1. Record Nr. UNINA9910254086203321

Titolo	Nonclinical Statistics for Pharmaceutical and Biotechnology Industries / / edited by Lanju Zhang
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2016
ISBN	3-319-23558-3
Edizione	[1st ed. 2016.]
Descrizione fisica	1 online resource (705 p.)
Collana	Statistics for Biology and Health, , 1431-8776
Disciplina	615.1
Soggetti	Statistics Medicine Pharmacology Statistics for Life Sciences, Medicine, Health Sciences Medicine/Public Health, general Pharmacology/Toxicology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Introduction to Nonclinical Statistics for Pharmaceutical and Biotechnology Industries -- Regulatory Nonclinical Statistics -- How to be a good nonclinical statistician -- Statistical Methods for Drug Discovery -- High-throughput Screening Data Analysis -- Quantitative-Structure Activity Relationship Modeling and Cheminformatics -- GWAS for Drug Discovery -- Statistical applications in Design and Analysis of In-Vitro Safety Screening Assays -- Nonclinical safety assessment: an introduction for statisticians -- General Toxicology, Safety Pharmacology, Reproductive Toxicology and Juvenile Toxicology Studies -- Clinical Assays for Biological Macromolecules -- Recent Research Projects by FDA's Pharmacology and Toxicology Statistics Team -- Design and evaluation of drug combination studies -- Biomarkers -- Overview of Drug Development and Statistical Tools for Manufacturing and Testing -- Assay Validation -- Lifecycle Approach to Bioassay -- Quality by Design: Building Quality into Products and Processes -- Process Validation -- Acceptance Sampling -- Process Capability and Statistical Process Control -- Statistical Considerations

	for Stability and the Estimation of Shelf Life.- In Vitro Dissolution Testing: Statistical Approaches and Issues -- Assessing Content Uniformity -- Chemometrics and Predictive Modelling -- Statistical Methods for Comparability Studies.
Sommario/riassunto	This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxiology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.