge to the multidimensional industries, fields, and applications of nanomaterials and nanoscience. This includes topics such as both natural and manmade nanomaterials; the size, shape, reactivity, and other essential characteristics of nanomaterials; challenges and potential effects of using nanomaterials; and the advantages of nanomaterials with multidisciplinary uses. This book is ideally designed for researchers, engineers, practitioners, industrialists, educators, strategists, policymakers, scientists, and students working in fields that include materials engineering, engineering science, nanotechnology, biotechnology, microbiology, drug design and delivery, medicine, and more.

This book defines, develops, and examines the foundations of the APQP (Advanced Product Quality Planning) methodology. It explains in detail the five phases, and it relates its significance to national, international, and customer specific standards. It also includes additional information on the PPAP (Production Part Approval Process), Risk, Warranty, GD&T (Geometric Dimensioning and Tolerancing), and the role of leadership as they apply to the continual improvement process of any organization. Features Defines and explains the five stages of APQP in detail Identifies and zeroes in on the critical steps of the APQP methodology Covers the issue of risk as it is defined in the ISO 9001, IATF 16949, the pending VDA, and the OEM requirements Presents the role of leadership and management in the APQP methodology Summarizes all of the change requirements of the IATF standard

The two-volume set IFIP AICT 639 and 640 constitutes the refereed post-conference proceedings of the 18th IFIP WG 5.1 International Conference on Product Lifecycle Management, PLM 2021, held in Curitiba, Brazil, during July 11-14, 2021. The conference was held virtually due to the COVID-19 crisis. The 107 revised full papers presented in these proceedings were carefully reviewed and selected from 133 submissions. The papers are organized in the following topical sections: Volume I: Sustainability, sustainable development and circular economy; sustainability and information technologies and services; green and blue technologies; AI and blockchain integration with enterprise applications; PLM maturity, PLM implementation and adoption within industry 4.0; and industry 4.0 and emerging technologies: Volume II: Design, education and management; lean, design and innovation technologies; information technology models and design; and models, manufacturing and information technologies and services.

Properties, Requirements, and Applications

Selected Papers from ISPR2020, September 24-26, 2020 Online - Turkey

Establishing a Medical Device Quality System

Handbook of Radiotherapy Physics

Distributed Computing and Monitoring Technologies for Older Patients

Quality of Information and Communications Technology

Design of Assistive Technology for Ageing Populations

This book presents the proceedings from the International Symposium for Production Research 2020. The cross-disciplinary papers presented draw on research from academics and practitioners from industrial engineering, management engineering, operational research, and production/operational management. It explores topics including: · computer-aided manufacturing; Industry 4.0 applications; simulation and modeling big data and analytics; flexible manufacturing systems; decision analysis quality management industrial robotics in production systems information technologies in production management; and optimization techniques. Presenting real-life applications, case studies, and mathematical models, this book is of interest to researchers, academics, and practitioners in the field of production and operation engineering.

This book constitutes the refereed proceedings of the 13th International Conference on the Quality of Information and Communications Technology, QUATIC 2020, held in Faro, Portugal*, in September 2020. The 27 full papers and 12 short papers were carefully reviewed and selected from 81 submissions. The papers are organized in topical sections: quality aspects in machine learning, AI and data analytics; evidence-based software quality engineering; human and artificial intelligences for software evolution; process modeling, improvement and assessment; software quality education and training; quality aspects in quantum computing; safety, security and privacy; ICT verification and validation; RE, MDD and agile. *The conference was held virtually due to the COVID-19 pandemic.

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.

Plastics in Medical Devices: Properties, Requirements, and Applications, Third Edition provides a comprehensive overview on the main types of plastics used in medical device applications. The book focuses on the applications and properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables. The book also covers other key aspects in detail, including regulations, compliance, purchasing controls and supplier controls, and process validation. This updated edition has been thoroughly revised with regard to new plastic materials, applications and requirements. This is a valuable resource for engineers, scientists and managers involved in the design and manufacture of medical devices. Presents detailed coverage of commercially available plastics used in medical device applications, organized by polymer type and supported by data Includes up-to-date regulatory requirements and practical information on purchasing and supplier controls, process validation and risk management Supports the development, marketing and commercialization of medical devices and materials for use in medical devices

From Fundamentals to Translational Medicine

Green and Blue Technologies to Support Smart and Sustainable Organizations : 18th IFIP WG 5. 1 International Conference, PLM 2021, Curitiba, Brazil, July 11-14, 2021, Revised Selected Papers

Managing Medical Devices within a Regulatory Framework

Application of Clinical Bioinformatics

Proceedings of the EMBEC 2020, November 29 – December 3, 2020 Portoro ž , Slovenia

Design of Biomedical Devices and Systems, 4th edition

Bioresorbable Polymers for Biomedical Applications

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

This fourth edition is a substantial revision of a highly regarded text, intended for senior design capstone courses within departments of biomedical engineering, bioengineering, biological engineering and medical engineering, worldwide. Each chapter has been thoroughly updated and revised to reflect the latest developments. New material has been added on entrepreneurship, bioengineering design, clinical trials and CRISPR. Based upon feedback from prior users and reviews, additional and new examples and applications, such as 3D printing have been added to the text. Additional clinical applications were added to enhance the overall relevance of the material presented. Relevant FDA regulations and how they impact the designer's work have been updated. Features Provides updated material as needed to each chapter Incorporates new examples and applications within each chapter Discusses new material related to entrepreneurship, clinical trials and CRISPR Relates critical new information pertaining to FDA regulations. Presents new material on "discovery" of projects "worth pursuing" and design for health care for low-resource environments Presents multiple case examples of entrepreneurship in this field Addresses multiple safety and ethical concerns for the design of medical devices and processes

This book constitutes the refereed proceedings of the 16th International Conference on Software Process Improvement and Capability Determination, SPICE 2016, held in Dublin, Ireland, in June 2016. The 28 full papers presented together with 5 short papers were carefully reviewed and selected from 52 submissions. The papers are organized in the following topical sections: SPI in regulated and safety critical domains; gamification and education issues in SPI; SPI in agile and small settings; SPI and assessment; SPI and project management concerns; empirical research case studies of SPI; knowledge and human communications issues in SPI.

The WHO technical specifications for neonatal resuscitation devices were developed based on existing international standards, evidence-based publications from reliable sources and field expert experience. For equipment without prior technical specifications, recommendations were made based on a literature research, depending on quality and significance of evidence. The purpose of WHO Technical Specifications of Neonatal Resuscitation Devices is to provide a minimum standard baseline to meet the increasing demand to procure good quality, affordable, accessible and appropriate neonatal resuscitation devices. The specifications are intended to support policy-makers, managers, procurement officers, manufacturers, regulators and nongovernmental agencies, especially in low- and middle-income countries to select, procure, use, reprocess and decommission appropriate neonatal resuscitation equipment. The end goal is to save the children, particularly in low-resource settings.

Mensch und Computer 2015 – Usability Professionals

Production, Applications, and Safety

Digital Conversion on the Way to Industry 4.0

Research Anthology on Synthesis, Characterization, and Applications of Nanomaterials

Trends in Development of Medical Devices

Principles and Perspectives

Usability, Accessibility and Ambient Assisted Living

Safety Risk Management for Medical DevicesAcademic Press

Bioresorbable Polymers for Biomedical Applications: From Fundamentals to Translational Medicine provides readers with an overview of bioresorbable polymeric materials in the biomedical field. A useful resource for materials scientists in industry and academia, offering information on the fundamentals and considerations, synthesis and processing, and the clinical and R and D applications of bioresorbable polymers for biomedical applications. Focuses on biomedical applications of bioresorbable polymers Features a comprehensive range of topics including fundamentals, synthesis, processing, and applications Provides balanced coverage of the field with contributions from academia and industry Includes clinical and R and D applications of bioresorbable polymers for biomedical applications

Many companies limp along from day-to-day treating the quality side of the business as a necessary evil, and doing only what is minimally necessary for compliance to regulations. This kind of approach to compliance almost always results in inefficiencies and sometimes can result in a curious kind of noncompliance. Documentation created with compliance as the sole consideration often ends up confusing the employees who must use the documentation. This book looks beyond what is necessary for compliance alone to address what makes a quality management system (QMS) both effective and efficient. This book also never forgets that real people must make any QMS work; the book provides a blueprint for creating a QMS that real people will find useful. After a review of the challenges that any medical device company faces in the world of today—the multiple sources of QMS requirements—the book poses a question: are we satisfied with the QMS we have now, or could we do better? If we want to do better, this book can help. This book offers: Advice that will lead to an effective and efficient QMS. Detailed guidance on the key decisions to be made regarding the quality system being established. Detailed ideas on how to execute those decisions. Up-to-date information on compliance to current regulations and standards and guidance on staying up to date. Specific examples of procedures. Information regarding requirements for combination products, such as a drug + device combination. Advice on incorporating risk management in the QMS.

Trends in Development of Medical Devices covers the basics of medical devices and their development, regulations and toxicological effects, risk assessment and mitigation. It also discusses the maintenance of a medical device portfolio during product lifecycle. This book provides up-to-date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare. Researchers and industry professionals from the fields of medical devices, surgery, medical toxicology, pharmacy and medical devices manufacture will find this book useful. The book's editors and contributors form a global, interdisciplinary base of knowledge which they bring to this book. Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, government regulations Presents new strategies that readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce imperfections in production and develop products that enable completely new treatment possibilities

Managing Clinical Risk

Materials for Medical Application

Safety Risk Management for Medical Devices

Nanomedicine

Advanced Product Quality Planning

Plastics in Medical Devices

Foundations of Health Information Engineering and Systems

Covering the entire spectrum of medical gases, this ready reference offers a comprehensive overview of production, medical gas equipment, medical gas verification, and medical gas safety standards. With a clear focus throughout on safety, the text recommends environmentally responsible manufacturing practices during each step of the process: manufacture, storage, transport, distribution, and in applications. It also discusses standards and regulations, in particular those of the European Union. An essential guide for researchers and professionals whose work includes the manufacture, handling, or use of medical gases.

This book focuses on various aspects of research on ageing, including in relation to assistive technology; dignity of aging; how technology can support a greater understanding of the experience of physically aging and cognitive changes; mobility issues associated with the elderly; and emerging technologies. The 80+ age group represents an expanding market, with an estimated worth of £21.4 billion a year. Everyone is affected by this shift in demographics - we are getting older and may become carers - and we need to prepare ourselves and adjust our surroundings for longer life. Products, services and environments have been changing in response to the changing population. Presenting international design research to demonstrate the thinking and ideas shaping design, this book is a valuable resource for designers; product developers; employers; gerontologists; and medical, health and service providers; as well as everyone interested in aging.

Decontamination in Hospitals and Healthcare, Second Edition, enables users to obtain detailed knowledge of decontamination practices in healthcare settings, including surfaces, devices, clothing and people, with a specific focus on hospitals and dental clinics. Offers in-depth coverage of all aspects of decontamination in healthcare Examines the decontamination of surgical equipment and endoscopes Expanded to include new information on behavioral principles in decontamination, control of microbiological problems, waterborne microorganisms, pseudomonas and the decontamination of laundry

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.

16th International Conference, SPICE 2016, Dublin, Ireland, June 9-10, 2016, Proceedings

8th European Medical and Biological Engineering Conference

Medical Device Design

Health Information Systems

Root Cause Analysis

Medical Device Regulatory Practices

Third International Workshop, RISK 2015, Berlin, Germany, June 15, 2015. Revised Selected Papers

This book elucidates how genetic, biological and medical information can be applied to the development of personalized healthcare, medication and therapies. Focusing on aspects of the development of evidence-based approaches in bioinformatics and computational medicine, including data integration, methodologies, tools and models for clinical and translational medicine, it offers an essential introduction to clinical bioinformatics for clinical researchers and physicians, medical students and teachers, and scientists working with human disease-based omics and bioinformatics. Dr. Xiangdong Wang is a distinguished Professor of Medicine. He is Director of Shanghai Institute of Clinical Bioinformatics, Director of Fudan University Center for Clinical Bioinformatics, Deputy Director of Shanghai Respiratory Research Institute, Director of Biomedical Research Center, Fudan University Zhongshan Hospital, Shanghai, China; Dr. Christian Baumgartner is a Professor of Health Care and Biomedical Engineering at Institute of Health Care Engineering with European Notified Body of Medical Devices, Graz University of Technology, Graz, Austria; Dr. Denis Shields is a Professor of Clinical Bioinformatics at Conway Institute, Belfield, Dublin, Ireland; Dr. Hong-Wen Deng is a Professor at Department of Biostatistics and Bioinformatics, Tulane University School of Public Health and Tropical Medicine, USA; Dr. Jacques S Beckmann is a Professor and Director of Section of Clinical Bioinformatics, Swiss Institute of Bioinformatics, Switzerland.

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

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.

Imaging modalities in radiology produce ever-increasing amounts of data which need to be displayed, optimized, analyzed and archived: a "big data" as well as an "image processing" problem. Computer programming skills are rarely emphasized during the education and training of medical physicists, meaning that many individuals enter the workplace without the ability to efficiently solve many real-world clinical problems. This book provides a foundation for the teaching and learning of programming for medical physicists and other professions in the field of Radiology and offers valuable content for novices and more experienced readers alike. It focuses on providing readers with practical skills on how to implement MATLAB® as an everyday tool, rather than on solving academic and abstract physics problems. Further, it recognizes that MATLAB is only one tool in a medical physicist's toolkit and shows how it can be used as the "glue" to integrate other software and processes together. Yet, with great power comes great responsibility. The pitfalls to deploying your own software in a clinical environment are also clearly explained. This book is an ideal companion for all medical physicists and medical professionals looking to learn how to utilize MATLAB in their work. Features Encompasses a wide range of medical physics applications in diagnostic and interventional radiology Advances the skill of the reader by taking them through real-world practical examples and solutions with access to an online resource of example code The diverse examples of varying difficulty make the book suitable for readers from a variety of backgrounds and with different levels of programming experience.

Handbook of Medical Device Regulatory Affairs in Asia

Medical Regulatory Affairs

Risk Assessment and Risk-Driven Testing

Excellence Beyond Compliance

A Handbook for Clinical and Biomedical Engineers

13th International Conference, QUATIC 2020, Faro, Portugal, September 9–11, 2020, Proceedings

Clinical Engineering

This is a practical book for health and IT professionals who need to ensure that patient safety is prioritized in the design and implementation of clinical information technology. Healthcare professionals are increasingly reliant on information technology to deliver care and inform their clinical decision making. Health IT provides enormous benefits in efficiency, communication and decision making. However a number of high-profile UK and US studies have concluded that when Health IT is poorly designed or sub-optimally implemented then patient safety can be compromised. Manufacturers and healthcare organizations are increasingly required to demonstrate that their Health IT solutions are proactively assured. Surprisingly the majority of systems are not subject to regulation so there is little in the way of practical guidance as to how risk management can be achieved. The book fills that gap. The author, a doctor and IT professional, harnesses his two decades of experience to characterize the hazards that health technology can introduce. Risk can never be eliminated but by drawing on lessons from other safety-critical industries the book systematically sets out how clinical risk can be strategically controlled. The book proposes the employment of a Safety Case to articulate and justify residual risk so that not only is risk proactively managed but it is seen to be managed. These simple techniques drive product quality and allow a technology's benefits to be realized without compromising patient safety.

This book aims at informing on new trends, challenges and solutions, in the multidisciplinary field of biomedical engineering. It covers traditional biomedical engineering topics, as well as innovative applications such as artificial intelligence in health care, tissue engineering , neurotechnology and wearable devices. Further topics include mobile health and electroporation-based technologies, as well as new treatments in medicine. Gathering the proceedings of the 8th European Medical and Biological Engineering Conference (EMBEC 2020), held on November 29 - December 3, 2020, in Portorož, Slovenia, this book bridges fundamental and clinically-oriented research, emphasizing the role of education, translational research and commercialization of new ideas in biomedical engineering. It aims at inspiring and fostering communication and collaboration between engineers, physicists, biologists, physicians and other professionals dealing with cutting-edge themes in and advanced technologies serving the broad field of biomedical engineering.

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.

From the essential background physics and radiobiology to the latest imaging and treatment modalities, the updated second edition of Handbook of Radiotherapy Physics: Theory & Practice covers all aspects of the subject. In Volume 1, Part A includes the Interaction of Radiation with Matter (charged particles and photons) and the Fundamentals of Dosimetry with an extensive section on small-field physics. Part B covers Radiobiology with increased emphasis on hypofractionation. Part C describes Equipment for Imaging and Therapy including MR-guided linear accelerators. Part D on Dose Measurement includes chapters on ionisation chambers, solid-state detectors, film and gels, as well as a detailed description and explanation of Codes of Practice for Reference Dose Determination including detector correction factors in small fields. Part E describes the properties of Clinical (external) Beams. The various methods (or 'algorithms') for Computing Doses in Patients irradiated by photon, electron and proton beams are described in Part F with increased emphasis on Monte-Carlo-based and grid-based deterministic algorithms. In Volume 2, Part G covers all aspects of Treatment Planning including CT-, MR- and Radionuclide-based patient imaging, Intensity-Modulated Photon Beams, Electron and Proton Beams, Stereotactic and Total Body Irradiation and the use of the dosimetric and radiobiological metrics TCP and NTCP for plan evaluation and optimisation. Quality Assurance fundamentals with application to equipment and processes are covered in Part H. Radionuclides, equipment and methods for Brachytherapy and Targeted Molecular Therapy are covered in Parts I and J, respectively. Finally, Part K is devoted to Radiation Protection of the public, staff and patients. Extensive tables of Physical Constants, Photon, Electron and Proton Interaction data, and typical Photon Beam and Radionuclide data are given in Part L. Edited by recognised authorities in the field, with individual chapters written by renowned specialists, this second edition of Handbook of Radiotherapy Physics provides the essential up-to-date theoretical and practical knowledge to deliver safe and effective radiotherapy. It will be of interest to clinical and research medical physicists, radiation oncologists, radiation technologists, PhD and Master's students.

Application of Risk Management to Medical Devices

Diagnostic Radiology Physics with MATLAB®

Medical Gases

Risk Management Using Failure Mode and Effect Analysis (FMEA)

An International Perspective

Medical Equipment Management

Musterhandbuch Medizin : DIN EN ISO 13485:2012 unter Berücksichtigung der ISO 14971:2012 ; prozessorientiert

This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case studies. Medical devices, like pharmaceuticals, are highly regulated, and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in their pursuit of commercial success. Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes practical solutions for a coherent, one-size-fits-all (or most) set of systems and processes in compliance with regulations in all key markets, throughout the life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets; important terminology needed to understand the regulators' language; and examples, case studies, and practical recommendations that bridge the gap between regulatory theory and practice.

Know What to Expect When Managing Medical Equipment and Healthcare Technology in Your Organization As medical technology in clinical care becomes more complex, clinical professionals and support staff must know how to keep patients safe and equipment working in the clinical environment. Accessible to all healthcare professionals and managers, Medical Equipment Management presents an integrated approach to managing medical equipment in healthcare organizations. The book explains the underlying principles and requirements and raises awareness of what needs to be done and what questions to ask. It also provides practical advice and refers readers to appropriate legislation and guidelines. Starting from the medical equipment lifecycle, the book takes a risk-based approach to improving the way in which medical devices are acquired and managed in a clinical context. Drawing on their extensive managerial and teaching experiences, the authors explain how organizational structures and policies are set up, how funding is allocated, how people and equipment are supported, and what to do when things go wrong.

This book constitutes the thoroughly refereed post-conference proceedings of the Third International Symposium on Foundations of Health Information Engineering and Systems, FHIES 2013, held in Macau, China, in August 2013. The 19 revised full papers presented together with 1 invited talk in this volume were carefully reviewed and selected from 22 submissions. The papers are organized in following subjects: panel position statements, pathways, generation and certification, interoperability, patient safety, device safety, formal methods and HIV/AIDS and privacy.

Clinical Engineering: A Handbook for Clinical and Biomedical Engineers, Second Edition, helps professionals and students in clinical engineering successfully deploy medical technologies. The book provides a broad reference to the core elements of the subject, drawing from a range of experienced authors. In addition to engineering skills, clinical engineers must be able to work with both patients and a range of professional staff, including technicians, clinicians and equipment manufacturers. This book will not only help users keep up-to-date on the fast-moving scientific and medical research in the field, but also help them develop laboratory, design, workshop and management skills. The updated edition features the latest fundamentals of medical technology integration, patient safety, risk assessment and assistive technology. Provides engineers in core medical disciplines and related fields with the skills and knowledge to successfully collaborate on the development of medical devices, via approved procedures and standards Covers US and EU standards (FDA and MDD, respectively, plus related ISO requirements) Includes information that is backed up with real-life clinical examples, case studies, and separate tutorials for training and class use Completely updated to include new standards and regulations, as well as new case studies and illustrations Workshop

WHO Technical Specifications for Neonatal Resuscitation Devices

Innovation from Concept to Market

Medical Device Use Error

Theory and Practice, Second Edition, Two Volume Set

Medical Devices

This book summarizes various approaches for the automatic detection of health threats to older patients at home living alone. The text begins by briefly describing those who would most benefit from healthcare supervision. The book then summarizes possible scenarios for monitoring an older patient at home, deriving the common functional requirements for monitoring technology. Next, the work identifies the state of the art of technological monitoring approaches that are practically applicable to geriatric patients. A survey is presented on a range of such interdisciplinary fields as smart homes, telemonitoring, ambient intelligence, ambient assisted living, gerontechnology, and aging-in-place technology. The book discusses relevant experimental studies, highlighting the application of sensor fusion, signal processing and machine learning techniques. Finally, the text discusses future challenges, offering a number of suggestions for further research directions.

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
Medical Device Design: Innovation from Concept to Market, Second Edition provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones; this book fills that need. It addresses medical devices' regulatory (FDA and EU) requirements, shows the essential methodologies medical designers must understand to ensure their products meet requirements, and brings together proven design protocols, thus enabling engineers and medical device manufacturers to rapidly bring new products to the marketplace. This book is unique because it takes the reader through the process of medical device development, from very early stages of conceptualization, to commercialization on the global market. This rare resource can be used by both professionals and newcomers to device design. Provides a reference to standards and regulations that have been updated, including ISO 13485:2016, FDA regulations and the European Medical Device Regulation Includes new case studies in the areas of classifying medical devices, the design process, quality, labeling, instructions for use, and more Presents additional content around software and biocompatibility concerns