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a practical guide to planning writing and reviewing medical device clinical evaluation reports guides readers through clinical data evaluation of medical devices in compliance with the eu mdr requirements and other similar regulatory requirements throughout the world this book brings together knowledge learned as the author constructed hundreds of cers and taught thousands of learners on how to conduct clinical data evaluations this book will support training for clinical engineers clinical evaluation scientists and experts reviewing medical device cers and will help individual writers teams and companies to develop stronger more robust cers identifies and explains data analysis for clinical evaluation of medical devices teaches readers how to understand and evaluate medical device performance and safety in the context of new regulations provides analysis of new clinical evaluation criteria in the context of medical device design as well as in hospital deployment and servicing

this book is intended to serve as a reference for professionals in the medical device industry particularly those seeking to learn from practical examples and case studies medical devices like pharmaceuticals are highly regulated and the bar is raised constantly as patients and consumers expect the best quality healthcare and safe and effectiv

the 76th meeting of the who expert committee on biological standardization was held from 24 to 28 october 2023 by zoom video conferencing the meeting was opened on behalf of the director general of who by dr clive ondari director health products policy and standards the expert committee on biological standardization reviews developments in the field of biological substances used in human medicine which include vaccines biotherapeutics blood products and related substances and in vitro diagnostic reagents it coordinates activities leading to a the adoption of who guidelines and recommendations for assuring the quality safety and efficacy of such substances and b the establishment of who international standards and other reference materials the use of international reference materials for designating the activity of biological substances used in prophylaxis or therapy or for ensuring the reliability of quality control or diagnostic procedures allows for the comparison of data worldwide target audience includes but is not limited to regulators manufacturers policymakers health workers developers of vaccines and other biological products and academia

this book is meant to be a guide to all who want to learn about a highly regulated industry my approach is to give you the reader an example of a fictitious device and we will take it from a conceptual idea all the way to launch and beyond my intention is to incorporate the best experiences that i and other contributors have had into this book and convert them into laymans terms for those who are in need these experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of their silo to help see how each of the systems relate to each as a whole however it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be in compliance in some instances there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that companies can adopt their systems which are solely designed for their purposes therefore this book will try to avoid complicated words and complex technical details of engineering and statistics this book will strive to be an embodiment of the honest to goodness everyday experiences and issues that folks experience while working in the medical device industry

coverage of publications outside the uk and in non english languages expands steadily until in 1991 it occupies enough of the guide to require publication in parts

this report discusses the need for an integrated and cyclical approach to managing health technology in order to mitigate clinical and financial risks and ensure acceptable value for money

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