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Nota di contenuto	1. The Role of Pharmacokinetics and Pharmacodynamics in the Development of Biotech Drugs -- 2. Pharmacokinetics of Peptides and Proteins -- 3. Pharmacokinetics of Monoclonal Antibodies -- 4. Pharmacokinetics and Pharmacodynamics of Antisense Oligonucleotides -- 5. Pharmacokinetics of Viral and Non-Viral Gene Delivery Vectors -- 6. Bioanalytical Methods Used for Pharmacokinetic Evaluation of Biotech Macromolecule Drugs: Issues, Assay Approaches, and Limitations -- 7. Limitations of Noncompartmental Pharmacokinetic Analysis of Biotech Drugs -- 8. Bioequivalence of Biologics -- 9. Biopharmaceutical Challenges: Pulmonary Delivery of Proteins and Peptides -- 10. Biopharmaceutical Challenges: Delivery of Oligonucleotides -- 11. Custom-Tailored Pharmacokinetics and Pharmacodynamics via Chemical Modifications of Biotech Drugs -- 12. Exposure-Response Relationships for Therapeutic Biologic Products -- 13. Preclinical and Clinical Drug Development of Tasidotin, a Depsi-Pentapeptide Oncolytic Agent.

Sommario/riassunto

This first ever coverage of the pharmacokinetic and pharmacodynamic characteristics of biopharmaceuticals meets the need for a comprehensive book in this field. It spans all topics from lead identification right up to final-stage clinical trials. Following an introduction to the role of PK and PD in the development of biotech drugs, the book goes on to cover the basics, including the pharmacokinetics of peptides, monoclonal antibodies, antisense oligonucleotides, as well as viral and non-viral gene delivery vectors. The second section discusses such challenges and opportunities as pulmonary delivery of proteins and peptides, and the delivery of oligonucleotides. The final section considers the integration of PK and PD concepts into the biotech drug development plan, taking as case studies the preclinical and clinical drug development of tasidotin, as well as the examples of cetuximab and pegfilgrastim. The result is vital reading for all pharmaceutical researchers.--publisher.
