



MEDICAL DEVICE USE ERROR

ROOT CAUSE ANALYSIS

Michael Wiklund
Andrea Dwyer
Erin Davis

Illustrations by Jonathan Kessler



CRC Press
Taylor & Francis Group

Medical Device Use Error Analysis

American Council on Education



Medical Device Use Error Analysis:

Medical Device Use Error Michael Wiklund,Andrea Dwyer,Erin Davis,2016-01-06 Medical Device Use Error Root Cause Analysis offers practical guidance on how to methodically discover and explain the root cause of a use error a mistake that occurs when someone uses a medical device Covering medical devices used in the home and those used in clinical environments the book presents informative case studies about the use errors **Medical Device Use Error** Michael E. Wiklund,Andrea M. Dwyer,Erin Davis,2016-01-12 Root Cause Analysis of Use Error delineates a systematic method of analyzing medical device use errors The book is to the specific needs of people developing medical devices people studying to serve this role and the folks responsible for evaluating device use error including the regulators Medical Device Use Error Michael Wiklund,Andrea Dwyer,Erin Davis,2016-01-06 Medical Device Use Error Root Cause Analysis offers practical guidance on how to methodically discover and explain the root cause of a use error a mistake that occurs when someone uses a medical device Covering medical devices used in the home and those used in clinical environments the book presents informative case studies about the use errors Applied Human Factors in Medical Device Design Mary Beth Privitera,2019-06-15 Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in depth descriptions of both empirical and analytical methodologies The book begins with an overview of the design control process integrating human factors as directed by AAMI TIR 59 and experienced practice It then explains each method describing why each method is important its potential impact when it s ideal to use and related challenges Also discussed are other barriers such as communication breakdowns between users and design teams This book is an excellent reference for professionals working in human factors design engineering marketing and regulation Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union EU Explains technology development and the application of human factors throughout the development process Covers FDA and MHRA regulations Includes case examples with each method **Quality and Safety in Radiotherapy** Todd Pawlicki,Peter Dunscombe,Arno J. Mundt,Pierre Scalliet,2010-12-20 The first text to focus solely on quality and safety in radiotherapy this work encompasses not only traditional more technically oriented quality assurance activities but also general approaches of quality and safety It includes contributions from experts both inside and outside the field to present a global view The task of assuring quality *Design Controls for the Medical Device Industry, Third Edition* Marie B. Teixeira,2019-08-02 This third edition provides a substantial comprehensive review of the latest design control requirements as well as proven tools and techniques to ensure a company s design control program evolves in accordance with current industry practice It assists in the development of an effective design control program that not only satisfies the US FDA Quality Systems Regulation QSR and 13485 2016 standards but also meets today s Notified Body Auditors and FDA Investigators expectations The book includes a review of the design control elements such as design planning input output

review verification validation change transfer and history as well as risk management inclusive of human factors and usability biocompatibility the FDA Quality System Inspection Technique QSIT for design controls and medical device regulations and classes in the US Canada and Europe Practical advice methods and appendixes are provided to assist with implementation of a compliant design control program and extensive references are provided for further study This third edition Examines new coverage of ISO 13485 2016 design control requirements Explores proven techniques and methods for compliance Contributes fresh templates for practical implementation Provides updated chapters with additional details for greater understanding and compliance Offers an easy to understand breakdown of design control requirements Reference to MDSAP design control requirements Advances in Human Factors and Ergonomics in Healthcare Vincent G.

Duffy,2010-06-11 Based on recent research this book discusses how to improve quality safety efficiency and effectiveness in patient care through the application of human factors and ergonomics principles It provides guidance for those involved with the design and application of systems and devices for effective and safe healthcare delivery from both a patient **The**

Patient's Guide to Preventing Medical Errors Karin J. Berntsen,2004-10-30 A nation watched in horror as 17 year old Jessica Santillian died needlessly after a heart lung transplant in 2003 She had been given organs with the wrong blood type That error killed her It is just one among tens of thousands of less publicized errors that occur in U S hospitals each year Author Karin Berntsen a veteran of the hospital and health care industry takes us through the headlines and the events never publicized into hospital wards and surgical rooms to see how errors are made causing disability or death She gives graphic examples of actual events that illustrate the problems cited in a federal Institute of Medicine report showing medical errors in the hospital cause 44 000 to 98 000 deaths each year Those errors include medication mistakes wrong site or side surgery and botched transfusions Berntsen explains why these are not just human errors with one or two people responsible they are systems failures that require a major culture change to remedy And that change she argues may not come without action by the very people the medical system is designed to help patients She offers clear actions consumers can take to assure they are not on the receiving end of a medical error The book details over 200 tips for improving patient safety U S hospitals have countless stories of miraculous healing and recovery the greatest technology most advanced medicines and best research in the world On the other hand we have a system where medical errors bring more than 120 fatalities each day across the country in hospitals An airline crash causing that many deaths daily would paralyze that industry But because the deaths and harm are diluted across and deep within the silence of hospitals it is easier to be complacent There is says Berntsen an urgent need to pause and take inventory a need for clinicians and consumers to come together as partners for change

Mastering Safety Risk Management for Medical and In Vitro Devices Jayet Moon,Arun Mathew,2024-05-10 When it comes to medical and in vitro devices risk management starts with a design assurance process that helps practitioners identify understand analyze and mitigate the risks of the healthcare product design for favorable benefit risk assessment Risk

management actively follows the product's life cycle into production and post market phases This book offers a blueprint for implementing an effective risk management system It provides risk management tools and a compliance framework for methods in conformance to ISO 13485 2016 ISO 14971 2019 European Union MDR IVDR and US FDA regulations including the new FDA QMSR

Clinical Engineering Handbook Ernesto Iadanza, 2019-12-06 Clinical Engineering Handbook Second Edition covers modern clinical engineering topics giving experienced professionals the necessary skills and knowledge for this fast evolving field Featuring insights from leading international experts this book presents traditional practices such as healthcare technology management medical device service and technology application In addition readers will find valuable information on the newest research and groundbreaking developments in clinical engineering such as health technology assessment disaster preparedness decision support systems mobile medicine and prospects and guidelines on the future of clinical engineering As the biomedical engineering field expands throughout the world clinical engineers play an increasingly important role as translators between the medical engineering and business professions In addition they influence procedures and policies at research facilities universities and in private and government agencies This book explores their current and continuing reach and its importance Presents a definitive comprehensive and up to date resource on clinical engineering Written by worldwide experts with ties to IFMBE IUPESM Global CE Advisory Board IEEE ACCE and more Includes coverage of new topics such as Health Technology Assessment HTA Decision Support Systems DSS Mobile Apps Success Stories in Clinical Engineering and Human Factors Engineering

Fitting the Human Katrin Kroemer Elbert, 2025-03-10 The aim of this book is to provide human engineering for workplaces tools machinery computers shift work lighting sound climate work demands offices vehicles healthcare and the home and everything else that we can produce to suit the human body and mind Now being published in its eighth edition *Fitting the Human* focuses on the primary ergonomic task of accommodating the human with the appropriate selection of equipment and tools work requirements and procedures physical and social conditions at work and working hours and shift arrangements This book provides the ergonomic information needed for the user friendly design of tasks equipment and workplaces It follows the successful format of previous editions with updated information and practical guidelines that augment the previous information It offers refreshed information on ergonomic design for the home and workplace contemporary ways of working healthcare and medicine and artificial intelligence and autonomy This text also recognizes that cultural differences in living and working vary around the world so additional insights are offered into ergonomics in global cultures and regions This title will help the reader understand how to plan and design an overall system and its details to fit the human Published under the mantra of solid information easy to read easy to understand easy to apply *Fitting the Human* is written for students and professionals in ergonomics human factors product and work design safety architecture management and all fields of engineering

Handbook of Human Factors and Ergonomics in Health Care and Patient Safety Pascale Carayon, 2016-04-19 The

first edition of Handbook of Human Factors and Ergonomics in Health Care and Patient Safety took the medical and ergonomics communities by storm with in depth coverage of human factors and ergonomics research concepts theories models methods and interventions and how they can be applied in health care Other books focus on particular human factors and ergonomics issues such as human error or design of medical devices or a specific application such as emergency medicine This book draws on both areas to provide a compendium of human factors and ergonomics issues relevant to health care and patient safety The second edition takes a more practical approach with coverage of methods interventions and applications and a greater range of domains such as medication safety surgery anesthesia and infection prevention New topics include work schedules error recovery telemedicine workflow analysis simulation health information technology development and design patient safety management Reflecting developments and advances in the five years since the first edition the book explores medical technology and telemedicine and puts a special emphasis on the contributions of human factors and ergonomics to the improvement of patient safety and quality of care In order to take patient safety to the next level collaboration between human factors professionals and health care providers must occur This book brings both groups closer to achieving that goal

Human-Centered Design for Mining Equipment and New Technology

Tim Horberry, Robin Burgess-Limerick, Lisa J. Steiner, 2018-02-07 Human Centered Design for Mining Equipment and New Technology first introduces Human Centered Design HCD and outlines the benefits of this approach for mining equipment and new technology HCD is a process that aims to make equipment and systems more usable and acceptable by explicitly focusing on the end user their tasks and their work environment use context The book outlines three linked areas of mining HCD key principles examples of design processes and what kinds of tools for data collection and evaluation are available The possible future uses of Human Centered Design in more fully automated mining are presented and the role of HCD within wider human system integration are outlined The how to nature of this book makes it attractive to mining equipment manufacturers technology developers mine site personnel human factors researchers safety scientists and regulators Features Includes an introduction useful to anyone wanting to learn about the field Provides extensive case studies of HCD which also show failures when HCD was not considered Covers cutting edge mining technology such as proximity detection devices and new mining automation systems Directly outlines the benefits of HCD for the minerals industry Human Centered Design for Mining Equipment and New Technology through case studies provides a much needed guide to undertaking HCD for mining equipment and new technology

Proceedings of the Future Technologies Conference (FTC) 2020,

Volume 3 Kohei Arai, Supriya Kapoor, Rahul Bhatia, 2020-10-30 This book provides the state of the art intelligent methods and techniques for solving real world problems along with a vision of the future research The fifth 2020 Future Technologies Conference was organized virtually and received a total of 590 submissions from academic pioneering researchers scientists industrial engineers and students from all over the world The submitted papers covered a wide range of important topics

including but not limited to computing electronics artificial intelligence robotics security and communications and their applications to the real world After a double blind peer review process 210 submissions including 6 poster papers have been selected to be included in these proceedings One of the meaningful and valuable dimensions of this conference is the way it brings together a large group of technology geniuses in one venue to not only present breakthrough research in future technologies but also to promote discussions and debate of relevant issues challenges opportunities and research findings The authors hope that readers find the book interesting exciting and inspiring Library of Congress Subject Headings Library of Congress,1991 *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 **Usability Testing of Medical Devices** Michael E. Wiklund P.E.,Jonathan Kendler,Allison Y. Storchlic,2010-12-20 To paraphrase a popular saying usability testing should be done early and often However it doesn t have to be an onerous process Informative practical and engaging Usability Testing of Medical Devices provides a simple easy to implement general understanding of usability testing It offers a general understanding of usability testing and re Library of Congress Subject Headings Library of Congress. Office for Subject Cataloging Policy,1991 **Systems Reliability and Usability for Engineers** B.S. Dhillon,2019-03-18 Engineering systems are an important element of world economy Each year billions of dollars are spent to develop manufacture operate and maintain various types of engineering systems about the globe The reliability and usability of these systems have become important because of their increasing complexity sophistication and non specialist users Global competition and other factors are forcing manufacturers to produce highly reliable and usable engineering systems Along with examples and solutions this book integrates engineering systems reliability and usability into a single volume for those individuals that directly or indirectly are concerned with these areas **Nursing Informatics** Ursula H. Hübner,Gabriela

Mustata Wilson,Toria Shaw Morawski,Marion J. Ball,2022-07-25 This new edition of the classic textbook on health informatics provides readers in healthcare practice and educational settings with an unparalleled depth of information on using informatics methods and tools However this new text speaks to nurses and in a departure from earlier editions of this title to all health professionals in direct patient care regardless of their specialty extending its usefulness as a textbook This includes physicians therapists pharmacists dieticians and many others In recognition of the evolving digital environments in all healthcare settings and of interprofessional teams the book is designed for a wide spectrum of healthcare professions including quality officers health information managers administrators and executives as well as health information technology professionals such as engineers and computer scientists in health care The book is of special interest to those who bridge the technical and caring domain particularly nurse and medical informaticians and other informaticians working in the health sciences Nursing Informatics An Interprofessional and Global Perspective contains real life case studies and other didactic features to illustrate the theories and principles discussed making it an ideal resource for use within health and nursing informatics curricula at both undergraduate and graduate level as well as for workforce development It honors the format established by the previous editions by including a content array and questions to guide the reader Readers are invited to look out of the box through a dedicated global perspective covering health informatics applications in different regions countries and continents

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Table of Contents Medical Device Use Error Analysis

1. Understanding the eBook Medical Device Use Error Analysis
 - The Rise of Digital Reading Medical Device Use Error Analysis
 - Advantages of eBooks Over Traditional Books
2. Identifying Medical Device Use Error Analysis
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Medical Device Use Error Analysis
 - User-Friendly Interface
4. Exploring eBook Recommendations from Medical Device Use Error Analysis
 - Personalized Recommendations
 - Medical Device Use Error Analysis User Reviews and Ratings
 - Medical Device Use Error Analysis and Bestseller Lists

5. Accessing Medical Device Use Error Analysis Free and Paid eBooks
 - Medical Device Use Error Analysis Public Domain eBooks
 - Medical Device Use Error Analysis eBook Subscription Services
 - Medical Device Use Error Analysis Budget-Friendly Options
6. Navigating Medical Device Use Error Analysis eBook Formats
 - ePub, PDF, MOBI, and More
 - Medical Device Use Error Analysis Compatibility with Devices
 - Medical Device Use Error Analysis Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Medical Device Use Error Analysis
 - Highlighting and Note-Taking Medical Device Use Error Analysis
 - Interactive Elements Medical Device Use Error Analysis
8. Staying Engaged with Medical Device Use Error Analysis
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Medical Device Use Error Analysis
9. Balancing eBooks and Physical Books Medical Device Use Error Analysis
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Medical Device Use Error Analysis
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Medical Device Use Error Analysis
 - Setting Reading Goals Medical Device Use Error Analysis
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Medical Device Use Error Analysis
 - Fact-Checking eBook Content of Medical Device Use Error Analysis
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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