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Nota di contenuto	1 Clinical Trials: Historical Aspects and Importance and New Drug Developments -- 2 The Definition of GCP -- 3 The Principles of GCP -- 4 The Drug Development Process and Evolution of Regulations -- 5 Planning Clinical Research -- 6 Preparation of Ethics Committee (IRB) Proposal -- 7 Preparation of Informed Consent -- 8 Preparation of Findings Tables -- 9 Setting the Ideal Statistical Methods -- 10 The Duties of a Clinical Research Coordinator -- 11 The Duties of Clinical Researchers -- 12 The Phases of Clinical Studies -- 13 Safety in Clinical Trials -- 14 Setting the Size -- 15 Setting the Ideal Method -- 16 Ethics of Clinical Research -- 17 Recruitment and Enrolment -- 18 Why we need Clinical Consent and Other Documentation -- 19 Monitoring the Trial -- 20 Inspection -- 21 Ethics - Institutional Review Board/Independent Ethics Committee(IRB/IEC) -- 22 Responsibilities of the Investigator -- 23 Responsibilities of the Sponsor -- 24.Clinical

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Sommario/riassunto	This brand-new book offers a reference guide to understanding and applying the rules for properly conducting clinical trials to meet the international quality standard – Good Clinical Practice – provided by the International Conference on Harmonization (ICH). The work offers an updated perspective on the clinical research landscape within the context of the clinical trial regulatory frameworks in Europe and the USA. In addition to providing a historical review and a detailed definition of GPC regulations, it includes step-by-step explanations of all the requirements that researchers should bear in mind when designing and performing new trials. Further topics covered include: ethics of clinical research; the drug development process and evolution of regulations; investigator and sponsor responsibilities; and clinical trial protocols. Written by clinicians for clinicians, the book represents a valuable read also for researchers, pharmacists and all professionals involved in applications to the ethic committees, whose approval is required for new clinical studies.