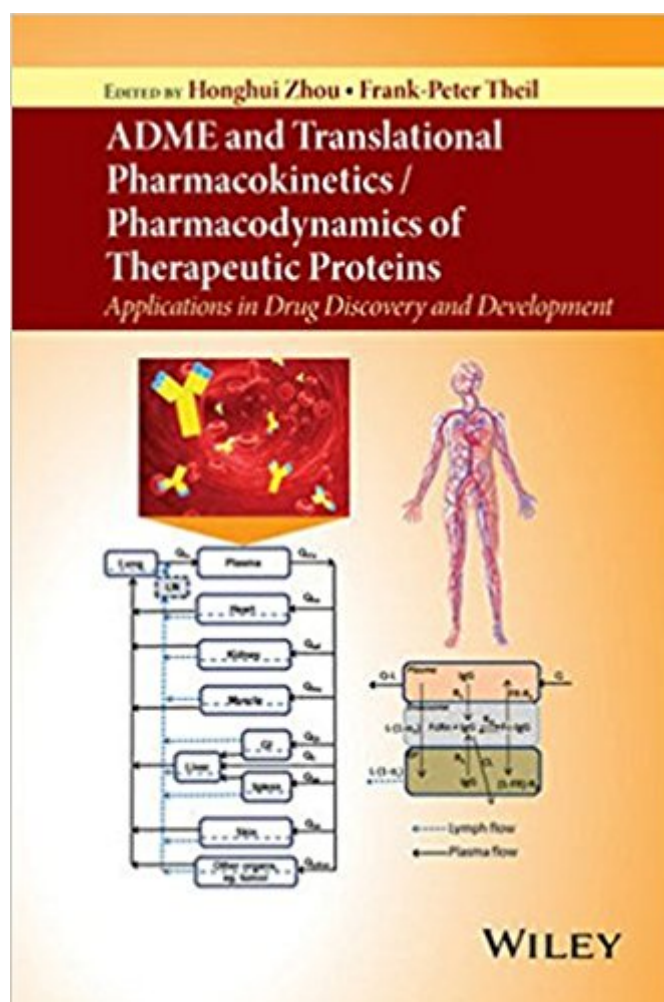


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ADME And Translational Pharmacokinetics / Pharmacodynamics Of Therapeutic Proteins: Applications In Drug Discovery And Development





Synopsis

With an emphasis on the fundamental and practical aspects of ADME for therapeutic proteins, this book helps readers strategize, plan and implement translational research for biologic drugs.

• Details cutting-edge ADME (absorption, distribution, metabolism and excretion) and PKPD (pharmacokinetic / pharmacodynamics) modeling for biologic drugs

• Combines theoretical with practical aspects of ADME in biologic drug discovery and development and compares innovator biologics with biosimilar biologics and small molecules with biologics, giving a lessons-learned perspective

• Includes case studies about leveraging ADME to improve biologics drug development for monoclonal antibodies, fusion proteins, pegylated proteins, ADCs, bispecifics, and vaccines

• Presents regulatory expectations and industry perspectives for developing biologic drugs in USA, EU, and Japan

• Provides mechanistic insight into biodistribution and target-driven pharmacokinetics in important sites of action such as tumors and the brain

Book Information

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Customer Reviews

"At the outset, one is impressed with the scope of the book; it provides an outline of very diverse topics starting with the basics of protein engineering and how these are used to design and manipulate the ADME properties of recombinant and synthetic proteins...The authors have to be congratulated on their endeavor to stitch these topics together in a single book...With such a wide range of topics, even an experienced scientific practitioner in this area is likely to find

something new to engage them and expand their knowledge...In summary, an excellent and comprehensive book for beginners to the CP/PK area to acquaint themselves with the area of biologics (specifically mAb) CP/PKPD principles and for experienced CP/PK scientists for reference." (CPT: Pharmacometrics & Systems Pharmacology, March 2017)

Improve the discovery and development of protein drugs Monoclonal antibodies, as the most successful class of protein therapeutics, have become a critical part of drug treatment regimens with more than 40 marketed modalities and hundreds under development. Some of them have become standards of care, in particular in areas such as oncology and immune-mediated inflammatory diseases; where they often provide safe and efficacious treatment alternatives. Nevertheless, limitations inherent in the canonical monospecific IgG-based monoclonal antibodies have prompted exploration of alternative molecular formats, such as antibody drug-conjugates (ADCs), bi- or multi-specific versions of antibodies. However, there is still scarcity of knowledge and data, combined with a lack of consistent strategies in effectively taking those candidate biologics from preclinical to clinical development. Recent years, though, have seen much progress in understanding ADME (absorption, distribution, metabolism and excretion) of biologics and how this knowledge can be used in research and development. With an emphasis on the theoretical and practical aspects of ADME for therapeutic proteins, this book helps readers strategize, plan and implement end-to-end translational research. Understanding of ADME has clearly illustrated its merits in the area of small molecule drugs in order to develop drugs successfully and more effectively. Novel therapeutic modalities will even more require an in-depth understanding of ADME to optimize delivery for a successful development. The authors, writing from the frontlines of biologics research and development, cover topics that include similarities and differences in ADME characteristics between small molecules and biologics, the types of therapeutic biologics (e.g. monoclonal antibodies, pegylated proteins, vaccines, ADCs, and bispecifics) and their unique ADME properties, and how protein engineering alters and optimizes ADME and PK/PD properties. A complete and valuable reference and resource for anyone working in the biopharmaceutical field, *ADME and Translational Pharmacokinetics / Pharmacodynamics of Therapeutic Proteins* offers features that include:

- Concepts of ADME and PK/PD modeling for biologics
- Comparison of small molecules with biologics, giving a lessons-learned perspective
- Mechanistic insight in target-driven and local PK/PD in sites of action like tumors and the brain
- Case studies about leveraging ADME to improve end-to-end biologics drug development
- Current thinking and strategies on biosimilar development

from ADME and PK/PD standpoints – Regulatory expectations and industry perspectives for biologic development in USA, EU, and Japan

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