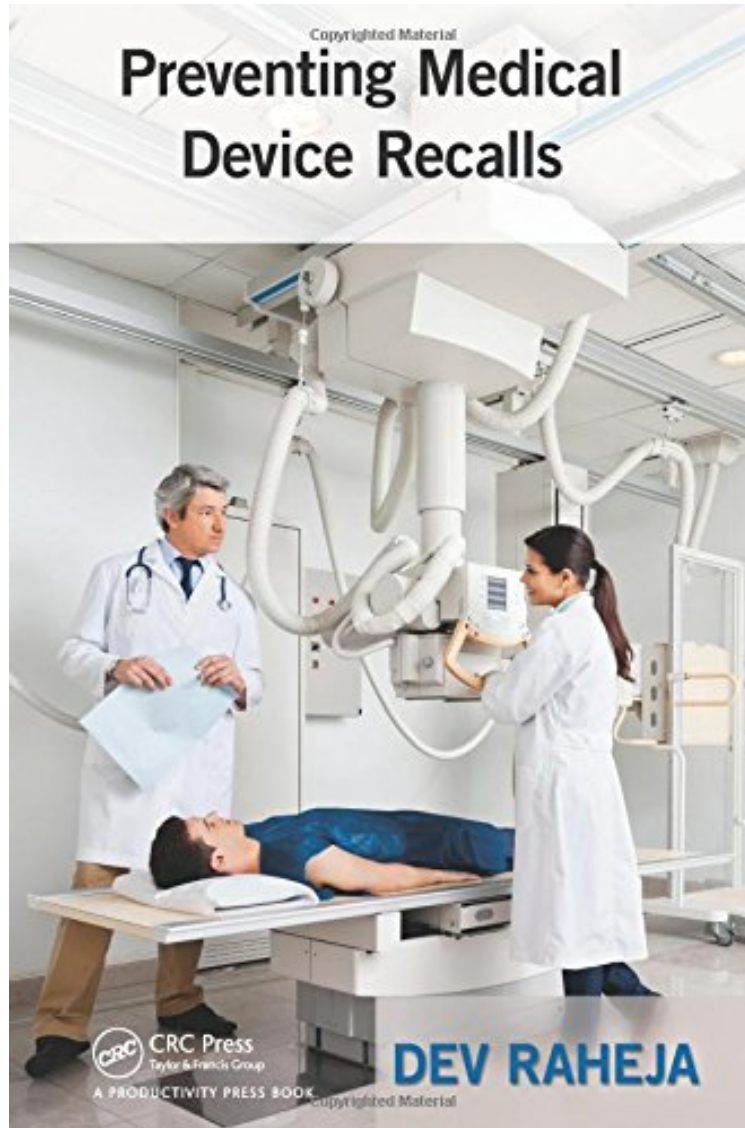


Preventing Medical Device Recalls

Dev Raheja

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Dev Raheja : Preventing Medical Device Recalls before purchasing it in order to gage whether or not it would be worth my time, and all praised Preventing Medical Device Recalls:

A critical and often overlooked aspect of preventing medical device recalls is the ability to implement systems thinking. Although systems thinking wont prevent every mistake, it remains one of the most effective tools for evaluating hidden risks and discovering robust solutions for eliminating those risks.Based on the authors extensive

experience in the medical device, aerospace, and manufacturing engineering industries, Preventing Medical Device Recalls presents a detailed structure for systems thinking that can help to prevent costly device recalls. Based on Dr. W. Edwards Demings System of Profound Knowledge, this structure can help medical device designers and manufacturers exceed their customers expectations for quality and safety. This book is among the first to demonstrate how to control safety risks from specifications all the way through to safely retiring products without harm to the environment. Supplying an accessible overview of medical device requirements and the science of safety, it explains why risk analysis must start with product specification and continue throughout the product life cycle. Covering paradigms for proactive thinking and doing, the text details methods that readers can implement during the specification writing, product design, and product development phases to prevent recalls. It also includes numerous examples from the authors experience in the medical device, consumer, and aerospace industries. Even in healthcare, where compliance with standards is at its highest level, more patients die from medical mistakes each week than would be involved in a jumbo jet crash. With coverage that includes risk assessment and risk management, this book provides you with an understanding of how mishaps happen so you can account for unexpected events and design devices that are free of costly recalls.

About the Author Dev Raheja, MS, CSP, has been an international risk management and quality assurance consultant in the healthcare, medical device, and aerospace industries for more than 25 years. He applies evidence-based safety techniques from a variety of industries to healthcare. He is a trainer, and author of the books Safer Hospital Care, Assurance Technologies Principles and Practices, and Design for Reliability. He shows clients how to create elegant solutions using creativity and innovation. Being a true international consultant, he has conducted training in several countries including Sweden, Australia, Japan, Germany, the United Kingdom, Singapore, Taiwan, South Africa, Finland, and Brazil. He helped a major company in the Midwestern United States avoid going out of business and become a world leader by eliminating safety mishaps. Prior to becoming a consultant in 1982, he worked at GE Healthcare as supervisor of quality assurance and manager of manufacturing, and at Booz-Allen Hamilton as a risk management consultant for the nuclear and mass transportation industry. Raheja served as adjunct professor at the University of Maryland for five years in its PhD program in reliability engineering, and is currently an adjunct professor at Florida Tech for its BBA degree in healthcare management. He is associate editor for healthcare safety for the Journal of System Safety, and teaches webinars on medical device safety and reliability. He has received several industry awards including the Scientific Achievement Award and Educator-of-the-Year Award from the System Safety Society and the Austin Bonis Reliability Education Award from the American Society for Quality. He served as part of the first group of examiners for the Malcolm Baldrige National Quality Award, and served for 15 years on the board of directors of the Annual Reliability and Maintainability Conference sponsored by ten engineering societies. Currently he is a member of the Institute of Electrical and Electronics Engineers (IEEE), Association for the Advancement of Medical Instrumentation (AAMI), the American Society of Patient Safety Professionals, and the American College of Healthcare Executives. Raheja majored in human factors engineering as a part of his masters degree in industrial engineering, is a Certified Safety Professional through the Board of Certified Safety Professionals, and serves as the chairman of the Design for Reliability Committee of the IEEE.