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Descrizione fisica	1 online resource (722 pages) : illustrations (some color)
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Sommario/riassunto	"Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies. Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines. Uses case studies to help readers understand and apply ICH guidelines. Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines. Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice

(GMP)"--
