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)
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