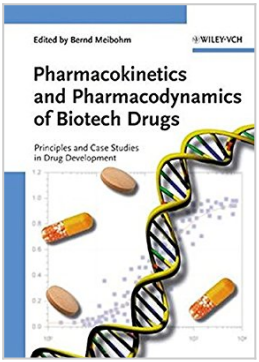

Pharmacokinetics and Pharmacodynamics of Biotech Drugs: Principles and Case Studies in Drug Development

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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.

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Editorial Review

Review
"... There is an urgent need to understand the PK and PD characteristics of these different types of drugs. This book meets that need. ..."
Anticancer Research

From the Back Cover
The characterization and optimization of pharmacokinetic properties and exposure-response relationships are crucial parts in the drug development of biotechnologically-derived drug products. Until recently, our understanding of pharmacokinetics and pharmacodynamics was limited to 'traditional' small-molecule, non-biological drugs. Now, with the current boom in drugs based on biological molecules, such as proteins and nucleotides, there is an urgent need to understand the pharmacokinetic and pharmacodynamic characteristics of these very different types of drugs. This book meets that need.
Comprehensive in its coverage, it spans relevant topics from early phase drug development right up to late-stage clinical trials. Following an introduction to the role of PK and PD in the development of biotech drugs, the first section covers 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 challenges and opportunities in the pharmaceutical development of biologics, including issues related to bioanalytical assays, bioequivalence and exposure-response assessments, as well as drug delivery. 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 set by cetuximab and pegfilgrastim.
Vital reading for all pharmaceutical scientists working with biologics.

About the Author
Bernd Meibohm is an Associate Professor of Pharmaceutical Sciences at the College of Pharmacy of the University of Tennessee Health Science Center, Memphis. He obtained his PhD from the University Carolo-Wilhelmina in Braunschweig, Germany, and underwent postdoctoral training in clinical pharmacology at the University of Florida, Gainesville. His research is focused on pharmacokinetics (PK), pharmacodynamics (PD), and pharmacogenetics (PG) with special emphasis on PK/PD/PG correlations. Professor Meibohm is a Fellow of the American College of Clinical Pharmacology (ACCP) and has received numerous awards, including the 'Young Investigator Award in PK, PD and Drug Metabolism' from the American Association of Pharmaceutical Scientists (AAPS) in 2000. He is currently serving as Section Editor for PK and PD for the 'Journal of Clinical Pharmacology' and on the Editorial Boards of the 'Journal of Pediatric Pharmacology and Therapeutics' and 'Die Pharmazie'.

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