

2013 Aaps National Biotechnology Conference

Mark Rogge, David R. Taft

Biosimilarity Sarfaraz K. Niazi, 2018-10-03 Summary: The focus of this book is on how the U.S. FDA will approve biosimilar drugs, as learned from recent approvals by the FDA. Understanding the limitations of the statutory limits and non-inferiority testing are presented as tools to obviate patient trials and minimize testing of immunogenicity. An in-depth scientific, mathematical and statistical view of the tools required to establish biosimilarity of biological drugs of different complexity -- a must for every developer of biosimilars. Features: First comprehensive analysis based on new guidelines and approval packages of several biosimilars Presents the first approach to challenge FDA in reducing or eliminating any testing in patients. Provides a comprehensive understanding of the U.S. statutory requirements vis-a-vis the regulatory guidelines Provides model CQA and Analytical Similarity testing protocols for cytokines and monoclonal antibodies Allow creation of a fast-to-market pathway to develop biosimilars

Drug Delivery Anya M Hillery, Kinam Park, 2016-09-15 This book provides a comprehensive introduction to advanced drug delivery and targeting, covering their principles, current applications, and potential future developments. This edition has been updated to reflect significant trends and cutting-edge advances that have occurred since the first edition was published. All the original chapters have been retained, but the material therein has been updated. Eight new chapters have been added that deal with entirely new technologies and approaches. Features: Offers a comprehensive introduction to the fundamental concepts and underlying scientific principles of drug delivery and targeting Presents an in-depth analysis of the opportunities and obstacles afforded by the application of nanotechnologies for drug delivery and targeting Includes a revised and expanded section on the major epithelial routes of drug delivery currently under investigation Describes the most recent, emerging, and innovative technologies of drug delivery Provides real-life examples of the clinical translation of drug delivery technologies through the use of case studies Discusses the pertinent regulatory hurdles and safety issues of drug delivery and targeting systems—crucial considerations in order to achieve licensing approval for these new technologies

Antibody-Drug Conjugates Jeffrey Wang, Wei-Chiang Shen, Jennica L. Zaro, 2015-03-05 This authoritative volume provides a holistic picture of antibody-drug conjugates (ADCs). Fourteen comprehensive chapters are divided into six sections including an introduction to ADCs, the ADC construct, development issues, landscape, IP and pharmacoeconomics, case studies, and the future of the field. The book examines everything from the selection of the antibody, the drug, and the linker to

a discussion of developmental issues such as formulations, bio-analysis, pharmacokinetic-pharmacodynamic relationships, and toxicological and regulatory challenges. It also explores pharmacoeconomics and intellectual properties, including recently issued patents and the cost analysis of drug therapy. Case studies are presented for the three ADCs that have received FDA approval: gemtuzumab ozogamicin (Mylotarg®), Brentuximab vedotin (Adcetris®), and ado-trastuzumab emtansine (Kadcyla®), as well as an ADC in late-stage clinical trials, glembatumumab vedotin (CDX-011). Finally, the volume presents a perspective by the editors on the future directions of ADC development and clinical applications. Antibody-Drug Conjugates is a practical and systematic resource for scientists, professors, and students interested in expanding their knowledge of cutting-edge research in this exciting field.

Biosimilars and Interchangeable Biologics Sarfaraz K. Niazi, 2016-01-05 What's the Deal with Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Tactical Elements explores the development and manufacturing of biosimilars and targets challenges surrounding the creation of these products. This includes manufacturing, production costs, and intellectual property barriers, particularly in regulated markets (regulatory agencies are still in the process of developing guidelines). It addresses the complexity of biological drugs, and it discusses specific structural elements vital to the functionality, immunogenicity, and safety of biosimilar products. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume provides an overall understanding of the hurdles, difficulties, and practicalities of developing a strong plan. It introduces a step-by-step approach for creating a strategy that helps develop and manufacture a biosimilar product while reducing overall production costs and meeting the requirements of biosimilarity based on analytical and functional, pharmacokinetic, pharmacodynamic (where applicable), and nonclinical toxicology or toxicokinetic similarity (where appropriate) while remaining competitive in the market.

Drug-Drug Interactions for Therapeutic Biologics Honghui Zhou, Bernd Meibohm, 2013-05-10 Strategize, plan, and execute comprehensive drug-drug interaction assessments for therapeutic biologics Offering both theory and practical guidance, this book fully explores drug-drug interaction assessments for therapeutic biologics during the drug development process. It draws together and

analyzes all the latest findings and practices in order to present our current understanding of the topic and point the way to new research. Case studies and examples, coupled with expert advice, enable readers to better understand the complex mechanisms of biologic drug-drug interactions. Drug-Drug Interactions for Therapeutic Biologics features contributions from leading international experts in all areas of therapeutic biologics drug development and drug-drug interactions. The authors' contributions reflect a thorough review and analysis of the literature as well as their own firsthand laboratory experience. Coverage includes such essential topics as: Drug-drug interaction risks in combination with small molecules and other biologics Pharmacokinetic and pharmacodynamic drug-drug interactions In vitro methods for drug-drug interaction assessment and prediction Risk-based strategies for evaluating biologic drug-drug interactions Strategies to minimize drug-drug interaction risk and mitigate toxic interactions Key regulations governing drug-drug interaction assessments for therapeutic biologics. Drug-Drug Interactions for Therapeutic Biologics is recommended for pharmaceutical and biotechnology scientists, clinical pharmacologists, medicinal chemists, and toxicologists. By enabling these readers to understand how therapeutic biologics may interact with other drugs, the book will help them develop safer, more effective therapeutic biologics.

Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry Richard K. Burdick, David J. LeBlond, Lori B. Pfahler, Jorge Quiroz, Leslie Sidor, Kimberly Vukovinsky, Lanju Zhang, 2017-02-14 This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and

nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.

Characterization of Protein Therapeutics using Mass Spectrometry Guodong Chen, 2014-07-08

This book highlights current approaches and future trends in the use of mass spectrometry to characterize protein therapies. As one of the most frequently utilized analytical techniques in pharmaceutical research and development, mass spectrometry has been widely used in the characterization of protein therapeutics due to its analytical sensitivity, selectivity, and specificity. This book begins with an overview of mass spectrometry techniques as related to the analysis of protein therapeutics, structural identification strategies, quantitative approaches, followed by studies involving characterization of process related protein drug impurities/degradants, metabolites, higher order structures of protein therapeutics. Both general practitioners in pharmaceutical research and specialists in analytical sciences will benefit from this book that details step-by-step approaches and new strategies to solve challenging problems related to protein therapeutics research and development.

Antibody-Drug Conjugates Kenneth J. Olivier, Jr., Sara A. Hurvitz, 2016-11-14 Providing practical and proven solutions for antibody-drug conjugate (ADC) drug discovery success in oncology, this book helps readers improve the drug safety and therapeutic efficacy of ADCs to kill targeted tumor cells. • Discusses the basics, drug delivery strategies, pharmacology and toxicology, and regulatory approval strategies • Covers the conduct and design of oncology clinical trials and the use of ADCs for tumor imaging • Includes case studies of ADCs in oncology drug development • Features contributions from highly-regarded experts on the frontlines of ADC research and development

Biosimilars of Monoclonal Antibodies Cheng Liu, K. John Morrow, Jr., 2016-12-09 Addressing a significant need by describing the science and process involved to develop biosimilars of monoclonal antibody (mAb) drugs, this book covers all aspects of biosimilar development: preclinical, clinical, regulatory, manufacturing. • Guides readers through the complex landscape involved with developing biosimilar versions of monoclonal antibody (mAb) drugs • Features flow charts, tables, and figures that clearly illustrate processes and makes the book comprehensible and accessible • Includes a review of FDA-approved mAb drugs as a quick reference to facts and useful information • Examines new technologies and strategies for improving biosimilar mAbs

Sample Preparation in LC-MS Bioanalysis Wenkui Li, Wenying Jian, Yunlin Fu, 2019-02-25 Revised and Expanded Handbook Provides Comprehensive Introduction and Complete Instruction for Sample Preparation in Vital Category of Bioanalysis Following in the footsteps of the previously published

Handbook of LC-MS Bioanalysis, this book is a thorough and timely guide to all important sample preparation techniques used for quantitative Liquid Chromatography–Mass Spectrometry (LC-MS) bioanalysis of small and large molecules. LC-MS bioanalysis is a key element of pharmaceutical research and development, post-approval therapeutic drug monitoring, and many other studies used in human healthcare. While advances are continually being made in key aspects of LC-MS bioanalysis such as sensitivity and throughput, the value of research/study mentioned above is still heavily dependent on the availability of high-quality data, for which sample preparation plays the critical role. Thus, this text provides researchers in industry, academia, and regulatory agencies with detailed sample preparation techniques and step-by-step protocols on proper extraction of various analyte(s) of interest from biological samples for LC-MS quantification, in accordance with current health authority regulations and industry best practices. The three sections of the book with a total of 26 chapters cover topics that include: Current basic sample preparation techniques (e.g., protein precipitation, liquid-liquid extraction, solid-phase extraction, salting-out assisted liquid-liquid extraction, ultracentrifugation and ultrafiltration, microsampling, sample extraction via electromembranes) Sample preparation techniques for uncommon biological matrices (e.g., tissues, hair, skin, nails, bones, mononuclear cells, cerebrospinal fluid, aqueous humor) Crucial aspects of LC-MS bioanalytical method development (e.g., pre-analytical considerations, derivation strategies, stability, non-specific binding) in addition to sample preparation techniques for challenging molecules (e.g., lipids, peptides, proteins, oligonucleotides, antibody-drug conjugates) Sample Preparation in LC-MS Bioanalysis will prove a practical and highly valuable addition to the reference shelves of scientists and related professionals in a variety of fields, including pharmaceutical and biomedical research, mass spectrometry, and analytical chemistry, as well as practitioners in clinical pharmacology, toxicology, and therapeutic drug monitoring.

Innovations for Next-Generation Antibody-Drug Conjugates Marc Damelin, 2018-05-29 Antibody-drug conjugates (ADCs) stand at the verge of a transformation. Scores of clinical programs have yielded only a few regulatory approvals, but a wave of technological innovation now empowers us to overcome past technical challenges. This volume focuses on the next generation of ADCs and the innovations that will enable them. The book inspires the future by integrating the field's history with novel strategies and cutting-edge technologies. While the book primarily addresses ADCs for solid tumors, the last chapter explores the emerging interest in using ADCs to treat other diseases. The therapeutic rationale of ADCs is strong: to direct small molecules to the desired site of action (and

away from normal tissues) by conjugation to antibodies or other targeting moieties. However, the combination of small and large molecules imposes deep complexity to lead optimization, pharmacokinetics, toxicology, analytics and manufacturing. The field has made significant advances in all of these areas by improving target selection, ADC design, manufacturing methods and clinical strategies. These innovations will inspire and educate scientists who are designing next-generation ADCs with the potential to transform the lives of patients.

Protein Analysis using Mass Spectrometry Mike S. Lee, Qin C. Ji, 2017-05-26 Presents Practical Applications of Mass Spectrometry for Protein Analysis and Covers Their Impact on Accelerating Drug Discovery and Development Covers both qualitative and quantitative aspects of Mass Spectrometry protein analysis in drug discovery Principles, Instrumentation, Technologies topics include MS of peptides, proteins, and ADCs , instrumentation in protein analysis, nanospray technology in MS protein analysis, and automation in MS protein analysis Details emerging areas from drug monitoring to patient care such as Identification and validation of biomarkers for cancer, targeted MS approaches for biomarker validation, biomarker discovery, and regulatory perspectives Brings together the most current advances in the mass spectrometry technology and related method in protein analysis

Rheumatology E-Book Marc C. Hochberg, Alan J. Silman, Josef S. Smolen, Michael E. Weinblatt, Michael H. Weisman, Ellen M Gravallese, 2018-01-08 Thoroughly revised and updated, the 7th Edition of Rheumatology remains a leading text in this fast-changing field, keeping you abreast of recent advances in medications, therapies, clinical trials, and much more. Dr. Mark Hochberg and his team of expert authors and editors cover everything you need to know -- from basic scientific principles to practical clinical management strategies, all in a user-friendly, accessible manner.

Protein Formulation and Delivery Eugene J. McNally, Eugene McNally, Jayne E. Hastedt, 2007-10-26 This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process, providing a comprehensive review of mechanisms and causes of protein instability in formulation development, coverage of accelerated stability testing methods and relevant analytica

Preclinical Drug Development Mark Rogge, David R. Taft, 2016-04-19 Preclinical Drug Development, Second Edition discusses the broad and complicated realm of preclinical drug development. Topics range from assessment of pharmacology and toxicology to industry trends and regulatory expectations to requirements that support clinical trials. Highlights of the Second Edition include: Pharmacokinetics Modeling and simula

Global Approach in Safety Testing Jan Willem van der Laan, Joseph J DeGeorge, 2013-02-11 This volume will consider one of ICH's major categories, Safety i.e. topics relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.). Since the start of the ICH process, many guidelines have been written, but even after ICH6 no explanations have been given during a formal Congress about the background of the ICH Guidance documents. Even more important than what has been written, might have been those thoughts of the experts that are not included in the Guidance documents. Why has the guideline been written as it is written, and why have some aspects been deleted. These and other related questions are the contents of this book, written by experts who were involved in the ICH process. Furthermore, the chapters will contain discussions on the "lessons learnt" and "future developments".

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries Lanju Zhang, 2016-01-13 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/Toxicology 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.

Computer Applications in Drug Discovery and Development Puratchikody, A., Prabu, S. Lakshmana, Umamaheswari, A., 2018-11-23 With more restrictions upon animal experimentations, pharmaceutical industries are currently focusing on a new generation of experiments and technologies that are considerably more efficient and less controversial. The integration of computational and experimental strategies has led to the identification and development of promising compounds. Computer Applications in Drug Discovery and Development is a pivotal reference source that provides innovative research on the application of computers for discovering and designing new drugs in modern molecular biology and medicinal chemistry. While highlighting topics such as chemical

structure databases and dataset utilization, this publication delves into the current panorama of drug discovery, where high drug failure rates are a major concern and properly designed virtual screening strategies can be a time-saving, cost-effective, and productive alternative. This book is ideally designed for chemical engineers, pharmacists, molecular biologists, students, researchers, and academicians seeking current research on the unexplored avenues and future perspectives of drug design.

Amorphous Solid Dispersions Navnit Shah, Harpreet Sandhu, Duk Soon Choi, Hitesh Chokshi, A. Waseem Malick, 2014-11-21 This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. *Amorphous Solid Dispersions: Theory and Practice* is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

Biotechnology and Biopharmaceuticals, 2013-12-16 *Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs*, Second Edition addresses the pivotal issues relating to translational science, including preclinical and clinical drug development, regulatory science, pharmacoeconomics and cost-effectiveness considerations. The new edition also provides an update on new proteins and genetic medicines, the translational and integrated sciences that continue to fuel the innovations in medicine, as well as the new areas of therapeutic development including cancer vaccines, stem cell therapeutics, and cell-based therapies.

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