Bs En Iso 14971 2012 Medical Devices Application Of Risk

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 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 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

This book constitutes the refereed proceedings of the 17th International Conference on Software Process Improvement and Capability Determination, SPICE 2017, held in Palma de Mallorca, Spain, in October 2017. The 34 full papers presented together with 4 short papers were carefully reviewed and selected from 65 submissions. The papers are organized in the following topical sections: SPI in agile approaches; SPI in small settings; SPI and assessment; SPI and models; SPI and functional safety; SPI in various settings; SPI and gamification; SPI case studies; strategic and knowledge issues in SPI; education issues in

SPI.
Joint Conference of the European Medical and Biological Engineering Conference (EMBEC) and the Nordic-Baltic Conference on Biomedical Engineering and Medical Physics (NBC), Tampere, Finland, June 2017
Report of the U.S. Preventive Services Task Force
Application of Risk Management to Medical Devices
15th International Conference, SPICE 2015, Gothenburg, Sweden, June 16-17, 2015. Proceedings
World Congress on Medical Physics and Biomedical Engineering May 26-31, 2012, Beijing, China
Strategies for the Real World

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 This volume presents the proceedings of the joint conference of the European Medical and Biological Engineering Conference (EMBEC) and the Nordic-Baltic Conference on Biomedical Engineering and Medical Physics (NBC), held in Tampere, Finland, in June 2017. The proceedings present all traditional biomedical engineering areas, but also highlight new emerging fields, such as tissue engineering, bioinformatics, biosensing, neurotechnology, additive manufacturing

technologies for medicine and biology, and bioimaging, to name a few. Moreover, it emphasizes the role of education, translational research, and commercialization. Software and Systems Traceability provides a comprehensive description of the practices and theories of software traceability across all phases of the software development lifecycle. The term software traceability is derived from the concept of requirements traceability. Requirements traceability is the ability to track a requirement all the way from its origins to the downstream work products that implement that requirement in a software system. Software traceability is defined as

the ability to relate the various types of software artefacts created during the development of software systems. Traceability relations can improve the quality of a product being developed, and reduce the time and cost of development. More specifically, traceability relations can support evolution of software systems, reuse of parts of a system by comparing components of new and existing systems, validation that a system meets its requirements, understanding of the rationale for certain design and implementation decisions, and analysis of the implications of changes in the system.
This third edition provides a

substantial comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure a company's design control program evolves in accordance with current industry practice. It assists in the development of an effective design control program that not only satisfies the US FDA Quality Systems Regulation (QSR) and 13485:2016 standards, but also meets today's Notified Body Auditors' and FDA Investigators' expectations. The book includes a review of the design control elements such as design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk

management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations and classes in the US, Canada, and Europe. Practical advice, methods and appendixes are provided to assist with implementation of a compliant design control program and extensive references are provided for further study. This third edition: Examines new coverage of ISO 13485-2016 design control requirements Explores proven techniques and methods for compliance Contributes fresh templates for practical implementation Provides

updated chapters with additional details for greater understanding and compliance Offers an easy to understand breakdown of design control requirements Reference to MDSAP design control requirements

Handbook of Radiotherapy Physics

Efektivní řízení kvality

Software and Systems Traceability 17th International Conference, SPICE 2017, Palma de Mallorca, Spain, October 4–5, 2017, Proceedings

Handbook of Human Factors in Medical Device Design

13th International Conference, SPICE 2013, Bremen, Germany, June 4-6, 2013. Proceedings

The congress's unique structure represents the two dimensions of technology and medicine: 13 themes on science and medical technologies intersect with five challenging main topics of medicine to create a maximum of synergy and integration of aspects on research, development and application. Each of the congress themes was chaired by two leading experts. The themes address specific topics of medicine and technology that provide multiple and excellent opportunities for exchanges. 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.
The broad and developing scope of ergonomics - the application of scientific knowledge to improve people's interaction with products, systems and environments - has been illustrated for 27 years by

the books which make up the Contemporary Ergonomics series.This book presents the proceedings of the international conference on Contemporary Ergonomics 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

Excellence Beyond Compliance

Application of Usability Engineering to Medical Devices

Decontamination in Hospitals and Healthcare

Medical Devices

Systems Design for Remote Healthcare

A Handbook for Clinical and Biomedical Engineers

This book constitutes the

refereed proceedings of the 14th International Conference on Software Process Improvement and Capability Determination, SPICE 2014, held in Vilnius, Lithuania, in November 2014. The 21 revised full papers presented together with 6 short papers were carefully reviewed and selected from 49 submissions. The papers are organized in topical sections on developing process models for assessment; software process and models; software models and product lines; assessment; agile processes; processes improvement and VSE. Outlines the correct

procedures for doing FMEAs and how to successfully apply them in design, development, manufacturing, and service applications There are a myriad of quality and reliability tools available to corporations worldwide, but the one that shows up consistently in company after company is Failure Mode and Effects Analysis (FMEA). Effective FMEAs takes the best practices from hundreds of companies and thousands of FMEA applications and presents streamlined procedures for veteran FMEA practitioners, novices, and everyone in between. Written

from an applications viewpoint—with many examples, detailed case studies, study problems, and tips included—the book covers the most common types of FMEAs, including System FMEAs, Design FMEAs, Process FMEAs, Maintenance FMEAs, Software FMEAs, and others. It also presents chapters on Fault Tree Analysis, Design Review Based on Failure Mode (DRBFM), Reliability-Centered Maintenance (RCM), Hazard Analysis, and FMECA (which adds criticality analysis to FMEA). With extensive study problems and a companion

Solutions Manual, this book is an ideal resource for academic curricula, as well as for applications in industry. In addition, Effective FMEAs covers: The basics of FMEAs and risk assessment How to apply key factors for effective FMEAs and prevent the most common errors What is needed to provide excellent FMEA facilitation Implementing a "best practice" FMEA process Everyone wants to support the accomplishment of safe and trouble-free products and processes while generating happy and loyal customers. This book will show readers how to use FMEA to anticipate

and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.

This book presents an introduction to biomaterials with the focus on the current development and future direction of biomaterials and medical devices research and development in Indonesia. It is the first biomaterials book written by selected academic and clinical experts experts on biomaterials and medical devices from various institutions and industries in Indonesia. It serves as a

reference source for researchers starting new projects, for companies developing and marketing products and for governments setting new policies. Chapter one covers the fundamentals of biomaterials, types of biomaterials, their structures and properties and the relationship between them. Chapter two discusses unconventional processing of biomaterials including nano-hybrid organic-inorganic biomaterials. Chapter three addresses biocompatibility issues including in vitro cytotoxicity, genotoxicity, in vitro cell models,

biocompatibility data and its related failure. Chapter four describes degradable biomaterial for medical implants, which include biodegradable polymers, biodegradable metals, degradation assessment techniques and future directions. Chapter five focuses on animal models for biomaterial research, ethics, care and use, implantation study and monitoring and studies on medical implants in animals in Indonesia. Chapter six covers biomimetic bioceramics, natural-based biocomposites and the latest research on natural-based

biomaterials in Indonesia. Chapter seven describes recent advances in natural biomaterial from human and animal tissue, its processing and applications. Chapter eight discusses orthopedic applications of biomaterials focusing on most common problems in Indonesia, and surgical intervention and implants. Chapter nine describes biomaterials in dentistry and their development in Indonesia.
"The book describes the design rules required to document, implement, and demonstrate quality management system effectiveness in compliance

with the latest version of the ISO 9000 International Standard. This systematic and engineering approach simplifies the many complexities in maintaining compliance with ISO standards. This hands-on guide is packed with tips and insights the author has garnered from personally designing quality management systems that integrate organizational strategy with quality management. Moreover, the book helps professionals create meaningful documentation and a user-friendly, informative quality manual that together

form the core of an effective and responsive quality management system."--Jacket.
Software Process Improvement and Capability Determination
Handbook of Laser Technology and Applications
Design of Biomedical Devices and Systems, 4th edition
Design of Assistive Technology for Ageing Populations
Integrated Safety and Risk Assessment for Medical Devices and Combination Products
Achieving Safe, Reliable, and Economical Products and Processes using Failure Mode and Effects Analysis
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.

Developed to promote the design of safe, effective, and usable medical devices, Handbook of Human Factors in Medical Device Design provides a single convenient source of authoritative information to support evidence-based design and evaluation of medical device user interfaces using rigorous human factors engineering principles. It offers guidance

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. 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
Biomaterials and Medical Devices
Guide to Clinical Preventive Services
Proceedings of the international conference on Ergonomics & Human Factors 2013, Cambridge, UK, 15-18 April 2013
Theory and Practice, Second Edition, Two Volume Set
Laser Applications: Medical, Metrology and

Communication (Volume Four)

Designing inclusively is no longer an option for companies. It is a business essential. Global populations are getting older, legislation is increasingly prohibitive of unnecessary exclusion and consumer attitudes are beginning to change. Exclusivity is out, inclusivity is in. Research communities the world over are responding to this change in design emphasis. Conferences such as the Cambridge Workshops on Universal Access and

Assistive Technology (CWUAAT) offer a forum for researchers from diverse and varied disciplines to bring their perspectives on inclusive design together. This book has been inspired by the second CWUAAT, held in Cambridge, England in March 2004. It contains chapters from an international group of leading researchers in this field. Contributions focus on the following topics: design issues for universal access and assistive technology; enabling computer access and new technologies; and, assistive

technology and rehabilitation robotics. This series of conferences is aimed at a broad range of interests, with a general focus on the development of products and solutions. Numerous case studies are used to raise awareness of the challenges faced in developing truly inclusive products, along with examples of good practice for design for a more inclusive world.
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.
Managing Medical Devices within a Regulatory FrameworkElsevier
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
Plastics in Medical Devices
Medical Devices [electronic Resource] : Quality Management Systems : Requirements for Regulatory Purposes
Design Controls for the Medical Device Industry, Third Edition
A Perspective from an Emerging Country

14th International Conference, SPICE 2014, Vilnius, Lithuania, November 4-6, 2014. Proceedings

Safer Healthcare

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

process models; studies of software development; agile development; IT service management; assessment for diagnosis.

Decontamination in Hospitals and Healthcare brings an understanding of decontamination practices and the development of technologies for cleaning and control of infection to a wide audience interested in public health, including healthcare specialists, scientists, students or patients. Part one highlights the importance and history of decontamination in hospitals and healthcare before exploring the role of standards in decontamination, infection control in Europe, and future

trends in the area. Part two focuses on decontamination practices in hospitals and healthcare. It considers the role of the nurse in decontamination, the issues of microbial biofilm in waterlines, control of waterborne microorganisms, and the use of gaseous decontamination technologies. Further chapters explore decontamination of prions, the use of protective clothing, no-touch automated room disinfection systems, and controlling the presence of microorganisms in hospitals. Part three discusses practices for decontamination and sterilization of surgical instruments and endoscopes. These chapters examine a range of guidance documents, including the choice

framework for local policy and procedures for decontamination of surgical instruments, as well as novel technologies for cleaning and detection of contamination. Decontamination in Hospitals and Healthcare provides a reference source on decontamination for public health professionals and students concerned with healthcare. It is particularly useful for scientists in microbiology and disinfection/decontamination laboratories, healthcare workers who use disinfectants, students in microbiology, clinicians, members of the Institute of Decontamination Sciences/Central Sterilising Club, and those employed in the Central Sterile Services departments of healthcare

facilities. Discusses decontamination processes in Europe Provides an in-depth understanding into decontamination in healthcare settings, specifically hospitals and dental practices Examines the decontamination of surgical equipment and endoscopes

The authors of this book set out a system of safety strategies and interventions for managing patient safety on a day-to-day basis and improving safety over the long term. These strategies are applicable at all levels of the healthcare system from the frontline to the regulation and governance of the system. There have been many advances in patient safety, but we now need a new and broader vision that

encompasses care throughout the patient's journey. The authors argue that we need to see safety through the patient's eyes, to consider how safety is managed in different contexts and to develop a wider strategic and practical vision in which patient safety is recast as the management of risk over time. Most safety improvement strategies aim to improve reliability and move closer toward optimal care. However, healthcare will always be under pressure and we also require ways of managing safety when conditions are difficult. We need to make more use of strategies concerned with detecting, controlling, managing and responding to risk. Strategies for

managing safety in highly standardised and controlled environments are necessarily different from those in which clinicians constantly have to adapt and respond to changing circumstances. This work is supported by the Health Foundation. The Health Foundation is an independent charity committed to bringing about better health and health care for people in the UK. The charity's aim is a healthier population in the UK, supported by high quality health care that can be equitably accessed. The Foundation carries out policy analysis and makes grants to front-line teams to try ideas in practice and supports research into what works to make people's

lives healthier and improve the health care system, with a particular emphasis on how to make successful change happen. A key part of the work is to make links between the knowledge of those working to deliver health and health care with research evidence and analysis. The aspiration is to create a virtuous circle, using what works on the ground to inform effective policymaking and vice versa. Good health and health care are vital for a flourishing society. Through sharing what is known, collaboration and building people's skills and knowledge, the Foundation aims to make a difference and contribute to a healthier population.

The purpose of this guidance

document is for the appropriate selection procurement utilization and maintenance of oxygen concentrators. This document also focuses on recommendations for the appropriate use and maintenance of oxygen concentrators in an effort to increase the availability management and quality of oxygen concentrators and ultimately to improve health outcomes in LRS. This document is intended to serve as a resource for the planning and provision of local and national oxygen concentrator systems for use by administrators clinicians and technicians who are interested in improving access to oxygen therapy and reducing global mortality associated with

hypoxaemia.

Biomedical Applications of Electrospinning and Electrospraying
Biocompatibility and Performance of Medical Devices
Medical Device Design
A Risk-based Approach to Compliant GxP Computerized Systems
GAMP 5
ISO 9001:2000 Quality Management System Design

This book provides a multidisciplinary overview of the design and implementation of systems for remote patient monitoring and healthcare. Readers are guided step-by-step through the components of such a

system and shown how they could be integrated in a coherent framework for deployment in practice. The authors explain planning from subsystem design to complete integration and deployment, given particular application constraints. Readers will benefit from descriptions of the clinical requirements underpinning the entire application scenario, physiological parameter sensing techniques, information processing approaches and overall, application dependent system integration. Each chapter ends with a discussion of practical design challenges and

two case studies are included to provide practical examples and design methods for two remote healthcare systems with different needs.

This book constitutes the refereed proceedings of the 15th International Conference on Software Process Improvement and Capability Determination, SPICE 2015, held in Gothenburg, Sweden, in June 2015. The 17 revised full papers presented together with three short papers were carefully reviewed and selected from 48 submissions. The papers are organized in topical sections on industrial frameworks; implementation and

assessment; process improvement; agile processes; assessment and maturity models; process and education.
Biomedical Applications of Electrospinning and Electrospraying describes the principles and laboratory set up for electrospinning and electrospraying, addressing a range of biomedical applications. Sections cover novel combinational approaches, such as electrospinning/spraying and 3D printing. Electrospinning has evolved from being a technique to prepare random networks of textile fibers to a technique to fabricate highly ordered patterns

of biomedical materials of defined scale. The technological advancements in recent years with regard to the way the jet is facilitated, how the jet path is controlled, and how the fibers are collected have provided invaluable insights into controlled fabrication of a material of choice. Additionally, the electrospray technique has also evolved from being a technique to prepare food formulations to a technique to prepare cell encapsulated beads for transplantation in clinics. Several innovations in this line, such as those leading to core-shell materials have tremendously changed the way the technique is

used. Thus, a combinational approach using electrospinning, electrospraying and 3D printing has emerged. Introduces electrospinning and electrospraying concepts and describes state-of-the-art methodologies Provides comprehensive coverage of electrospun/spray materials in drug delivery, tissue engineering and biosensor applications Presents details of instrumentation involved, along with novel devices for bench to bedside translation, Covers novel combinational approaches using electrospinning, electrospraying and 3D printingIntroduces

electrospinning and electrospraying concepts and describes state-of-the-art methodologies Provides comprehensive coverage of electrospun/spray materials in drug delivery, tissue engineering and biosensor applications Presents details of instrumentation involved, along with novel devices for bench to bedside translation Covers novel combinational approaches using electrospinning, electrospraying and 3D printing

Průvodce správným fungováním v managementu kvality. Publikace je na českém trhu unikátní: obsahuje souhrnné informace o

systémech řízení, příklady ze skutečných firem i návrhy správných řešení. Na jednom místě čtenář najde nejběžněji používané, v praxi vyzkoušené metody a aktuální požadavky pro systémové normy. Dozví se, jak metody kvalitně aplikovat, jak zvýšit efektivitu a snížit nákladovost vybudovaného systému. Příručka se hodí pro širokou veřejnost, poslouží v podnikové praxi i v rámci vysokoškolského studia. Autor v ní zúročil více než dvacet let zkušeností v oboru – působí jako lektor, konzultant a auditor systému řízení. O řízení kvality a podnikovém řízení také přednáší

na akademické půdě.

Contemporary Ergonomics and Human Factors 2013

WHO Medical Device Technical Series

Innovation from Concept to Market

EMBEC & NBC 2017

Establishing a Medical Device Quality System

Effective FMEAs

While the safety assessment ("biocompatibility") of medical devices has been focused on issues of local tissue tolerance (irritation, sensitization, cytotoxicity) and selected quantal effects (genotoxicity and acute lethality) since first being regulated in the late 1950s, this has

changed as devices assumed a much more important role in healthcare and became more complex in both composition and in their design and operation. Add to this that devices now frequently serve as delivery systems for drugs, and that drugs may be combined with devices to improve device performance, and the problems of ensuring patient safety with devices has become significantly more complex. A part of this, requirements for ensuring safety (once based on use of previously acceptable materials – largely polymers and metals) have come to requiring determining which chemical entities are potentially released from a device into patients (and how much

is released). Then an appropriate and relevant (yet also conservative) risk assessment must be performed for each identified chemical structure. The challenges inherent in meeting the current requirements are multifold, and this text seeks to identify, understand, and solve all of them. • Identify and verify the most appropriate available data. • As in most cases such data is for a different route of exposure, transform it for use in assessing exposure by the route of interest. • As the duration (and rate) of exposure to moieties released from a device are most frequently different (longer) than what available data speaks to, transformation across tissue is

required. • As innate and adaptive immune responses are a central part of device/patient interaction, assessing potential risks on this basis are required. • Incorporating assessments for special populations such as neonates. • Use of (Q)SAR (Quantitative Structure Activity Relationships) modeling in assessments. • Performance and presentation of integrative assessments covering all potential biologic risks. Appendices will contain summarized available biocompatibility data for commonly used device materials (polymers and metals) and safety assessments on the frequently seen moieties in extractions from devices.

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.

Mechanical Circulatory and Respiratory Support is a comprehensive overview of the past, present and future development of mechanical circulatory and respiratory support devices. Content

from over 60 internationally-renowned experts focusses on the entire life-cycle of mechanical circulatory and respiratory support – from the descent into heart and lung failure, alternative medical management, device options, device design, implantation techniques, complications and medical management of the supported patient, patient-device interactions, cost effectiveness, route to market and a view to the future. This book is written as a useful resource for biomedical engineers and clinicians who are designing new mechanical circulatory or respiratory support devices, while also providing a comprehensive guide of the entire

field for those who are already familiar with some areas and want to learn more. Reviews of the most cutting-edge research are provided throughout each chapter, along with guides on how to design new devices and which areas require specific focus for future research and development. Covers a variety of disciplines, from anatomy of organs and evolution of cardiovascular devices, to their clinical applications and the manufacturing and marketing of devices Provides engineering and clinical perspectives to assist readers in the design of a market appropriate device Discusses history, design, usage, and development of mechanical

circulatory and respiratory support systems

This comprehensive handbook gives a fully updated guide to lasers and laser technologies, including the complete range of their technical applications. This forth volume covers laser applications in the medical, metrology and communications fields. Key Features: • Offers a complete update of the original, bestselling work, including many brand-new chapters. • Deepens the introduction to fundamentals, from laser design and fabrication to host matrices for solid-state lasers, energy level diagrams, hosting materials, dopant energy levels, and lasers based on nonlinear effects. •

Covers new laser types, including quantum cascade lasers, silicon-based lasers, titanium sapphire lasers, terahertz lasers, bismuth-doped fiber lasers, and diode-pumped alkali lasers. • Discusses the latest applications, e.g., lasers in microscopy, high-speed imaging, attosecond metrology, 3D printing, optical atomic clocks, time-resolved spectroscopy, polarization and profile measurements, pulse measurements, and laser-induced fluorescence detection. • Adds new sections on laser materials processing, laser spectroscopy, lasers in imaging, lasers in environmental sciences, and lasers in communications. This handbook is the ideal companion for scientists,

engineers, and students working with lasers, including those in optics, electrical engineering, physics, chemistry, biomedicine, and other relevant areas.
Mechanical Circulatory and Respiratory Support
WHO Technical Specifications for Neonatal Resuscitation Devices
Technical Specifications for Oxygen Concentrators
Designing a More Inclusive World
Properties, Requirements, and Applications
Clinical Engineering