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Nota di contenuto	Preface, Introduction, Chapter 1: Stage 1 Quality by Design Product Development QbD product development methodologies -- Chapter 2: Stage 1 Scale Up, Tech Transfer Process -- Considerations for process scale up and transfer -- Chapter 3: Stage 2 Batch determination, Sampling & Testing Plan -- PPQ batch determination method, scientifically supported sampling and testing plans -- Chapter 4: Stage 3A Continued Process Verification -- Stage 3A assessment methodology for newly launched products -- Chapter 5: Stage 3B Continued Process Verification -- Routine CPV monitoring plan for commercial products.
Sommario/riassunto	The textbook addresses the lifecycle concepts (Stage 1, 2, 3) of Process Validation. Regulatory bodies such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. Organizations have an opportunity to harmonize and align PV activities for all regulated markets. The concepts discussed provides a direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Oral Dose Process Validation, Lifecycle Approach: Application, Volume Two and the companion Volume One, Solid Dose Process Validation, The Basics, also available as a set, provide directions and solutions for the pharmaceutical industry. The topics and chapters give a systematic

understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach. This set is published as a comprehensive solution for solid dose process validation.