



Preventing Medical Device Recalls

Dev Raheja

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A critical and often overlooked aspect of preventing medical device recalls is the ability to implement systems thinking. Although systems thinking won't 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 author's 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 Deming's 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 author's 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.

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