

Iso 14971 2012

ISO/TR 24971 : medical devices - guidance on the application of ISO 14971 ISO. 2013

Quality Risk Management in the FDA-Regulated Industry

José Rodríguez-Pérez

2017-02-21 The purpose of this new edition is to offer an updated view of the risk management field as it applies to medical products. Since the publication of the first edition (2012), the emphasis on risk-based processes has grown exponentially across all sectors, and risk management is now considered as significant as quality management. ISO 9001 was revised and now requires that top management promote the use of risk-based thinking. ISO 13485:2016, which specifies the requirements for a quality management system specific to the medical devices industry, also now shows a greater emphasis on risk management

and risk-based decision making. In addition, the FDA Food Safety Modernization Act (FSMA) is the most important reform of U.S. food safety laws in more than 70 years. This indispensable book presents a systematic and comprehensive approach to quality risk management. It will assist medical and food product manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practice or good laboratory practice. All chapters have been updated and revised, and a new chapter has been added to discuss some of the most common pitfalls and misunderstandings

regarding risk management, specifically those related to the use of FMEA as the only element of risk management programs. One of the appendices includes 12 case studies, and the companion CD-ROM contains dozens of U.S. FDA and European guidance documents as well as international harmonization documents (ICH and GHTF-IMDRF) related to risk management activities, as well as a 30-question exam (with answers) on the material discussed in the book.

Student Conference Medical Engineering Science 2012 T. M. Buzug et al. 2012-09-10 Anthology from the year 2012 in the subject Medicine - Biomedical Engineering, University Lübeck (Medisert), course: Studierendentagung, language: English, abstract: The Student Conference on Medical Engineering Science is an annual event at the BioMedTec Science Campus Luebeck. The Student Congress is organized by the University of Lübeck and supported by NORGENTA, the

life science cluster agency in north Germany. Master students of programs related to medical engineering science present results of their recent research projects. Die Studierendentagung Medizintechnik findet jährlich auf dem BioMedTec Wissenschaftscampus Lübeck statt. Der Kongress wird von der Universität zu Lübeck organisiert und von der norddeutschen Life-Science-Clusteragentur NORGENTA unterstützt. Studierende in Masterprogrammen der Medizintechnik und der Lebenswissenschaften präsentieren die Ergebnisse ihrer jüngsten Forschungsprojekte.

Digital Conversion on the Way to Industry 4.0

Numan M. Durakbasa 2020-10-25 This book presents the proceedings from the International Symposium for Production Research 2020. The cross-disciplinary papers presented draw on research from academics and practitioners from industrial engineering, management engineering,

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operational research, and production/operational management. It explores topics including: · computer-aided manufacturing; Industry 4.0 applications; simulation and modeling big data and analytics; flexible manufacturing systems; decision analysis quality management industrial robotics in production systems information technologies in production management; and optimization techniques. Presenting real-life applications, case studies, and mathematical models, this book is of interest to researchers, academics, and practitioners in the field of production and operation engineering. *Advances in Informatics, Management and Technology in Healthcare* Emmanouil Zoulias 2022-08-15 Data science, informatics and technology have inspired health professionals and informaticians to improve healthcare for the benefit of all patients, and the field of biomedical and health informatics is one which has

become increasingly important in recent years. This volume presents the papers delivered at ICIMTH 2022, the 20th International Conference on Informatics, Management, and Technology in Healthcare, held in Athens, Greece, from 1-3 July 2022. The ICIMTH Conference is an annual scientific event attended by scientists from around the world working in the field of biomedical and health informatics. This year, thanks to the improvement in the situation as regards the COVID-19 pandemic and the consequent lifting of restrictions, the conference was once again a live event, but virtual sessions by means of teleconferencing were also enabled for those unable to travel due to local restrictions. The field of biomedical and health informatics was examined from a very broad perspective, with participants presenting the research and application outcomes of informatics from cell to populations, including several technologies such as imaging,

sensors, biomedical equipment, and management and organizational aspects, including legal and social issues. More than 230 submissions were received, with a total of 130 accepted as full papers and 19 as short communication and poster papers after review. As expected, a significant number of papers were related to the COVID-19 pandemic. Providing a state-of-the-art overview of biomedical and health informatics, the book will be of interest to all those working in the field of healthcare, researchers and practitioners alike

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

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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

Small-bore Connectors for Liquids and Gases in Healthcare Application 2016
Ежегодный библиографический указатель книг России 2014

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Monthly Bulletin of Statistics

2012-03
Fleischer's Sonography in Obstetrics & Gynecology: Principles and Practice, Eighth Edition Arthur C. Fleischer
 2017-12-29 The definitive guide to sonography in obstetrics and gynecology—thoroughly updated and enhanced by the addition of teaching cases
 Doody's Core Titles for 2021!
 This acclaimed guide is a clinically relevant reference text, an atlas, and a teaching/learning resource. Presented in full color and enriched by more than 2,000 illustrations, it expertly examines the full spectrum of disorders and conditions likely to be encountered in gynecologic and maternal-fetal care. You will find expert, all-inclusive coverage of everything from sonographic operating instruments and screening the fetal patient for syndromes and anomalies, to diagnosing the female patient for cysts, infertility, and incontinence. This edition has been updated to include coverage of the latest

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procedures and diagnostic guidelines for the use of sonography in ob/gyn, including 3D and 4D US and enhanced image processing, contrast enhanced sonography, ultrasound guided fetal therapy, sonographic evaluation of pelvic pain, and much more. The Eighth Edition also features an extensive series of teaching cases. Each case consists of the patient's medical history, representative US images, cineloop videos, Q&A, and teaching points with references. Fleischer's Sonography in Obstetrics & Gynecology, Eighth Edition opens with general obstetric sonography, covering such pivotal topics as normal pelvic anatomy and fetal echocardiography, before moving into fetal anomalies and disorders. Risk assessment and therapy, including first trimester screening and amniocentesis, are explored in the next section, while the remaining parts of the book focus on maternal disorders, gynecologic sonography, and the newest complementary

imaging modalities.

Hotărâri ale guvernului României și alte acte normative
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Technical Report Series
2018

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Книжная летопись 2014

Safety Risk Management for Medical Devices Bijan Elahi

2021-11-11 Safety Risk Management for Medical Devices, Second Edition teaches the essential safety risk management

methodologies for medical devices compliant with the requirements of ISO

14971:2019. Focusing exclusively on safety risk assessment practices required in the MedTech sector, the book outlines sensible, easily comprehensible, state-of-the-art methodologies that are rooted in current industry best practices, addressing safety risk management of medical devices, thus making it useful for those in the MedTech sector who are responsible for safety risk management or need to understand risk management, including design

engineers, product engineers, development engineers, software engineers, Quality assurance and regulatory affairs. Graduate-level engineering students with an interest in medical devices will also benefit from this book. The new edition has been fully updated to reflect the state-of-the-art in this fast changing field. It offers guidance on developing and commercializing medical devices in line with the most current international standards and regulations. - Includes new coverage of ISO 14971:2019, ISO/TR 24971 - Presents the latest information on the history of risk management, lifetime of a medical device, risk management review, production and post production activities, post market risk management - Provides practical, easy-to-understand and state-of-the-art methodologies that meet the requirements of international regulation

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

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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.

Plastics in Medical Devices

Vinny R. Sastri 2021-11-24
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

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medical devices and materials
for use in medical devices
*Biological Evaluation of
Medical Devices* 2018
I.S. EN ISO 14971 : medical
devices - application of risk
management to medical
devices (ISO 14971:2007,
corrected version 2007-10-01).
NSAI. National Standards
Authority of Ireland 2012

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