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Advances in Software Engineering, Education, and e-Learning - Hamid R. Arabnia 2021-09-09
This book presents the proceedings of four conferences: The 16th International Conference on Frontiers in Education: Computer Science and Computer Engineering + STEM (FECS'20), The 16th International Conference on Foundations of Computer Science (FCS'20), The 18th International Conference on Software Engineering Research and Practice (SERP'20), and The 19th International Conference on e-Learning, e-Business, Enterprise Information Systems, & e-Government (EEE'20). The conferences took place in Las Vegas, NV, USA, July 27-30, 2020 as part of the larger 2020 World Congress in Computer Science, Computer Engineering, & Applied Computing (CSCE'20), which features 20 major tracks. Authors include academics, researchers, professionals, and students. This book contains an open access chapter entitled, "Advances in Software Engineering, Education, and e-Learning". Presents the proceedings of four conferences as part of the 2020 World Congress in Computer Science, Computer Engineering, & Applied Computing (CSCE'20); Includes the tracks Computer Engineering + STEM, Foundations of Computer Science, Software Engineering Research, and e-Learning, e-Business, Enterprise Information Systems, & e-Government; Features papers from FECS'20, FCS'20, SERP'20, EEE'20, including one open access chapter.
Medical Device Software Verification, Validation and Compliance - David A. Vogel 2010
HereOCOs the first book written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software.Offering you a much broader, higher-level picture than other books in this field, this book helps you think critically about software validation -- to build confidence in your softwareOCOs safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process.From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, in compliance with regulations."
Computer Safety, Reliability, and Security - Floor Koornneef 2015-09-15
This book constitutes the refereed proceedings of the 34th International Conference on Computer Safety, Reliability, and Security, SAFECOMP 2015, held in Delft, The Netherlands, in September 2014. The 32 revised full papers presented together with 3 invited talks were carefully reviewed and selected from 104 submissions. The papers are organized in topical sections on flight systems, automotive embedded systems, automotive software, error detection, medical safety cases, medical systems, architecture and testing, safety cases, security attacks, cyber security and integration, and programming and compiling.
DESIGN CONTROLS, RISK MANAGEMENT & PROCESS VALIDATION FOR MEDICAL DEVICE PROFESSIONALS - Vernon Geckler 2017-02-11
This handbook provides the most up to date resource currently available for interpreting and understanding design controls. This handbook is the most exhaustive resource ever written about FDA & ISO 13485 design controls for medical devices with a collection of all applicable regulations and real-world examples. Four-hundred & forty, 8.5" X 11" pages provides an extensive evaluation of FDA 21 CFR 820 and is cross-referenced with ISO 13485 to provide readers with a broad and in-depth review of practical design control implementation techniques. This handbook also covers basic, intermediate and advanced design control topics and is an ideal resource for implementing new design control processes or upgrading an existing process into medical device quality systems. This critical resource also specifically outlines key topics which will allow quality managers and medical device developers to improve compliance quickly to pass internal and external audits and FDA inspections. The author breaks down the regulation line by line and provides a detailed interpretation by using supportive evidence from the FDA design control guidance and the quality systems preamble. Numerous examples, case studies, best practices, 70+ figures and 45+ tables provide practical implementation techniques which are based on the author's extensive experience launching numerous medical device products and by integrating industry consultant expertise. In addition, bonus chapters include: explanation of medical device classification, compliance to design controls, risk management, and the design control quality system preamble. 20-40 pages are dedicated to each of the major design control topics: Design and Development Planning, Design Input, Design Output, Design Transfer, Design Verification, Design Validation, Design Change and Design History File.
Systems, Software and Services Process Improvement - Fergal McCaffery 2013-06-12
This volume constitutes the refereed proceedings of the 20th EuroSPI conference, held in Dundalk, Ireland, in June 2013. The 31 revised papers presented in this volume were carefully reviewed and selected. They are organized in topical sections on SPI Safety and Regulation Issues; SPI Lifecycle and Models; SPI Quality and Testing Issues; SPI Networks and Teams; SPI and Reference Models; SPI Implementation; Agile organisations and an agile management process group; Managing Diversity and Innovation; SPI and Measurement; Risk Management and Functional Safety Standards.
Healthcare Technology Management - A Systematic Approach - Francis Hegarty 2017-01-06

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

Safety Risk Management for Medical Devices - Bijan Elahi 2018-06-29

Safety Risk Management for Medical Devices demystifies risk management, providing clarity of thought and confidence to the practitioners of risk management as they do their work. Written with practicing engineers, safety management professionals, and students in mind, this book will help readers tackle the difficult questions, such as how to define risk acceptance criteria and how to determine when to stop risk reduction. This book delivers not only theory, but also practical guidance for applying the theory in daily risk management work. The reader is familiarized with the vocabulary of risk management and guided through a process to ensure compliance with the international standard ISO 14971—a requirement for all medical devices. This book outlines sensible, easily comprehensible, and state-of the-art methodologies that are rooted in current industry best practices. Opening chapters introduce the concept of risk, the legal basis for risk management, and the requirements for a compliant risk-management process. The next group of chapters discusses the connection between risk management and quality systems, usability engineering and biocompatibility. This book delves into the techniques of risk management, such as fault tree analysis and failure modes and effects analysis, and continues with risk estimation, risk control, and risk evaluation. Special topics such as software risk management, clinical investigations, and security are also discussed. The latter chapters address benefit-risk analysis, and production and postproduction monitoring. This book concludes with advice and wisdom for sensible, efficient, and successful safety risk management of medical devices. Teaches industry best practices on medical-device risk management in compliance with ISO 14971 Provides practical, easy-to-understand, and step-by-step instructions on how to perform hazard analysis and manage the risks of medical devices Offers a worked-out example applying the risk management process on a hypothetical device

YY/T 0595-2020: Translated English of Chinese Standard. (YYT 0595-2020, YY/T0595-2020, YYT0595-2020) - https://www.chinesestandard.net 2021-03-20

[After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] This standard provides guidelines for the application of medical device quality management system requirements in YY/T 0287-2017. This standard applies to organizations of various sizes and types, as well as suppliers or other external parties that provide products and services for them, which involves one or more stages of the life cycle of medical devices.

Systems, Software and Services Process Improvement - Rory V. O'Connor 2015-10-15

This volume constitutes the refereed proceedings of the 22st EuroSPI conference, held in Ankara, Turkey, in September/October 2015.The 18 revised papers presented together with 9 selected key notes and workshop papers were carefully reviewed and selected from 49 submissions. They are organized in topical sections on SPI themed case studies; SPI approaches in safety-critical domains; SPI in social and organizational issues; software process improvement best practices; models and optimization approaches in SPI; SPI and process assessment; creating environments supporting innovation and improvement; social aspects of SPI: conflicts, games, gamification and other social approaches; risk management and functional safety management.

Software Process Improvement and Capability Determination - Antanas Mitasiunas 2014-10-13

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.

Software für Medizingeräte - Georg Heidenreich 2015-07-06

Programme für Medizingeräte müssen der Norm IEC 62304 entsprechen. Diese Software-Norm ist sehr vielseitig und eignet sich für alle möglichen Projektarten und -größen. Immer wieder treten dabei Spezialfälle auf, in denen die Norm individuell ausgelegt werden muss. Aus der Mitarbeit an der Norm, einer umfangreichen FAQ-Liste, der Beratung von Software-Entwicklern und vielen Diskussionen und Schulungen haben die Autoren eine Fülle von Erfahrungen gesammelt, die sie in dem Buch präsentieren. Dabei nutzen sie den Arbeitsablauf des Praktikers, um auf die möglichen Fallbeispiele und deren Lösung hinzuführen. Entwicklungsleiter, Programmierer, Qualitätsverantwortliche sowie Studenten der Medizintechnik erhalten mit diesem kompakten Buch eine praktische und vielseitige Auslegung der gesetzlichen Anforderungen an Software-Entwicklungsprozesse. Entwicklungsleiter finden darin eine normgerechte Vorgehensweise für ihre Prozesse, Qualitätsverantwortliche Informationen zu Koordination, Dokumentation und Controlling und Programmierer eine Einführung in die Umsetzung der anwendbaren Norm aus ihrer Sicht. Die Autoren machen dabei deutlich, was der Entwickler beachten muss und wo für ihn die Verantwortung und damit verbunden auch die Haftung für sein Produkt liegen.

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.

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

Managing Medical Devices within a Regulatory Framework helps administrators, designers, manufacturers, clinical engineers, and biomedical support staff to navigate worldwide regulation, carefully consider the parameters for medical equipment patient safety, anticipate problems with equipment, and efficiently manage medical device acquisition budgets throughout the total product life cycle. This contributed book contains perspectives from industry professionals and academics providing a comprehensive look at health technology management (HTM) best practices for medical records management, interoperability between and among devices outside of healthcare, and the dynamics of implementation of new devices. Various chapters advise on how to achieve patient confidentiality compliance for medical devices and their software, discuss legal issues surrounding device use in the hospital environment of care, the impact of device failures on patient safety, methods to advance skillsets for HTM professionals, and resources to assess digital technology. The authors bring forth relevant challenges and demonstrate how management can foster increased clinical and non-clinical collaboration to enhance patient outcomes and the bottom line by translating the regulatory impact on operational requirements. Covers compliance with FDA and CE regulations, plus EU directives for service and maintenance of medical devices Provides operational and clinical practice recommendations in regard to regulatory changes for risk management Discusses best practices for equipment procurement and maintenance Provides guidance on dealing with the challenge of medical records management and compliance with patient confidentiality using information from medical devices

MEDINFO 2019: Health and Wellbeing e-Networks for All - L. Ohno-Machado 2019-11-12

Combining and integrating cross-institutional data remains a challenge for both researchers and those involved in patient care. Patient-generated data can contribute precious information to healthcare professionals by enabling monitoring under normal life conditions and also helping patients play a more active role in their own care. This book presents the proceedings of MEDINFO 2019, the 17th World Congress on Medical and Health Informatics, held in Lyon, France, from 25 to 30 August 2019. The theme of this year's conference was 'Health and Wellbeing: E-Networks for All', stressing the increasing importance of networks in healthcare on the one hand, and the patient-centered perspective on the other. Over 1100 manuscripts were submitted to the conference and, after a thorough review process by at least three reviewers and assessment by a scientific program committee member, 285 papers and 296 posters were accepted, together with 47 podium abstracts, 7 demonstrations, 45 panels, 21 workshops and 9 tutorials. All accepted paper and poster contributions are included in these proceedings. The papers are grouped under four thematic tracks: interpreting health and biomedical data, supporting care delivery, enabling precision medicine and public health, and the human element in medical informatics. The posters are divided into the same four groups. The book presents an overview of state-of-the-art informatics projects from multiple regions of the world; it will be of interest to anyone working in the field of medical informatics.

Software Process Improvement and Capability Determination - Antonia Mas 2012-06-02

This book constitutes the refereed proceedings of the 12th International Conference on Software Process Improvement and Capability Determination, SPICE 2012, held in Palma de Mallorca, Spain, in May 2012. The 21 revised full papers presented and 14 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on organizational process improvement; SPI in small and very small enterprises; process models; SPI in automotive software and security; SPI in medical and safety critical systems; short papers.

Sicurezza delle informazioni: valutazione del rischio; i sistemi di gestione per la sicurezza delle informazioni; la norma ISO/IEC 27001 - Cesare Gallotti 2019-01-28

In questo libro (aggiornato nel 2019) si trattano: la sicurezza delle informazioni, i relativi processi di valutazione e trattamento del rischio (con un'ampia parte teorica bilanciata da molti esempi), i controlli di sicurezza. Il testo si basa sulle norme ISO/IEC 27001 e ISO/IEC 27002, secondo interpretazioni maturate durante i lavori di scrittura della norma stessa a cui l'autore ha partecipato. Le appendici riportano brevi presentazioni (sulla gestione degli auditor, sulla certicazione ISO/IEC 27001, sui Common Criteria e sulle FIPS 140) e delle check list (per la gestione dei cambiamenti, l'identificazione delle minacce e i contratti con i fornitori).

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.

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

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

software processes; design and use of process models; studies of software development; agile development; IT service management; assessment for diagnosis.

On the Move to Meaningful Internet Systems: OTM 2019 Workshops - Christophe Debruyne 2020-02-12

This volume constitutes the refereed proceedings of the Confederated International International Workshop on Enterprise Integration, Interoperability and Networking (EI2N), Fact Based Modeling (FBM), Industry Case Studies Program (ICSP), International Workshop on Methods, Evaluation, Tools and Applications for the Creation and Consumption of Structured Data for the e-Society (Meta4eS) and, 1st International Workshop on Security via Information Analytics and Applications (SIAnA 2019) held as part of OTM 2018 in October 2019 in Rhodes, Greece. As the three main conferences and the associated workshops all share the distributed aspects of modern computing systems, they experience the application pull created by the Internet and by the so-called Semantic Web, in particular developments of Big Data, increased importance of security issues, and the globalization of mobile-based technologies.

Computer Safety, Reliability, and Security - Bettina Buth 2009-09-03

Computer-based systems have become omnipresent commodities within our - vironment. While for a large variety of these systems such as transportation systems, nuclear or chemical plants, or medical systems their relation to safety is obvious, we often do not re?ect that others are as directly related to risks concerning harm done to persons or matter as, for example, elevator control or mobile phones. At least we are not aware of the risk in our daily use of them. Safecomp as a community and a conference series has accompanied this - velopment for 30 years up to Safecomp 2009, which was the 28th of the series. During this time the topics and methods as well as the community have und- gone changes. These changes re?ect the requirements of the above-mentioned ubiquitious presence of safety-related systems. Safecomp has always encouraged and will further encourage academia and industry to share and exchange their ideas and experiences. After 30 years, we as the organizers of Safecomp 2009, found it imperative to take stock: which methods found their way into the application areas; which new approaches need to be checked for their practical applicability. As di?erent application domains developed their own approaches over the previous decades, we tried to attract people with di?erent backgrounds for this conference. - though the years 2008 and 2009 were not easy with regard to the overall global economic situation, we succeeded with this goal.

Health Information Systems - Adrian Stavert-Dobson 2015-12-21

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.

Diagnostic Radiology Physics with MATLAB® - Johan Helmenkamp 2020-11-23

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.

Electrical Machines - Jacek F. Gieras 2016-10-14

This book endeavors to break the stereotype that basic electrical machine courses are limited only to transformers, DC brush machines, induction machines, and wound-field synchronous machines. It is intended to serve as a textbook for basic courses on Electrical Machines covering the fundamentals of the electromechanical energy conversion, transformers, classical electrical machines, i.e., DC brush machines, induction machines, wound-field rotor synchronous machines and modern electrical machines, i.e., switched reluctance machines (SRM) and permanent magnet (PM) brushless machines. In addition to academic research and teaching, the author has worked for over 18 years in US high-technology corporative businesses providing solutions to problems such as design, simulation, manufacturing and laboratory testing of large variety of electrical machines for electric traction, energy generation, marine propulsion, and aerospace electric systems.

Software and Systems Traceability - Jane Huang 2012-02-02

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.

Druggable Lipid Signaling Pathways - Yasuyuki Kihara 2020-09-07

Lipids are responsible not just for constituting cellular membrane but also for storing energy, transducing signaling, and modifying proteins. Bioactive lipids, or lipid mediators, transduce signaling as intracellular messenger like phosphoinoitides, and also regulate cell-cell communication through G protein-coupled receptors (GPCRs) that are potentially valuable drug targets in many diseases. Until now, about 40 GPCRs within ~300 rhodopsin-like (class A) GPCRs, are identified as lipid GPCRs. Advances of lipid research have enabled to develop novel small molecules targeting lipid GPCRs for several diseases. Most notably, fingolimod (FTY720), a sphingosine 1-phosphate (S1P) receptor modulator, became the first FDA-approved medicine as an orally bioavailable drug for treating relapsing forms of multiple sclerosis (MS). In addition to fingolimod, other drugs targeting lipid GPCRs had been developed such as latanoprost (prostaglandin F2a analogue, used for ocular hypertension and glaucoma), epoprostenol and treprostinil (prostaglandin I2 analogue, used for pulmonary arterial hypertension), montelukast and pranlukast (cysteinyl leukotriene receptor antagonist, used for asthma and allergies), etc. Novel drugs are also expected like lysophosphatidic acid (LPA) receptor antagonist for treatment of pulmonary fibrosis. Drug development targeting lipid signalling pathways are backdated to more than a century, when aspirin was synthesized and selling by Bayer, while the basic mechanism of aspirin's effects (block prostanoid synthesis by inhibiting cyclooxygenases) had not been discovered until 1970s. Nowadays, non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin and ibuprophen are commonly used as antipyretic analgesics and available readily over-the-counter oral drugs. Both upstream and downstream enzymes, such as phospholipase A2s and prostaglandin E synthases, respectively, are also potential therapeutic targets for inflammatory diseases. Recent studies of lipid metabolism expand the lipid biology field from pro-inflammatory lipid mediators to anti-inflammatory epoxy fatty acids (epoxyeicosatrienoic acids), and also omega-3 fatty acid-derived pro-resolving lipid mediators (lipoxin, resolvin, and neuroprotectin). These bioactive lipids, their metabolic pathways and receptors are of great interest in developing next-generation anti-inflammatory and pro-resolving drugs for a wide variety of diseases including. This book summarizes not only historical overview of lipid signaling pathways but also provides summary of cutting-edge studies that may provide some hints of novel “druggable” lipid signaling targets.

Software Process Improvement and Capability Determination - Terry Rout 2015-06-02

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.

Information security: risk assessment, management systems, the ISO/IEC 27001 standard - Cesare Gallotti 2019-01-17

In this book, the following subjects are included: information security, the risk assessment and treatment processes (with practical examples), the information security controls. The text is based on the ISO/IEC 27001 standard and on the discussions held during the editing meetings, attended by the author. Appendixes include short presentations and check lists. CESARE GALLOTTI has been working since 1999 in the information security and IT process management fields and has been leading many projects for companies of various sizes and market sectors. He has been leading projects as consultant or auditor for the compliance with standards and regulations and has been designing and delivering ISO/IEC 27001, privacy and ITIL training courses. Some of his certifications are: Lead Auditor ISO/IEC 27001, Lead Auditor 9001, CISA, ITIL Expert and CBCI, CIPP/e. Since 2010, he has been Italian delegate for the the editing group for the ISO/IEC 27000 standard family. Web: www.cesaregallotti.it.

Software Process Improvement and Capability Determination - Paul M. Clarke 2016-05-11

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.

Atlas of Fatigue Curves - Howard E. Boyer 1985-12-31

Contains more than 500 fatigue curves for industrial ferrous and nonferrous alloys. Also includes an explanation of fatigue testing and interpretation of test results. Each curve is presented independently and includes an explanation of its particular importance.

Embedded Software Development for Safety-Critical Systems - Chris Hobbs 2017-09-07

"I highly recommend Mr. Hobbs' book." - Stephen Thomas, PE, Founder and Editor of FunctionalSafetyEngineer.com Safety-critical devices, whether medical, automotive, or industrial, are increasingly dependent on the correct operation of sophisticated software. Many standards have appeared in the last decade on how such systems should be designed and built. Developers, who previously only had to know how to program devices for their industry, must now understand remarkably esoteric development practices and be prepared to justify their work to external auditors. Embedded Software Development for Safety-Critical Systems discusses the development of safety-critical systems under the following standards: IEC 61508; ISO 26262; EN 50128; and IEC 62304. It details the advantages and disadvantages of many architectural and design practices recommended in the standards, ranging from replication and diversification, through anomaly detection to the so-called "safety bag" systems. Reviewing the use of open-source components in safety-critical systems, this book has evolved from a course text used by QNX Software Systems for a training module on building embedded software for safety-critical devices, including medical devices, railway systems, industrial systems, and driver assistance devices in cars. Although the book describes open-source tools for the most part, it also provides enough information for you to seek out commercial vendors if that’s the route you decide to pursue. All of the techniques described in this book may be further explored through hundreds of learned articles. In order to provide you with a way in, the author supplies references he has found helpful as a working software developer. Most of these references are

available to download for free.
The Biomedical Quality Auditor Handbook, Third Edition - Heather Crawford 2017-09-08
The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge (BoK) and reference list for ASQ□s Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably it has been re-organized to align more closely with the BoK.
Plastics in Medical Devices - Vinny R. Sastri 2021-10-01
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
Systems, Software and Services Process Improvement - Rory V. Connor 2011-06-24
This volume constitutes the refereed proceedings of the 18th EuroSPI conference, held in Roskilde, Denmark, in June 2011. The 18 revised full papers presented together with 9 key notes were carefully reviewed and selected. They are organized in topical sections on SPI and assessments; SPI and implementation; SPI and improvement methods; SPI organization; SPI people/ teams; SPI and reuse; selected key notes for SPI implementation.
Embedded Software Development for Safety-Critical Systems, Second Edition - Chris Hobbs 2019-08-16
This is a book about the development of dependable, embedded software. It is for systems designers, implementers, and verifiers who are experienced in general embedded software development, but who are now facing the prospect of delivering a software-based system for a safety-critical application. It is aimed at those creating a product that must satisfy one or more of the international standards relating to safety-critical applications, including IEC 61508, ISO 26262, EN 50128, EN 50657, IEC 62304, or related standards. Of the first edition, Stephen Thomas, PE, Founder and Editor of FunctionalSafetyEngineer.com said, "I highly recommend Mr. Hobbs' book."
Práticas de Gestão da Inovação. Volume II - Fábio Luís Falchi de Magalhães 2022-08-24
O livro “Práticas de Gestão da Inovação. Volume II”, com um total de nove capítulos, busca refletir a partir das quatro fases do modelo do processo de inovação: busca, seleção, implementação, captura de valor, proposto dentro da obra "Gestão da inovação", de Joe Tidd e John Bessant. Redigido em um ambiente interdisciplinar, é formado por autores com formações distintas, livro indicado para alunos de graduação, pós-graduação e gestores, independente da área de atuação.
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
Medical Instrument Design and Development - Claudio Becchetti 2013-07-29
This book explains all of the stages involved in developing medical devices; from concept to medical approval including system engineering, bioinstrumentation design, signal processing, electronics, software and ICT with Cloud and e-Health development. Medical Instrument Design and Development offers a comprehensive theoretical background with extensive use of diagrams, graphics and tables (around 400 throughout the book). The book explains how the theory is translated into industrial medical products using a market-sold Electrocardiograph disclosed in its design by the Gamma Cardio Soft manufacturer. The sequence of the chapters reflects the product development lifecycle. Each chapter is focused on a specific University course and is divided into two sections: theory and implementation. The theory sections explain the main concepts and principles which remain valid across technological evolutions of medical instrumentation. The Implementation sections show how the theory is translated into a medical product. The Electrocardiograph (ECG or EKG) is used as an example as it is a suitable device to explore to fully understand medical instrumentation since it is sufficiently simple but encompasses all the main areas involved in developing medical electronic equipment. Key Features: Introduces a system-level approach to product design Covers topics such as bioinstrumentation, signal processing, information theory, electronics, software, firmware, telemedicine, e-Health and medical device certification Explains how to use theory to implement a market product (using ECG as an example) Examines the design and applications of main medical instruments Details the additional know-how required for product implementation: business context, system design, project management, intellectual property rights, product life cycle, etc. Includes an accompanying website with the design of the certified ECG product (www.gammacardiosoft.it/book) Discloses the details of a marketed ECG Product

(from Gamma Cardio Soft) compliant with the ANSI standard AAMI EC 11 under open licenses (GNU GPL, Creative Common) This book is written for biomedical engineering courses (upper-level undergraduate and graduate students) and for engineers interested in medical instrumentation/device design with a comprehensive and interdisciplinary system perspective.

Federal Register - 2013

Software Process Improvement and Capability Determination - Rory O'Connor 2011-05-20

This book constitutes the refereed proceedings of the 11th International Conference on Software Process Improvement and Capability Determination, SPICE 2011, held in Dublin, Ireland, in May/June 2011. The 15 revised full papers presented and 15 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on process modelling and assessment, safety and security, medi SPICE, high maturity, implementation and improvement.

MEDINFO 2015: EHealth-enabled Health - I.N. Sarkar 2015-08-12

Health and Biomedical Informatics is a rapidly evolving multidisciplinary field; one in which new developments may prove crucial in meeting the challenge of providing cost-effective, patient-centered healthcare worldwide. This book presents the proceedings of MEDINFO 2015, held in São Paulo, Brazil, in August 2015. The theme of this conference is ‘eHealth-enabled Health’, and the broad spectrum of topics covered ranges from emerging methodologies to successful implementations of innovative applications, integration and evaluation of eHealth systems and solutions. Included here are 178 full papers and 248 poster abstracts, selected after a rigorous review process from nearly 800 submissions by 2,500 authors from 59 countries. The conference brings together researchers, clinicians, technologists and managers from all over the world to share their experiences on the use of information methods, systems and technologies to promote patient-centered care, improving patient safety, enhancing care outcomes, facilitating translational research and enabling precision medicine, as well as advancing education and skills in Health and Biomedical Informatics. This comprehensive overview of Health and Biomedical Informatics will be of interest to all those involved in designing, commissioning and providing healthcare, wherever they may be.