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Nota di contenuto	Machine generated contents note: pt. I Background -- ch. 1 Evolution of Medical Device Software Validation and the Need for This Book -- Evolution of Validation in the Medical Device Industry -- Building a Language to Discuss Validation -- Terminology is the Foundation -- Correct Versus Consistent Terminology -- Terminology Need Not Be Entertaining --
Sommario/riassunto	Here's the first book written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software. Offering you a much broader, higher-level picture than other books in this field, this book helps you think critically about software validation -- to build confidence in your software's safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process. From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, and in compliance with regulations. Additionally, an entire part of the book is devoted to the

validation of software that automates any part of a manufacturer's quality system and is regulated by 21 CFR 820.70(i). DVD Included! Contains a collection of FDA regulations and guidance documents related to software in the medical device industry, valuable sample forms and templates, and supplemental figures that support key topics covered in the book.