



MEDICAL DEVICE USE ERROR

ROOT

CAUSE

ANALYSIS

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Andrea Dwyer
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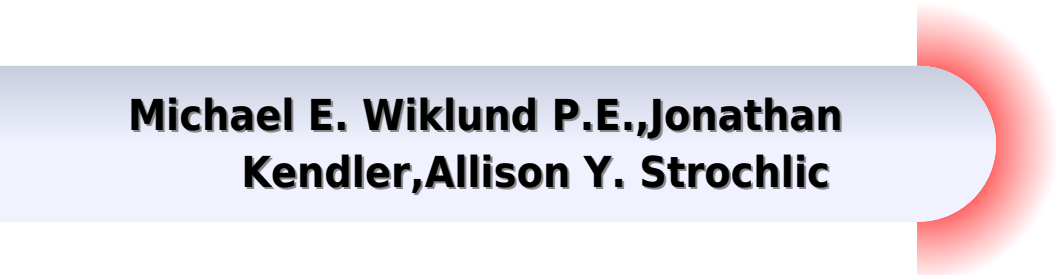
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**Michael E. Wiklund P.E., Jonathan
Kendler, Allison Y. Strohlic**



Medical Device Use Error Analysis:

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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

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

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

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 Usability Testing of Medical Devices Michael E. Wiklund P.E., Jonathan Kendler, Allison Y. Strohlic, 2015-12-23 Usability Testing of Medical Devices covers the nitty gritty of usability test planning conducting and results reporting The book also discusses the government regulations and industry standards that motivate many medical device manufacturers to conduct usability tests Since publication of the first edition the FDA and other regulatory groups have **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 **Engineering Open-Source Medical Devices** Arti Ahluwalia, Carmelo De Maria, Andrés Díaz Lantada, 2022-02-23 This book focuses on the challenges and potentials of open source and collaborative design approaches and strategies in the biomedical field It provides a comprehensive set of good practices and methods for making these safe innovative and certifiable biomedical devices reach patients and provide successful solutions to healthcare issues The chapters are sequenced to follow the complete lifecycle of open source medical technologies The information provided is eminently practical as it is supported by real cases of study in which collaboration among medical professionals

engineers and technicians patients and patient associations policy makers regulatory bodies and citizens has proven beneficial The book is also supported by an online infrastructure UBORA through which open source medical devices can be collaboratively developed and shared for the democratization of medical technology and for promoting accessible biomedical engineering education **Distributed Computing and Internet Technology** Chittaranjan Hota,Pradip K.

Srimani,2013-01-11 This book constitutes the refereed proceedings of the 9th International Conference on Distributed Computing and Internet Technology ICDCIT 2013 held in Bhubaneswar India in February 2013 The 40 full papers presented together with 5 invited talks in this volume were carefully reviewed and selected from 164 submissions The papers cover various research aspects in distributed computing internet technology computer networks and machine learning

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