Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics

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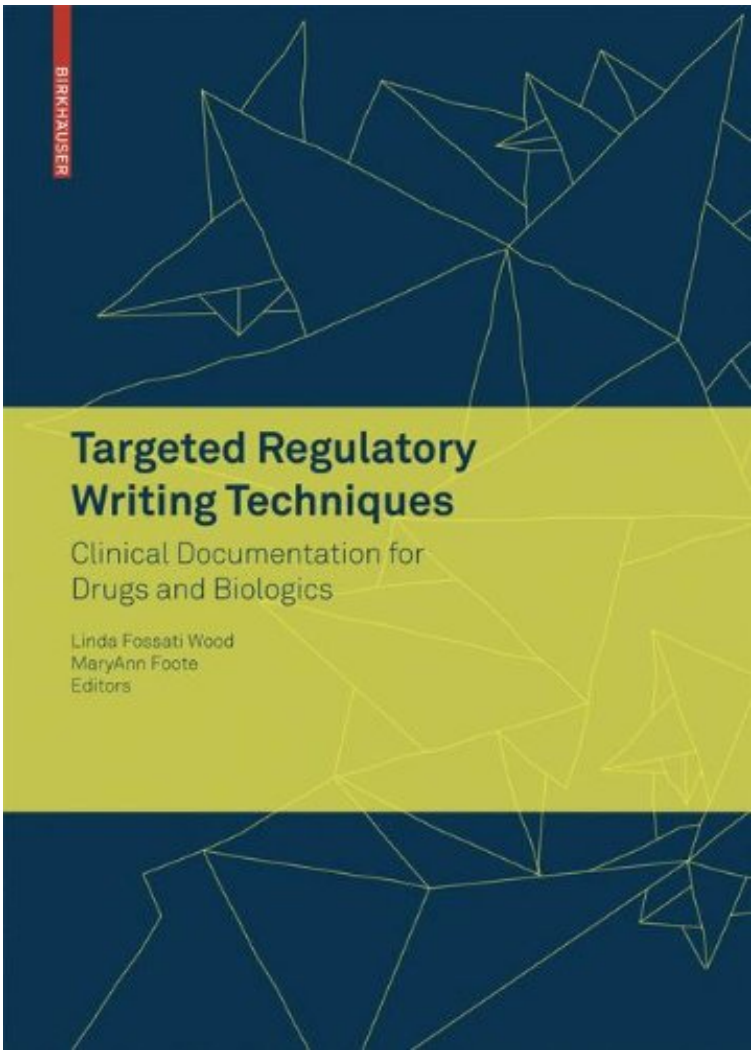

#705544 in Books Birkhuser 2008-12-05Original language:EnglishPDF # 1 9.00 x .57 x 6.25l, .90 #File Name: 3764383615238 pages | File size: 26.Mb

From Brand: Birkhuser : Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics before purchasing it in order to gage whether or not it would be worth my time, and all praised Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics:

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great reference and teaching book for a newer medical writer also as each document type is presented, from protocols and Investigator's Brochures to Clinical Study Reports.This book belongs in every medical writer's reference library.A great investment book for writers and companies.20 of 20 people found the following review helpful. MUST READ FOR CLINICAL DEVELOPMENT PROFESSIONALSBy Jay HersonWhile ICH has told the global clinical development community what they want there has been confusion as to how to implement the guidelines. The confusion is particularly acute in the small biotech firms where MDs, PhDs and PharmDs are given the sole authority to write protocols, clinical study reports, integrated summaries of safety and efficacy without the oversight and SOPs that guide these steps in Big Pharma. Wood and Foote have created an outstanding book which should serve as a reference for clinical development professionals worldwide. Through clear narratives and templates they tell the reader how to create all the documents needed in a clinical development program even including this information for Japan which has long been a source of confusion even in Big Pharma.0 of 0 people found the following review helpful. Five StarsBy CustomerGreat book but it was delayed in getting to me because the UPS label had been ripped off :(

This book describes the authors standard or best practices used in writing regul- ed clinical documents for the drug and biologics industry. The fundamental premise of this book is that the end (documents submitted to a health authority) is dep- dent on the beginning (the planning and strategy that go into organizing written documentation). Each regulatory document inherently exists within a constellation of related documents. This book attempts to show the relationships between and among these documents and suggests strategies for organizing and writing these documents to maximize ef?ciency while developing clear and concise text. At all times, and irrespective of applicable laws and guidelines, good communication skills and a sense of balance are essential to adequately, accurately, and clearly describe a products characteristics. At no time should the reader perceive these suggestions to be the only viable solution to writing regulatory documents nor should the reader expect that these suggestions guarantee product success. The audience for this book is the novice medical writer, or those who would like to explore or enhance regulatory-writing skills. We assume the reader will have a basic understanding of written communication, but little experience in applying this skill to the task of regulatory writing. Extensive knowledge of science, clinical me- cine, mathematics, or regulatory affairs law is not required to use the best practices described in this book.