Medical Device Software Software Life Cycle Processes

Software Process Improvement and Capability Determination
Engineering Open-Source Medical Devices
Software Process Improvement
An International Perspective
Introduction to Medical Software
Software Life Cycle Processes
11th International Conference, SPICE 2011, Dublin, Ireland, May 30 – June 1, 2011. Proceedings
16th International Conference, SPICE 2016, Dublin, Ireland, June 9-10, 2016, Proceedings
Software and Systems Traceability
Proceedings of the 17th World Congress on Medical and Health Informatics
Medical Device Software-Software Life Cycle Processes
Properties, Requirements, and Applications
Software Process Improvement and Capability Determination
Medical Instrument Design and Development
Software Process Improvement and Capability Determination
Medical Device Software
Software Process Improvement and Capability Determination
17th International Conference, SPICE 2017, Palma de Mallorca, Spain, October 4–5, 2017, Proceedings
Medical Devices and IVDs
Medical Device Software, Software Life-cycle Processes
Medical Device Software
10 Years of Innovation in IEEE Computer
Foundations for Digital Health, Devices, and Diagnostics
International Conference on Software Process, ICSP 2008 Leipzig, Germany, May 10-11, 2008, Proceedings
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Software Technology
A Road Map for Safety and Effectiveness
Regulations, Standards, Methodologies and Tools for Certification
Product-Focused Software Process Improvement
Plastics in Medical Devices
Product-Focused Software Process Improvement
Process reference model of medical device software life cycle processes (IEC 62304)
15th International Conference, PROFES 2014, Helsinki, Finland, December 10-12, 2014, Proceedings
Medical Device Software. Process Reference Model of Medical Device Software Life Cycle Processes (IEC 62304)
Engineering High Quality Medical Software
Making Globally Distributed Software Development a Success Story
The ASQ Certified Medical Device Auditor Handbook, Fourth Edition

SANTOS KASEY

Software Process Improvement and Capability Determination Springer
Electrical medical equipment, Electrical equipment, Medical equipment, Computer software, Life cycle, Life (durability), Design, Maintenance, Equipment safety, Safety measures, Hazards, Software engineering techniques, Computer technology, Quality management, Risk assessment, Identification methods, Quality assurance systems

Engineering Open-Source Medical Devices Springer
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.

Software Process Improvement CRC Press
This volume constitutes the refereed proceedings of the 21st EuroSPI conference, held in Luxembourg, in June 2014. The 18 revised papers presented together with 11 invited papers in this volume were carefully reviewed and selected. They are organized in topical sections on SPI and very small entities; process improvement frameworks; testing and improvement issues; SPI and people issues; SPI and quality issues; software processes in various contexts. The volume also contains selected keynote papers from EuroSPI workshops and invited papers covering the topic of creating environments supporting innovation and improvement.

An International Perspective IOS Press
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.

Introduction to Medical Software Springer Nature
This textbook is intended for SPI (software process improvement) managers and - searchers, quality managers, and experienced project and research managers. The papers constitute the research proceedings of the 16th EuroSPI (European Software Process Improvement, www.eurospi.net) conference held in Alcala (Madrid region), September 2–4, 2009, Spain. Conferences have been held since 1994 in Dublin, 1995 in Vienna (Austria), 1997 in Budapest (Hungary), 1998 in Gothenburg (Sweden), 1999 in Pori (Finland), 2000 in Copenhagen (Denmark), 2001 in Limerick (Ireland), 2002 in Nuremberg (G- many), 2003 in Graz (Austria), 2004 in Trondheim (Norway), 2005 in Budapest (Hungary), 2006 in Joensuu (Finland), 2007 in Potsdam (Germany), 2008 in Dublin (Ireland), and 2009 in Alcala (Spain). EuroSPI established an experience library (library.eurospi.net) which will be conti- ously extended over the next few years and will be made available to all attendees. EuroSPI also created an umbrella initiative for establishing a European Qualification Network in which different SPINs and national initiatives join mutually beneficial collaborations (ECQA – European Certification and Qualification Association, www.ecqa.org). With a general assembly during October 15–16, 2007 through Euro-SPI partners and networks, in collaboration with the European Union (supported by the EU L- nardo da Vinci Programme) a European certification association has been created (www.eu-certificates.org, www.ecqa.org) for the IT and services sector to offer SPI knowledge and certificates to industry, establishing close knowledge transfer links between research and industry.

Software Life Cycle Processes Springer Nature
This book constitutes the refereed proceedings of the 15th International Conference on Product-Focused Software Process Improvement, PROFES 2014, held in Helsinki, Finland, in December 2014. The 18 revised full papers presented together with 14 short papers were carefully reviewed and selected from 45 initial submissions. The papers are organized in topical sections on agile development, decision-making, development practices and issues, product planning, and project management.

11th International Conference, SPICE 2011, Dublin, Ireland, May 30 – June 1, 2011. Proceedings Springer Nature
This book contains the best papers of the First International Conference on Software and Data Technologies (ICSOFT 2006), organized by the Institute for Systems and Technologies of Information, Communication and Control (INSTICC) in cooperation with the Object Management Group (OMG). Hosted by the School of Business of the Polytechnic Institute of Setubal, the conference was sponsored by Enterprise Ireland and the Polytechnic Institute of Setúbal. The purpose of ICSOFT 2006 was to bring together researchers and practitioners int- ested in information technology and software development. The conference tracks were "Software Engineering", "Information Systems and Data Management", "Programming Languages", "Distributed and Parallel Systems" and "Knowledge Engineering." Being crucial for the development of information systems, software and data te- nologies encompass a large number of research topics and applications: from imp- mentation-related issues to more abstract theoretical aspects of software engineering; from databases and data-warehouses to management information systems and kno- edge-base systems; next to that, distributed systems, pervasive computing, data quality and other related topics are included in the scope of this conference. ICSOFT included in its program a panel to discuss the future of software devel- ment, composed by six distinguished world-class researchers. Furthermore, the c- ference program was enriched by a tutorial and six keynote lectures. ICSOFT 2006 received 187 paper submissions from 39 countries in all continents.

16th International Conference, SPICE 2016, Dublin, Ireland, June 9-10, 2016, Proceedings Springer
A concise and accessible overview of the design, implementation and management of medical software.

Software and Systems Traceability Springer
This book explains all of the stages involved in developingmedical devices; from concept to medical approval including systemengineering, bioinstrumentation design, signal processing,electronics, software and ICT with Cloud and e-Healthdevelopment. Medical Instrument Design and Development offers a comprehensivetheoretical background with extensive use of diagrams, graphics andtables (around 400 throughout the book). The book explains how thetheory is translated into industrial medical products using amarket-sold Electrocardiograph disclosed in its design by the GammaCardio Soft manufacturer. The sequence of the chapters reflects the product developmentlifecycle. Each chapter is focused on a specific University courseand is divided into two sections: theory and implementation. Thetheory sections explain the main concepts and principles whichremain valid across technological evolutions of medicalinstrumentation. The Implementation sections show how the theory istranslated into a medical product. The Electrocardiograph(ECG or EKG) is used as an example as it is a suitable device toexplore to fully understand medical instrumentation since it issufficiently simple but encompasses all the main areas involved indeveloping 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 (usingECG as an example) Examines the design and applications of main medicalinstruments Details the additional know-how required for productimplementation: business context, system design, projectmanagement, intellectual property rights, product life cycle,etc. Includes an accompanying website with the design of thecertified ECG product (ahref="http://www.gammacardiosoft.it/book"www.gammacardiosoft.it/book/a) Discloses the details of a marketed ECG Product (from GammaCardio Soft) compliant with the ANSI standard AAMI EC 11under open licenses (GNU GPL, Creative Common) This book is written for biomedical engineering courses(upper-level undergraduate and graduate students) and for engineersinterested in medical instrumentation/device design with acomprehensive and interdisciplinary system perspective.
Proceedings of the 17th World Congress on Medical and Health Informatics John Wiley & Sons
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.
Medical Device Software-Software Life Cycle Processes Springer
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
Properties, Requirements, and Applications BoD – Books on Demand
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
Springer Science & Business Media
Software engineering requires specialized knowledge of a broad spectrum of topics, including the construction of software and the platforms, applications, and environments in which the software operates as well as an understanding of the people who build and use the software. Offering an authoritative perspective, the two volumes of the Encyclopedia of Software Engineering cover the entire multidisciplinary scope of this important field. More than 200 expert contributors and reviewers from industry and academia across 21 countries provide easy-to-read entries that cover software requirements, design, construction, testing, maintenance, configuration management, quality control, and software engineering management tools and methods. Editor Phillip A. Laplante uses the most universally recognized definition of the areas of relevance to software engineering, the Software Engineering Body of Knowledge (SWEBOK®), as a template for organizing the material. Also available in an electronic format, this encyclopedia supplies software engineering students, IT professionals, researchers, managers, and scholars with unrivaled coverage of the topics that encompass this ever-changing field. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk
Medical Instrument Design and Development Springer
With this book, you get a really complete seminar for the new Regulations on medical devices and IVDs in the EU, ready at hand, at any time. These EU regulations create new rules for medical technology and laboratory diagnostics in Europe. Concise regulatory know-how is now required to keep or reposition medical devices and in vitro diagnostics on the European market, from syringes, contact lenses, medical device apps, pregnancy tests, nuclear magnetic resonance tomography to cancer tests, genetic diagnostics, HIV tests, hip implants, heart catheters, artificial spinal discs, stents and pacemakers. Concise regulatory training and further education of employees in companies and health care facilities is the order of the day. This also applies to biomedical and medical technology students at universities of applied sciences and biomedical universities, start-ups and spin-offs, who must make use of this know-how from the initial product idea through the further stages of product development to market access. The book provides a thorough, compact course on the new regulations, starting with perfect overview and easy navigation and going into depth where you need it: this book will make you fit and confident for the new European challenges!
Software Process Improvement and Capability Determination Springer
Medical Device Software Verification, Validation and ComplianceArtech House
Medical Device Software William Andrew
A comprehensive collection of influential articles from one of IEEE Computer magazine's most popular columns This book is a compendium of extended and revised publications that have appeared in the "Software Technologies" column of IEEE Computer magazine, which covers key topics in software engineering such as software development, software correctness and related techniques, cloud computing, self-managing software and self-aware systems. Emerging properties of software technology are also discussed in this book, which will help refine the developing framework for creating the next generation of software technologies and help readers predict future developments and challenges in the field. Software Technology provides guidance on the challenges of developing software today and points readers to where the best advances are being made. Filled with one insightful article after another, the book serves to inform the conversation about the next wave of software technology advances and applications. In addition, the book: Introduces the software landscape and challenges associated with emerging technologies Covers the life cycle of software products, including concepts, requirements, development, testing, verification, evolution, and security Contains rewritten and updated articles by leaders in the software industry Covers both theoretical and practical topics Informative and thought-provoking throughout, Software Technology is a valuable book for everyone in the software engineering community that will inspire as much as it will teach all who flip through its pages.
Software Process Improvement and Capability Determination Medical Device Software Verification, Validation and Compliance
Medical equipment, Electrical medical equipment, Electrical equipment, Computer software, Risk assessment, Life cycle, Life (durability), Design, Maintenance, Equipment safety, Safety measures, Hazards, Software engineering techniques, Computer technology, Quality management, Quality assurance systems
17th International Conference, SPICE 2017, Palma de Mallorca, Spain, October 4–5, 2017, Proceedings Taylor & Francis
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 Devices and IVDs Artech House
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.
Springer
This book constitutes the refereed proceedings of the 22nd International Conference on Product-Focused Software Process Improvement, PROFES 2021, held in Turin, Italy, in November 2021. Due to COVID-19 pandemic the conference was held as a hybrid event. The 20 revised papers, including 14 full papers, 3 short papers and 3 industry papers, presented were carefully reviewed and selected from 48 submissions. The papers cover a broad range of topics related to professional software development and process improvement driven by product and service quality needs. They are organized in the following topical sections: agile and migration, requirements, human factors, and software quality.

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