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Titolo	Statistics in regulatory science / / by Shein-Chung Chow
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Edizione	[1st ed.]
Descrizione fisica	1 online resource (553 pages)
Collana	Chapman and Hall/CRC Biostatistics Series
Disciplina	615.19
Soggetti	Drugs - Testing Clinical trials - Statistical methods Pharmacy - Research Research - Statistical methods
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Totality-of-the-evidence -- Hypotheses testing versus confidence interval -- Endpoint selection -- Non-inferiority margin -- Missing data -- Multiplicity -- Sample size -- Reproducible research -- Extrapolation -- Consistency evaluation -- Drug products with multiple components -- Adaptive trial design -- Selection criteria in adaptive dose finding -- Generic drugs and biosimilars -- Precision and personalized medicine -- Big data analytics -- Rare disease drug development.
Sommario/riassunto	"The proposed book will focus on practical issues in pharmaceutical/clinical research and development from both regulatory and scientific perspectives. The book will outline and clarify those issues that have been commonly misused in the subject area of regulatory science"--