ICH Quality Guidelines: An Implementation Guide
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DESCRIPTION

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)
ABOUT THE AUTHOR

Andrew Teasdale, PhD, is a principal scientist in pharmaceutical development with AstraZeneca. He has over 20 years' experience within the industry and has held a number of leadership roles both internally and externally at a cross industry level encompassing key ICH topic areas.

David Elder, PhD, is an independent CMC consultant. He has 40 years' experience within the pharmaceutical industry. He was formerly a director within GlaxoSmithKline's platform technology and science function. He is an expert member for the British Pharmacopoeia and has extensive CMC experience encompassing many of the key ICH topics.

Raymond W. Nims, PhD, is a Senior Consultant at RMC Pharmaceutical Solutions, with experience in a variety of GMP quality assurance and quality control topics from a biologics point of reference. He has served on ad hoc panels supporting a number of USP chapters and ANSI Standards.

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