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written by an expert with twenty years experience in regulatory affairs in a number of multi national companies this book guides  
readers through the legislative minefield of registering medicinal products in the european union taking a step by step approach the  
book demystifies all of the regulatory requirements and gives a clear understanding of how to achieve compliance the author gathers  
all the relevant requirements puts them into context and provides regulatory information in an easily accessible format headings  
subheadings and key points organized in tabular format make the information easy for readers to find and the book easy for readers to

use

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clinical trial project management provides a detailed overview of how to conduct clinical trials in an international context the process of conducting clinical studies across nations is based on a set of regulatory regimes developed by respective regulatory agencies the book focuses on clinical study protocol approval processes ethics committee approval processes clinical study feasibilities site selection site initiation site monitoring database lock sit close out clinical data processing and management sae reporting and compensation randomization procedure pharmacovigilance statistical tools ba be studies and clinical study report writing etc covering entire clinical trial process of conductance in addition to that the author also incorporated the clinical trial approval process of usfda ema and japan to conduct the clinical trials covers how to conduct clinical trials in detail present useful basic and advanced statistical tools provides real time project management methods like program evaluation review technique pert and critical path method cpm to manage complex projects are described in the book

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