

Mohammad A. Tabrizi
Gadi G. Bornstein
Scott L. Klakamp *Editors*

Development of Antibody-Based Therapeutics

Translational Considerations



Springer

Development Of Antibody Based Therapeutics Translational Considerations

Honghui Zhou, Diane R. Mould



Development Of Antibody Based Therapeutics Translational Considerations:

Development of Antibody-Based Therapeutics Mohammad A. Tabrizi, Gadi G. Bornstein, Scott L. Klakamp, 2012-04-24 Translational strategies for development of antibody based therapeutics should allow understanding of the relationship between the unit dose and unit effect with respect to both beneficial and deleterious effects from early stages of development The flow of information from later to earlier stages of development should provide opportunities to facilitate selection of more effective novel and next generation drug candidates Selection and evaluation of relevant biomarkers in early preclinical development in relevant animal models should allow for identifying potential risks to humans and establishing safe First In Human FIH dosing strategies Hence integration of knowledge with respect to target antigen properties such as antigen distribution expression profile kinetic properties target pharmacology antigen isoforms and pharmacological redundancy in health and disease as well as antibody design criteria such as antibody isotype affinity PK PD and safety is a critical necessity for the design of effective translational strategies Additionally these factors will further offer critical differentiating characteristics for next generation antibodies and novel technologies prove instrumental in generation of biosuperior antibody candidates for market entry This book will examine many important considerations necessary for the design of effective translational strategies during the development of antibody based therapeutics Development of Antibody-Based Therapeutics Mohammad A. Tabrizi, Gadi G. Bornstein, Scott L. Klakamp, 2018-09-11 With a key focus on recent developments and advances in the field this book provides in depth coverage of topics fundamental to the development of targeted therapeutics The expansion of targeted modalities in rapidly evolving therapeutic areas such as immune oncology and developments with respect to combination therapies novel technologies and the therapeutic application of antibody drug conjugates are presented Additionally the book builds upon topics discussed in the first edition 2012 where recent innovations warrant elaboration This the second edition of Development of Antibody Based Therapeutics Translational Considerations represents a comprehensive evaluation of progress in the field which sits alongside the first edition to inform in detail professional and academic researchers as well as graduate students **Development of Antibody-Based Therapeutics**, 2012-04-25 *Haschek and Rousseaux's Handbook of Toxicologic Pathology, Volume 1: Principles and Practice of Toxicologic Pathology* Wanda M. Haschek, Colin G. Rousseaux, Matthew A. Wallig, Brad Bolon, 2021-10-20 Haschek and Rousseaux's Handbook of Toxicologic Pathology recognized by many as the most authoritative single source of information in the field of toxicologic pathology has been extensively updated to continue its comprehensive and timely coverage The fourth edition has been expanded to four separate volumes due to an explosion of information in this field requiring new and updated chapters Completely revised with a number of new chapters Volume 1 Principles and the Practice of Toxicologic Pathology covers the practice of toxicologic pathology in three parts Principles of Toxicologic Pathology Methods in Toxicologic Pathology and the Practice of Toxicologic Pathology Other volumes in this work round out the depth

and breadth of coverage Volume 2 encompasses Toxicologic Pathology in Safety Assessment and Environmental Toxicologic Pathology These two sections cover the application of toxicologic pathology in developing specific product classes principles of data interpretation for safety assessment and toxicologic pathology of major classes of environmental toxicants Volumes 3 and 4 provide deep and broad treatment of Target Organ Toxicity emphasizing the comparative and correlative aspects of normal biology and toxicant induced dysfunction principal methods for toxicologic pathology evaluation and major mechanisms of toxicity These volumes comprise the most authoritative reference on toxicologic pathology for pathologists toxicologists research scientists and regulators studying and making decisions on drugs biologics medical devices and other chemicals including agrochemicals and environmental contaminants Each volume is being published separately Provides new chapters on digital pathology juvenile pathology in vitro in vivo correlation big data technologies and in depth discussion of timely topics in the area of toxicologic pathology Offers high quality and trusted content in a multi contributed work written by leading international authorities in all areas of toxicologic pathology Features hundreds of full color images in both the print and electronic versions of the book to highlight difficult concepts with clear illustrations

Pharmaco-Imaging in Drug and Biologics Development Brian R. Moyer, Narayan P.S. Cheruvu, Tom C.-C. Hu, 2013-11-08 The volume aim to be a comprehensive overview of the drug and biologic development process that is often called the valley of death pre IND through approval where high costs of studies and high rates of product failure are part of the drug development landscape Imaging tools can serve in this period by adding high value data the images and the kinetic information they can provide and cost effective development alternative tools which potentially improve pivotal study designs Imaging may identify safety issues early such as unwanted organ or tissue distributions and then can serve advanced development with added certainty of a drug or biologic s success to senior corporate management and investors There are numerous textbooks reference texts and treatises on medical imaging technologies teaching tools on medical cases and physics books on the science of detector and computer interface systems Rarely in each of these are examples of medical imaging protocols and animal models of disease i e a text on methodology in drug development is currently unavailable

Quantitative Pharmacology and Individualized Therapy Strategies in Development of Therapeutic Proteins for Immune-Mediated Inflammatory Diseases

Honghui Zhou, Diane R. Mould, 2019-02-18 Thorough Overview Identifies and Addresses Critical Gaps in the Treatment of Several Chronic Diseases With increasing numbers of patients suffering from Immune Mediated Inflammatory Diseases IMIDs and with the increasing reliance on biopharmaceuticals to treat them it is imperative that researchers and medical practitioners have a thorough understanding of the absorption distribution metabolism and excretion ADME of therapeutic proteins as well as translational pharmacokinetic pharmacodynamic PK PD modeling for them This comprehensive volume answers that need to be addressed Featuring eighteen chapters from world renowned experts and opinion leaders in pharmacology translational medicine and immunology editors Honghui Zhou and Diane Mould have curated a much needed

collection of research on the advanced applications of pharmacometrics and systems pharmacology to the development of biotherapeutics and individualized treatment strategies for the treatment of IMiDs. Authors discuss the pathophysiology of autoimmune diseases in addition to both theoretical and practical aspects of quantitative pharmacology for therapeutic proteins, current translational medicine research methodologies and novel thinking in treatment paradigm strategies for IMiDs. Other notable features include Contributions from well known authors representing leading academic research centers, specialized contract research organizations and pharmaceutical industries whose pipelines include therapeutic proteins. Chapters on a wide range of topics e.g. pathophysiology of autoimmune diseases, biomarkers in ulcerative colitis, model based meta analysis use in the development of therapeutic proteins, Case studies of applying quantitative pharmacology approaches to guiding therapeutic protein drug development in IMiDs such as psoriasis, inflammatory bowel disease, multiple sclerosis and lupus. Zhou and Mould's timely contribution to the critical study of biopharmaceuticals is a valuable resource for any academic and industry researcher working in pharmacokinetics, pharmacology, biochemistry or biotechnology as well as the many clinicians seeking the safest and most effective treatments for patients dealing with chronic immune disorders.

ADME and Translational Pharmacokinetics / Pharmacodynamics of Therapeutic Proteins
Honghui Zhou, Frank-Peter Theil, 2015-10-26. 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 PK/PD, 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.

Novel Approaches and Strategies for Biologics, Vaccines and Cancer Therapies
Manmohan Singh, Maya Salnikova, 2014-12-30. Novel Approaches and Strategies for Biologics, Vaccines and Cancer Therapies takes a look at the current strategies, successes and challenges involved with the development of novel formulations of biologics, vaccines and cancer therapy. This thorough reference on the latest trends in the development of diverse modalities will appeal to a broad community of scientists, students and clinicians. Written by leading authors across academia and industry, this book covers important topics such as unique drug delivery devices, non parenteral delivery trends, novel approaches to the treatment of cancer, immunotherapy and more. It includes real world cases and examples which highlight formulations with therapeutic proteins, monoclonal antibodies, peptides and biobetters as well as cases on novel vaccines, formulations including evolving pathogens, novel modalities of vaccines.

universal vaccines This book is a thorough and useful resource on the development of novel biologics vaccines and cancer therapies Provides strategies for the development of safe and efficacious novel formulations for various modalities of biologics vaccines and for cancer therapy Highlights novel cases from current clinical trials as well as marketed products Reviews overall successes and challenges in the development of novel formulations including new molecular targets for the treatment of diseases design of target specific therapies regulatory considerations individualized therapies *Identification and Quantification of Drugs, Metabolites, Drug Metabolizing Enzymes, and Transporters* Shuguang Ma, Swapan Chowdhury, 2020-07-09 Identification and Quantification of Drugs Metabolites Drug Metabolizing Enzymes and Transporters Second Edition is completely updated to provide an overview of the last decade s numerous advances in analytical technologies for detection and quantification of drugs metabolites and biomarkers This new edition goes beyond LC MS and features all new chapters on how to evaluate drug absorption distribution metabolism and excretion potential for hepatic and renal toxicity immunogenicity of biotherapeutics and translational tools for predicting human dosage safety and efficacy of small molecules and biologics This book will be an important handbook and desk reference for pharmacologists toxicologists clinical scientists and students interested in the fields of pharmacology biochemistry and drug metabolism Four sections in the book with 24 chapters give readers an overview of state of the art techniques for identifying and quantifying drugs metabolites and biomarkers including a chapter on new approaches for quantification of enzymes and transporters in different tissues Focuses on the role of drug metabolism enzymes transporters in disposition and drug drug interactions as well as strategies for evaluating drug metabolism and safety using advanced liver and kidney models Discussions on immunogenicity risks of biologics and their evaluation methods have been included Includes several chapters on advanced translational sciences to predict human dosage pharmacokinetics and efficacy for small molecules and biotherapeutics All chapters are written by experts with a wide range of practical experience from the industry and academia **Translational Medicine** Joy A. Cavagnaro, Mary Ellen Cosenza, 2021-11-25 Translational Medicine Optimizing Preclinical Safety Evaluation of Biopharmaceuticals provides scientists responsible for the translation of novel biopharmaceuticals into clinical trials with a better understanding of how to navigate the obstacles that keep innovative medical research discoveries from becoming new therapies or even making it to clinical trials The book includes sections on protein based therapeutics modified proteins oligonucleotide based therapies monoclonal antibodies antibody drug conjugates gene and cell based therapies gene modified cell based therapies combination products and therapeutic vaccines Best practices are defined for efficient discovery research to facilitate a science based efficient and predictive preclinical development program to ensure clinical efficacy and safety Key Features Defines best practices for leveraging of discovery research to facilitate a development program Includes general principles animal models biomarkers preclinical toxicology testing paradigms and practical applications Discusses rare diseases Discusses What Why When How highlighting different considerations based upon

product attributes Includes special considerations for rare diseases About the Editors Joy A Cavagnaro is an internationally recognized expert in preclinical development and regulatory strategy with an emphasis on genetic medicines Her 40 year career spans academia government FDA and the CRO and biotech industries She was awarded the 2019 Arnold J Lehman Award from the Society of Toxicology for introducing the concept of science based case by case approach to preclinical safety evaluation which became the foundation of ICH S6 She currently serves on scientific advisory boards for advocacy groups and companies and consults and lectures in the area of preclinical development of novel therapies Mary Ellen Cosenza is a regulatory toxicology consultant with over 30 years of senior leadership experience in the biopharmaceutical industry in the U S Europe and emerging markets She has held leadership position in both the American College of Toxicology ACT and the International Union of Toxicology IUTOX and is also an adjunct assistant professor at the University of Southern California where she teaches graduate level courses in toxicology and regulation of biologics

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