

1. Record Nr.	UNINA9910271046603321
Titolo	ICH quality guidelines : an implementation guide // edited by Andrew Teasdale, AstraZeneca, London, United Kingdom, David Elder, Consultant (fGSK), Hertford, Hertfordshire, SG14 2DE, United Kingdom, Raymond W. Nims, RMC Pharmaceutical Solutions, Inc., Longmont, CO, USA
Pubbl/distr/stampa	Hoboken, New Jersey : , : Wiley, , 2018 ©2018
ISBN	1-118-97113-2 1-118-97112-4 1-118-97114-0
Descrizione fisica	1 online resource (722 pages) : illustrations (some color)
Classificazione	MED071000TEC032000SCI013060
Disciplina	615.19
Soggetti	Drug development Drugs - Testing Drugs - Quality control Electronic books.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
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)"--
