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Sommario/riassunto	Currently there are no process validation (PV) textbooks addressing the lifecycle concepts (Stage 1, 2, 3). Recent regulatory guidance's such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. The concepts are now harmonized across regulatory guidance's and organizations have an opportunity to align PV activities for all regulated markets. Therefore a need exists for consensus and direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Dose Process Validation: The Basics, Volume One and companion Solid Dose Process Validation: Lifecycle Approach Application, Volume Two, also available as a set, provide directions and solutions for these unmet needs for the pharmaceutical industry. The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. All approaches meet the regulatory requirements enlisted in the guidance’

s, which is the precursor to applying the concepts. This set is published as a comprehensive solution for solid dose process validation. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach.