Managing Medical Devices within a Regulatory Framework

From Fiedler Beth Ann
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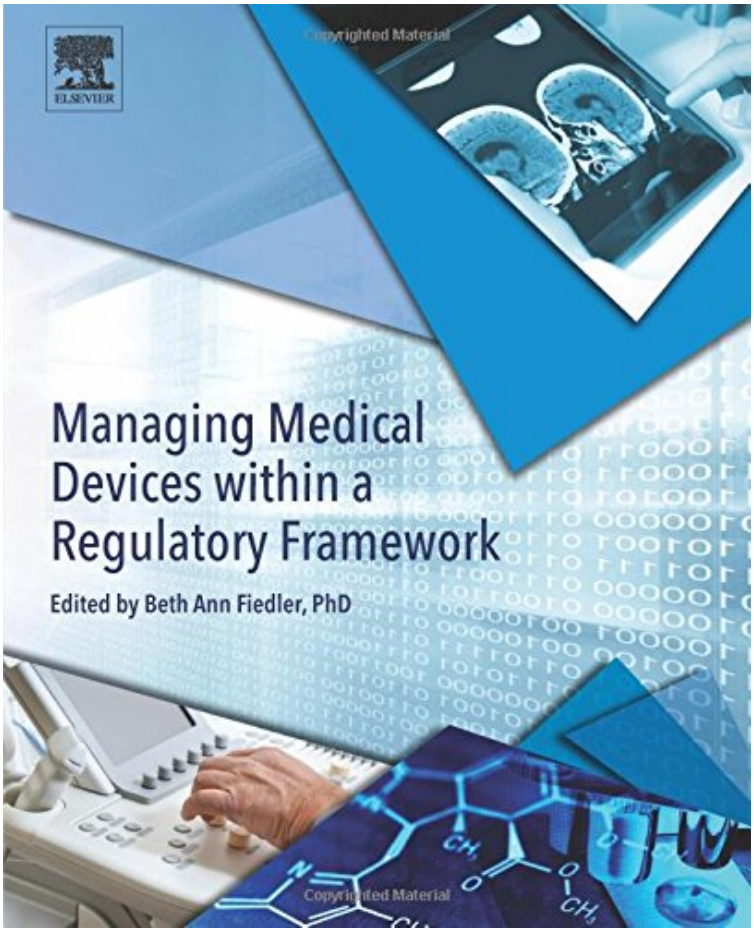

#3318124 in Books Fiedler Beth Ann 2016-09-26 2016-09-12Original language:English 9.25 x .90 x 7.50l, 1.82 #File Name: 012804179X380 pagesManaging Medical Devices Within a Regulatory Framework | File size: 41.Mb

From Fiedler Beth Ann : Managing Medical Devices within a Regulatory Framework before purchasing it in order to gage whether or not it would be worth my time, and all praised Managing Medical Devices within a Regulatory Framework:

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.Covers compliance with FDA and CE regulations, plus EU directives for service and maintenance of medical devicesProvides operational and clinical practice recommendations in regard to regulatory changes for risk managementDiscusses best practices for equipment procurement and maintenanceProvides guidance on dealing with the challenge of medical records management and compliance with patient confidentiality using information from medical devices

About the AuthorBeth Ann earned her doctorate in Public Affairs at the University of Central Florida. The author of books on innovative approaches to healthcare quality; Dr. Fiedler has also successfully completed quality-award winning management projects for the private sector and the US military. Her research includes policy analysis focused on healthcare quality and business development presented to U.S. Congressional representatives, medical, technology and business audiences in the US and abroad. She has published in several peer-reviewed journals, was named a Founders Fellow by the American Society for Public Administration in 2014 and was featured by the US National Center for Policy Analysis for Ideas Changing the World on Health Issues.