Medical Device Risk Management

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices
The Medical Device Industry
Medical Devices
Medical Device Software Verification, Validation and Compliance
The Role of Human Factors in Home Health Care
Handbook of Medical Device Regulatory Affairs in Asia
RISK MANAGEMENT FOR THE MEDICAL DEVICE INDUSTRY
Safety Risk Management for Medical Devices
Integrated Safety and Risk Assessment for Medical Devices and Combination Products
Risk Management of Medical Devices for Healthcare Organisations
Risk Assessment in the Federal Government
Risk Management Handbook for Health Care Organizations, 3 Volume Set
Managing Medical Devices within a Regulatory Framework
Guidelines for Failure Mode and Effects Analysis (FMEA), for Automotive, Aerospace, and General Manufacturing Industries
Application of Risk Management for IT-Networks Incorporating Medical Devices.
Guidance for the Disclosure and Communication of Medical Device Security Needs, Risks and Controls
An Analysis of the Risk Management Process in a Medical Device Company
Software As a Medical Device
Risk Management for the Medical Device Industry
Risk Management: ISO 14971
DESIGN CONTROLS, RISK MANAGEMENT & PROCESS VALIDATION FOR MEDICAL DEVICE PROFESSIONALS
Design Control, Medical Device Risk and Medical Device Regulation (MDR 2017/745)
Medical Equipment Management
Systems, Software and Services Process Improvement
Foundations of Quality Risk Management
Guidelines for Failure Modes and Effects Analysis for Medical Devices
Cybersecurity for Connected Medical Devices
Implementation of Risk Management in the Medical Device Industry
User Interface Requirements for Medical Devices
Risk-Based Quality Management in Healthcare Organization
Change Control for FDA Regulated Industries
Analyzing the Impacts of Industry 4.0 in Modern Business Environments
Application of Risk Management for IT-networks Incorporating Medical Devices
Application of Risk Management for IT-networks Incorporating Medical Devices
Trends in Development of Medical Devices
Pluralistic Medical Device Risk Management
Design Controls for the Medical Device Industry
Benefit-Risk Assessment Methods in Medical Product Development

Risk Management for Medical Device Manufacturers
Safety of Electromedical Devices

HANA JACK

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices CRC Press
This study looks at the implementation and effectiveness of risk management (RM) activities in the medical device industry. An online survey was distributed to medical device professionals who were asked to identify RM-related activities performed during the device life cycle. RM activities and techniques included Establishing Risk Acceptance Criteria, Hazard Identification, Human Factors/Usability, Fault Tree Analysis (FTA), Design Failure Mode and Effects Analysis (DFMEA), Process Failure Mode and Effects Analysis (PFMEA), Hazard and Operability Study (HAZOP), Hazard Analysis and Critical Control Point (HACCP), Risk Benefit Analysis, and Risk Assessment of Customer Complaint. Devices were identified by type (therapeutic, surgical/clinical tools, diagnostic, instrument disposable, implantable, etc.), development history (new, second, third or later generation device), and time since market release. Respondents were also asked to indicate the degree of change made to the device as a result of RM activities and to rate the effectiveness of associated RM activities for the device. Survey results indicated that RM's impact and level of effectiveness on a medical device are dependent primarily on the device type and life-cycle stage (i.e., pre-market versus post-market). There is also some impact of development history and the time since the device was released to market.
The Medical Device Industry Notion Press
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."
Medical Devices Springer Nature
In order to improve competitiveness and performance, corporations must embrace advancements in digitalization. Successful implementation of knowledge management is a huge factor in corporate success. Analyzing the Impacts of Industry 4.0 in Modern Business Environments is a critical scholarly publication that explores digital transformation in business environments and the requirement for not only a

substantial management change plan but equally the two essential components of knowledge management: knowledge sharing and knowledge transfer. Featuring a broad range of topics such as strategic planning, knowledge transfer, and cybersecurity risk management, this book is geared toward researchers, academicians, and students seeking current and relevant research on organizational knowledge intensity and monitoring of knowledge management development.

Medical Device Software Verification, Validation and Compliance Academic Press

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

Safety Risk Management for Medical Devices

Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs.

The Role of Human Factors in Home Health Care CRC Press

This reference provides real-world examples, strategies, and templates for the implementation of effective design control programs that meet current ISO 9000 and FDA QSR standards and regulations-offering product development models for the production of safe, durable, and cost-efficient medical devices and systems. Details procedures utilize

Handbook of Medical Device Regulatory Affairs in Asia Elsevier

The operation of the currently existing

institutions and processes for managing risks associated with the use of medical devices are reviewed and analyzed. Questions addressed include the definition(s) of device failure, the establishment of acceptable failure rates, and the selection of the parties to be involved in these risk-management processes, both prospectively and retrospectively. Currently perceived difficulties associated with the unilateral risk-management activities of both the FDA regulatory apparatus plus the product liability and medical malpractice litigation systems are described. A pluralistic risk-management approach based upon marketplace incentives is proposed. This marketplace-in-centive approach encourages the development and use of performance standards both to enhance benefits to patients and to reduce the adversarial tension between the FDA and the private sector as well.

RISK MANAGEMENT FOR THE MEDICAL DEVICE INDUSTRY Quality Press

The cybersecurity of connected medical devices is one of the biggest challenges facing healthcare today. The compromise of a medical device can result in severe consequences for both patient health and patient data. Cybersecurity for Connected Medical Devices covers all aspects of medical device cybersecurity, with a focus on cybersecurity capability development and maintenance, system and software threat modeling, secure design of medical devices, vulnerability management, and integrating cybersecurity design aspects into a medical device manufacturer's Quality Management Systems (QMS). This book is geared towards engineers interested in the medical device cybersecurity space, regulatory, quality, and human resources specialists, and organizational leaders interested in building a medical device cybersecurity program. Lays out clear guidelines for how to build a medical device cybersecurity program through the development of capabilities Discusses different regulatory requirements of cybersecurity and how to incorporate them into a Quality Management System Provides a candidate method for system and software threat modelling Provides an overview of cybersecurity risk management for medical devices Presents technical cybersecurity controls for secure design of medical devices Provides an overview of cybersecurity verification and validation for medical devices Presents an approach to logically structure cybersecurity regulatory submissions

Safety Risk Management for Medical Devices CRC Press

With many medical device applications and the potential risks to patient safety, medical device manufacturers are challenged with the concern of product liability. This research focused on quality factors within the risk management process at Company XYZ that may contribute to product failures and recalls by regulatory bodies. History recall data was collected from U.S. FDA website on Company XYZ and analyzed for common trend. In addition, a check-sheet assessment based on ISO 14971 and the quality management system concepts was developed to compare the risk management process in the effort to mitigate device failures. Results indicated that Company XYZ device recall reached the highest numbers during the 2011 calendar year with a total of 95. Further observation revealed that recall categories totaled the highest in design and development. The results from the gap analysis check-sheet

indicated the lack of proficiency in risk control efforts by employees. The lack of risk assessment tools such as preliminary hazard analysis inhibits a full extraction of the failure modes in early design and development stages. To improve the risk management system, upper management is recommended to create a risk-based culture to ensure adequate training and competency in risk assessments, methods and controls.

Integrated Safety and Risk Assessment for Medical Devices and Combination Products Wasatch Consulting Resources LLC

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

Risk Management of Medical Devices for Healthcare Organisations CRC Press

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.

Risk Assessment in the Federal Government Springer Science & Business Media

Continuing its superiority in the health care risk management field, this sixth edition of The Risk Management Handbook for Health Care Organizations is written by the key practitioners and consultant in the field. It contains more practical chapters and health care examples and additional material on methods and techniques of risk reduction and management. It also revises the structure of the previous edition, and focuses on operational and organizational structure rather than risk areas and functions. The three volumes are written using a practical and user-friendly approach.

Risk Management Handbook for Health Care Organizations, 3 Volume Set Artech House

Preface Development in the feld of medical technology has resulted in a manifold of medical devices enabling us to diagnose illnesses more reliably, treat them more effciently and compensate for handicaps more effectively. However, these improvements are also - sociated with safety risks. Today, patients are in contact with an increasing number of medical devices longer and more intensively then before. Applied parts are put into contact with the body, probes may be introduced into the body via natural or surgical orifces, and even whole devices may be implanted for many years. The application of devices is no longer restricted to medical locations only. Home use by lay people is increasing and involves even critical devices such as for dialysis, nerve and muscle stimulation and ventilation. In contrast to users' patients are in a special situation. Their life could depend on the performance of a device, they might be unconscious, may have impaired reactions, or have been made insensitive to pain by medication, and hence they may be exposed to hazards without their awareness and protection by their own reaction. Therefore, medical devices must meet particularly stringent safety requirements. However, the question arises how safe is safe enough? The readiness to accept risks depends on a variety of accompanying circumstances. In fact, subjective risk p- ception varies among individuals and differs from country to country, and frequently only in rare cases it is in agreement with assessments of objective scientifc ana- ses.

Managing Medical Devices within a Regulatory Framework John Wiley & Sons

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.

Guidelines for Failure Mode and Effects Analysis (FMEA), for Automotive, Aerospace, and General Manufacturing Industries CRC Press

This book is a practical guide for individuals responsible for creating products that are safe, effective, usable, and satisfying in the hands of the intended users. The contents are intended to reduce the number of use errors involving medical devices that have led to injuries and deaths. The book presents the strong connection between user interface requirements and risk management for medical devices and instructs readers how to develop specific requirements that are sufficiently comprehensive and detailed to produce good results – a user-friendly product that is likely to be used correctly. The book's tutorial content is complemented by many real-world examples of user interface requirements, including ones pertaining to an inhaler, automated external defibrillator, medical robot, and mobile app that a patient might use to manage her diabetes. The book is intended for people representing a variety of product development disciplines who have responsibility for producing safe, effective, usable, and satisfying medical devices, including those who are studying or working in human factors engineering, psychology, mechanical engineering, biomedical engineering, systems engineering, software programming, technical writing, industrial design, graphic design, and regulatory affairs.

Application of Risk Management for IT-Networks Incorporating Medical Devices. Guidance for the Disclosure and Communication of Medical Device Security Needs, Risks and Controls Academic Press

In today's uncertain times, risk has become the biggest part of management. Risk management is central to the science of prediction and decision-making; holistic and scientific risk management creates resilient organizations, which survive and thrive by being adaptable. This book is the perfect guide for anyone interested in understanding and excelling at risk management. It begins with a focus on the foundational elements of risk management, with a thorough explanation of the basic concepts, many illustrated by real-life examples. Next, the book focuses on equipping the reader with a working knowledge of the subject from an organizational process and systems perspective. Every concept in almost every chapter is calibrated to

not only ISO 9001 and ISO 31000, but several other international standards. In addition, this book presents several tools and methods for discussion. Ranging from industry standard to cutting edge, each receives a thorough analysis and description of its role in the risk management process. Finally, you'll find a detailed and practical discussion of contemporary topics in risk management, such as supply chain risk management, risk-based auditing, risk in 4.0 (digital transformation), benefit-risk analyses, risk-based design thinking, and pandemic/epidemic risk management. Jayet Moon is a Senior ASQ member and holds ASQ CQE, CSQP, and CQIA certifications. He is also a chartered quality professional in the U.K. (CQP-MCQI). He earned a master's degree in biomedical engineering from Drexel University in Philadelphia and is a Project Management Institute (PMI) Certified Risk Management Professional (PMI-RMP). He is a doctoral candidate in Systems and Engineering Management at Texas Tech University

An Analysis of the Risk Management Process in a Medical Device Company Notion Press

Safety Risk Management for Medical DevicesAcademic Press

Software As a Medical Device CRC Press

The regulation of potentially hazardous substances has become a controversial issue. This volume evaluates past efforts to develop and use risk assessment guidelines, reviews the experience of regulatory agencies with different administrative arrangements for risk assessment, and evaluates various proposals to modify procedures. The book's conclusions and recommendations can be applied across the entire field of environmental health.

Risk Management for the Medical Device Industry AuthorHouse

"Risk Management for the Medical Device Industry: A Guide based on ISO 14971" is an essential resource for professionals in the fast-paced medical device industry. Authored by Dr. Akash Sharma, Ms. Vriti Gamta, and Mr. Gaurav Luthra, experts in regulatory affairs and quality management systems, this practical guide offers comprehensive insights into risk management and compliance. Covering the entire risk management lifecycle, it includes case studies, best practices, and practical examples, along with discussions on integrating risk management with quality management systems and emerging technologies. Equip yourself with the knowledge and tools to ensure safety and effectiveness in the global market.

Risk Management: ISO 14971 Springer

Challenged by stringent regulations, vigorous competition, and liability lawsuits, medical device manufactures must develop safe, reliable, and cost-effective products, and managing and reducing risk is a vital element of reaching that goal. A practical guide to achieving corporate consistency while dramatically cutting the time required for studies, Guidelines for Failure Modes and Effects Analysis for Medical Devices focuses on Failure Modes and Effects Analysis (FMEA) and its application throughout the life cycle of a medical device. It outlines the major U.S. and E.U. standards and regulations and provides a detailed yet easy-to-read overview of risk management and risk analysis methodologies, common FMEA pitfalls, and FMECA-Failure Mode, Effects, and Criticality Analysis. Discover how the FMEA methodology can help your company achieve a more cost-effective manufacturing process by

improving the quality and reliability of your products. This new FMEA manual from the experts at Dyadem is the ultimate resource for you and your colleagues to learn more about Failure Modes and Effects Analysis and then teach others at your facility. This comprehensive manual is sure to become a standard reference for engineering professionals.

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