Biosimilars Regulatory Clinical And Biopharmaceut

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Biosimilars of Monoclonal Antibodies Cheng Liu 2016-12-12 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

Biopharmaceuticals Basanta Kumara Behera 2020-12-07 Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by

3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals

Biosimilar Drug Product Development Laszlo Endrenyi 2017-02-24 When a biological drug patent expires, alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps. The assessment of biosimilarity and interchangeability is also complicated and difficult. Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre- and post-approval issues.

Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional Raymond A. Huml 2012-06-15 This Brief defines competitive intelligence (CI) as a tool for making investment decisions within the pharmaceutical industry. It provides an overview of processes that the regulatory affairs professional must take into account when evaluating data impacting product-based risk evaluations. These apply particularly to evaluations that focus on outputs such as regulatory approval, or the commercial impact of product labeling on the sales forecast over a limited timeframe. The Brief also provides an overview of intellectual property assessment that can impact a product’s lifespan on the market due to patent protection itself (or loss of patent protection) or via regulatory exclusivity. Case examples are discussed to illustrate the importance of keeping up with the ever-changing regulations, and how to interpret them in the context of CI. In addition, there is a section on virtual data rooms (VDRs) which currently function as the cornerstone of due diligence investigations. While aimed primarily at regulatory affairs professionals in the United States, this publication provides a useful adjunct for other pharmaceutical executives, especially those new to product-based investments, and regulatory affairs professionals in other regions.

Biosimilars Shein-Chung Chow 2013-07-29 As many biological products face losing their patents in the next decade, the pharmaceutical industry needs an abbreviated regulatory pathway for approval of biosimilar drug products, which are cost-effective, follow-on/subsequent versions of the innovator’s biologic products. But scientific challenges remain due to the complexity of both the manufacturing process and the structures of biosimilar products. Written by a top biostatistics researcher, Biosimilars: Design and Analysis of Follow-on Biologics is the first book entirely devoted to the statistical design and analysis of biosimilarity and interchangeability of biosimilar products. It includes comparability tests of important quality attributes at critical stages of the manufacturing processes of biologic products. Connecting the pharmaceutical/biotechnology industry, government regulatory agencies, and academia, this state-of-the-art book focuses on the scientific factors and practical issues related to the design and analysis of biosimilar studies. It covers most of the statistical questions encountered in various study designs at different stages of research and development of biological products.

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, pharmaco-economics 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.

Medical Applications of Mass Spectrometry Karoly Vekey 2011-08-11 Mass spectrometry is fast becoming an indispensable field for medical professionals. The mass spectrometric analysis of metabolites and proteins promises to revolutionize medical research and clinical diagnostics. As this technology rapidly enters the medical field, practicing professionals and students need to prepare to take full advantage of its capabilities. Medical Applications of Mass Spectrometry addresses the key issues in the medical applications of mass spectrometry at the level appropriate for the intended readership. It will go a long way to help the utilization of mass spectrometry in medicine. The book comprises five parts. A general overview is followed by a description of the basic sampling and separation methods in analytical chemistry. In the second part a solid foundation in mass spectrometry and modern techniques of data analysis is presented. The third part explains how mass spectrometry is used in exploring various classes of biomolecules, including proteins and lipids. In the fourth section mass spectrometry is introduced as a diagnostic tool in clinical treatment, infectious pathogen research, neonatal diagnostics, cancer, brain and allergy research, as well as in various fields of medicine: cardiology, pulmonology, neurology, psychiatric diseases, hemato-oncology, urologic diseases, gastrointestinal diseases, gynecology and pediatrics. The fifth part covers emerging applications in biomarker discovery and in mass spectrometric imaging. * Provides a broad look at how the medical field is benefiting from advances in mass spectrometry. * Guides the reader from basic principles and methods to cutting edge applications. * There is NO comparable book on the market to fill this fast growing field.

Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Health 2008

Rift-lines Within European Regulatory Framework for Biosimilars when Taking Heterogeneity and Variation During Lifecycle of the Reference Biologic and the Biosimilar Into Account Malik Osmane 2014 Biopharmaceutical medicinal products (biologics) represent a huge financial market. Thus upon patent protection expiry of the innovator (reference) biologic there is interest from industry to gain a portion of this market by launching a 'similar' biologic at a reduced development cost, thus boosting potential gains. The EMA responded to this desire and lead the guidance process with industry on the topic of biosimilars. Based on the experience gained with biosimilars in the past, the EMA started to introduce a second generation series of guidance documents, which take into account the past, current and possibly future challenges of biosimilars. Those proposals were evaluated by EMA and partially incorporated into new guidance documents. This work highlights the challenges and risks associated with biosimilar submissions for large and complex bio-molecules such antibodies. Results: There are unaddressed questions for the regulator with regard to the unsolved dynamic of heterogeneity and variations of the quality profile, which have potential implications on safety and efficacy. This is neglected and not taken into account seriously enough by the stakeholders. Solution: Further, the only (in my view) progressive way to deal with such foreseeable situations from the biosimilar developer’s point of view is to incorporate

a design space.

The Oxford Handbook of the Economics of the Biopharmaceutical Industry Patricia M. Danzon 2012-04-12 The biopharmaceutical industry has been a major driver of technological change in health care, producing unprecedented benefits for patients, cost challenges for payers, and profits for shareholders. As consumers and companies benefit from access to new drugs, policymakers around the globe seek mechanisms to control prices and expenditures commensurate with value. More recently the 1990s productivity boom of new products has turned into a productivity bust, with fewer and more modest innovations, and flat or declining revenues for innovative firms as generics replace their former blockbuster products. This timely volume examines the economics of the biopharmaceutical industry, with eighteen chapters by leading academic health economists. Part one examines the economics of biopharmaceutical innovation including determinants of the costs and returns to new drug development; how capital markets finance R&D and how costs of financing the biopharmaceutical industry compare to financing costs for other industries; the effects of safety and efficacy regulation by the Food and Drug Administration (FDA) and of price and reimbursement regulation on incentives for innovation; and the role of patents and regulatory exclusivities. Part two examines the market for biopharmaceuticals with chapters on prices and reimbursement in the US, the EU, and other industrialized countries, and in developing countries. It looks at the optimal design of insurance for drugs and the effects of cost sharing on spending and on health outcomes; how to measure the value of pharmaceuticals using pharmacoeconomics, including theory, practical challenges, and policy issues; how to measure pharmaceutical price growth over time and recent evidence; empirical evidence on the value of pharmaceuticals in terms of health outcomes; promotion of pharmaceuticals to physicians and consumers; the economics of vaccines; and a review of the evidence on effects of mergers, acquisitions and alliances. Each chapter summarizes the latest insights from theory and recent empirical evidence, and outlines important unanswered questions and areas for future research. Based on solid economics, it is nevertheless written in terms accessible to the general reader. The book is thus recommended reading for academic economists and non-economists, and for those in industry and policy who wish to understand the economics of this fascinating industry.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals John Geigert 2019-05-08 Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through

market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.

Bayesian Methods in Pharmaceutical Research Emmanuel Lesaffre 2020-04-28 Since the early 2000s, there has been increasing interest within the pharmaceutical industry in the application of Bayesian methods at various stages of the research, development, manufacturing, and health economic evaluation of new health care interventions. In 2010, the first Applied Bayesian Biostatistics conference was held, with the primary objective to stimulate the practical implementation of Bayesian statistics, and to promote the added-value for accelerating the discovery and the delivery of new cures to patients. This book is a synthesis of the conferences and debates, providing an overview of Bayesian methods applied to nearly all stages of research and development, from early discovery to portfolio management. It highlights the value associated with sharing a vision with the regulatory authorities, academia, and pharmaceutical industry, with a view to setting up a common strategy for the appropriate use of Bayesian statistics for the benefit of patients. The book covers: Theory, methods, applications, and computing Bayesian biostatistics for clinical innovative designs Adding value with Real World Evidence Opportunities for rare, orphan diseases, and pediatric development Applied Bayesian biostatistics in manufacturing Decision making and Portfolio management Regulatory perspective and public health policies Statisticians and data scientists involved in the research, development, and approval of new cures will be inspired by the possible applications of Bayesian methods covered in the book. The methods, applications, and computational guidance will enable the reader to apply Bayesian methods in their own pharmaceutical research. Emmanuel Lesaffre is Professor of Biostatistics at KU Leuven, Belgium. Gianluca Baio is Professor of Statistics and Health Economics at University College London, UK. Bruno Boulanger is Chief Scientific Officer at PharmaLex, Belgium.

Biopharmaceuticals Yuan-Chuan Chen 2018 Biopharmaceuticals are derived from biological sources, either live organisms or their active components; nowadays, they are mainly produced by biotechnologies. Biopharmaceuticals are extensively used in the treatment of various diseases such as cardiovascular, metabolic, neurological diseases, cancer, and others for which there are no available therapeutic methods. With the advance of science, biopharmaceuticals have revolutionized the treatment, prevention, and diagnosis of many patients with disabling and life-threatening diseases. Innovative biopharmaceuticals definitely improve the life quality of patients and enhance the effectiveness of the healthcare system. This book encompasses the discovery, production, application, and regulation of biopharmaceuticals to demonstrate their research achievement, prospects, and challenges. We expect the significance of biopharmaceuticals to be revealed and emphasized by this book.

Oncology Biosimilars Giuseppe Curigliano 2019

Quality by Design for Biopharmaceuticals Anurag S. Rathore 2011-09-20 The concepts, applications, and practical issues of Quality byDesign Quality by Design (QbD) is a new framework currently beingimplemented by the FDA, as well as EU and Japanese regulatoryagencies, to ensure better understanding of the process so as toyield a consistent and high-quality pharmaceutical product. QbDbreaks from past approaches in assuming that drug quality cannot betested into products; rather, it must be built into every step ofthe product creation process. Quality by Design: Perspectives and Case Studies presentsthe first systematic approach to QbD in the biotech industry. Acomprehensive resource, it combines an in-depth explanation ofbasic concepts with real-life case studies that illustrate thepractical aspects of QbD implementation. In this single source, leading authorities from thebiotechnology industry and the FDA discuss such topics as: The understanding and development of the product's criticalquality attributes (CQA) Development of the design space for a manufacturingprocess How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates toQbD Relevant PAT tools and applications for the pharmaceuticalindustry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) toQbD Filled with vivid case studies that illustrate QbD at work incompanies today, Quality by Design is a core reference forscientists in the biopharmaceutical industry, regulatory agencies,and students.

Twenty Years of G-CSF Graham Molineux 2012-01-07 Granulocyte colony-stimulating factor (G-CSF or GCSF) is a secreted glycoprotein that stimulates the proliferation and differentiation of granulocyte precursor cells, and induces mobilization of peripheral blood progenitor cells from the bone marrow. Development of recombinant human G-CSF has had a profound impact on the treatment of many diseases, including severe chronic neutropenia and cancer, and has enabled peripheral stem cell transplantation to supplant bone marrow transplantation in the autologous setting. This Milestones in Drug Therapy volume describes the experience of the last 20 years of treatment with recombinant human G-CSF, including the basic science, the use of recombinant human G-CSF in both the oncology and nononcology settings, and the safety and economics of its use. Many of the authors were the original investigators of recombinant human G-CSF and other authors are key researchers who provide their outlook for the next 20 years for use of and research with recombinant human G-CSF.

Biosimilars and Interchangeable Biologics Sarfaraz K. Niazi 2018-10-30 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: Strategic Elements explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters. This includes principal patents and intellectual property, regulatory pathways, and concerns about affordability on a global scale. It addresses the complexity of biosimilar products, and it discusses the utilization of biosimilars and related biological drugs in expanding world markets. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume examines the science, technology, finance, legality, ethics, and politics of biosimilar drugs. It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars, and it provides detailed descriptions of the legal, regulatory, and commercial

characteristics. The book also presents a global strategy on how to build, take to market, and manage the next generation of biosimilars throughout their life cycle.

Biosimilars Hiten J. Gutka 2018-12-13 This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

Making Medicines Affordable National Academies of Sciences, Engineering, and Medicine 2018-03-01 Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicinesâ€"and health care at largeâ€"more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription drugsâ€"coupled with the broader trends in overall health care costsâ€"is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address

significant needs in health care.

Biosimilar Clinical Development: Scientific Considerations and New Methodologies Kerry B. Barker 2016-11-25 Biosimilars have the potential to change the way we think about, identify, and manage health problems. They are already impacting both clinical research and patient care, and this impact will only grow as our understanding and technologies improve. Written by a team of experienced specialists in clinical development, this book discusses various potential drug development strategies, the design and analysis of pharmacokinetics (PK) studies, and the design and analysis of efficacy studies.

Biopharmaceutical Processing Gunter Jagschies 2018-01-18 Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Biologics and Biosimilars Congressional Research Service 2017-11-13 A biological product, or biologic, is a preparation, such as a drug or a vaccine, that is made from living organisms. Compared with conventional chemical drugs, biologics are relatively large and complex molecules. They may be composed of proteins (and/or their constituent amino acids), carbohydrates (such as sugars), nucleic acids (such as DNA), or combinations of these substances. Biologics may also be cells or tissues used in transplantation. A biosimilar, sometimes referred to as a follow-on biologic, is a therapeutic drug that is similar but not structurally identical to the brand-name biologic made by a pharmaceutical or biotechnology company. In contrast, a generic chemical drug is an exact copy of a brand-name chemical drug. Because biologics are more complex than chemical drugs, both in composition and method of manufacture, biosimilars will not be exact replicas of the brand-name product, but may instead be shown to be highly similar. The Food and Drug Administration (FDA) regulates both biologics and chemical drugs. Biologics and biosimilars frequently require special handling (such as refrigeration) and processing to avoid contamination by microbes or other unwanted substances. Also, they are usually administered to patients via injection or infused directly into the bloodstream. For these reasons, biologics often are referred to as specialty drugs, which can be very costly. In April 2006, the European Medicines Agency (EMA) authorized for marketing in Europe the first biosimilar product, Omnitrope, a human growth hormone. Today a total of 35 biosimilars are EMA-authorized for the European market. The introduction of biosimilars in Europe has reduced prices for biologics by up to 33%. For one drug in Portugal, the price reduction was 61%. In contrast, the pathway to marketing biosimilars in the United States has had several barriers. FDA approved Omnitrope in June 2006, following an April 2006 court ruling requiring the FDA to move forward with

consideration of the application. At the time the FDA indicated that this action "does not establish a pathway" for approval of other follow-on biologic drugs and stated that Congress must change the law before the agency can approve copies of nearly all other such products. In March 2010 Congress established a new regulatory authority for FDA by creating an abbreviated licensure pathway for biological products demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-licensed biological product. The new authority was accomplished via the Biologics Price Competition and Innovation Act (BPCIA) of 2009, enacted as Title VII of the Affordable Care Act. Congress authorized FDA to collect associated fees via the Biosimilar User Fee Act of 2012 (BsUFA). The five-year biosimilars user fee authority was set to expire on September 30, 2017. Congress reauthorized the biosimilar user fee program via the Food and Drug Administration Reauthorization Act of 2017. As more biosimilars enter the U.S. market, analysts expect to see U.S. price reductions similar to those that have occurred in Europe. However, of the seven biosimilars approved by FDA, sales of five biosimilars have been delayed, or (allegedly) adversely impacted, by actions of the brand-name manufacturers, including patent infringement lawsuits and suits over alleged anticompetitive contracts with insurers in order to prevent coverage of biosimilars that are less expensive substituted for best-selling biologics. The high costs of pharmaceuticals in general-and biologics in particular-has led to an increased interest in understanding the federal government's role in the development of costly new therapeutics. In the case of six of the seven biosimilars approved by FDA, the associated brand-name drug was originally discovered by scientists at public-sector research institutions.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals John Geigert 2014-07-08 This book highlights the challenges facing quality assurance/quality control (QA/QC) in today's biopharmaceutical environment and presents the strategic importance and value generated by QA/QC for their involvement in control of manufacturing. It will put into perspective the need for a graded approach to QA/QC from early clinical trials through market approval. Since the first edition published in 2004, there have been more than 50 new regulatory guidances released by the Food and Drug Administration (FDA), European Medicines Agency (EMA) and ICH that affect the CMC regulatory compliance of biopharmaceuticals; also the application of biosimilars has been developed in Europe and is under development in the USA. The revised update will be broadened to include not only biopharmaceuticals (biotech drugs) but also other biologics (vaccines, cell therapy, plasma-derived proteins, etc.)

Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics Lisa Plitnick 2013-06-27 Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics is a complete reference devoted to the nonclinical safety assessment of novel biopharmaceuticals, biosimilars, vaccines, cell and gene therapies and blood products. This book compares and contrasts these types of biologics with one another and with small molecule drugs, while incorporating the most current and essential international regulatory documents. Each section discusses a different type of biologic, as well as early characterization strategies, principles of study design, preclinical pharmacokinetics and pharmacodynamics and preclinical assays. An edited book that is authored by leading experts in the field, this comprehensive reference provides critical insights to all researchers involved in early through late stage biologics. Provides in-depth coverage of the process of nonclinical safety assessment and comprehensive reviews of each type of biopharmaceutical Contains the most pertinent international regulatory guidance documents for nonclinical evaluation Covers early de-risking strategies and designs of safety assessment programs for

novel biopharmaceuticals and vaccines, as well as follow-on biologics or "biosimilars" A multi-authored book with chapters written by qualified experts in their respective fields

Biosimilars and Biologics Steven Lucio 2018

Drug Prices Kevin J. Hickey 2021

Biologics, Biosimilars, and Biobetters Iqbal Ramzan 2021-01-05 A comprehensive primer and reference, this book provides pharmacists and health practitioners the relevant science and policy concepts behind biologics, biosimilars, and biobetters from a practical and clinical perspective. Explains what pharmacists need to discuss the equivalence, efficacy, safety, and risks of biosimilars with physicians, health practitioners, and patients about Guides regulators on pragmatic approaches to dealing with these drugs in the context of rapidly evolving scientific and clinical evidence Balances scientific information on complex drugs with practical information, such as a checklist for pharmacists

Pharmacovigilance in the European Union Michael Kaeding 2017-02-20 This book is open access under a CC BY 4.0 license. The book presents the results of an in-depth comparative study assessing the implementation of the EU Pharmacovigilance Directive in six EU Member States. By going beyond legal transposition and instead focusing on practical implementation, this study aims to close a gap in EU compliance research. Based on qualitative interviews with relevant actors in Germany, Poland, Portugal, France, Finland and the UK, the authors identify perceived challenges and best-practices, issue recommendations, and thereby contribute to a better understanding of the factors that incentivize or impede the practical implementation of EU law at the national level.

Manufacturing of Pharmaceutical Proteins Stefan Behme 2015-05-06 Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control. The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.

Biologics Development Mark P. Mathieu 1997-01-01

Pharmaceutical Medicine and Translational Clinical Research Divya Vohora 2017-11-14 Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the safety profile of medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features. As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine, clinical research, pharmacology and pharmacy, as well as professionals working in the pharmaceutical industry, this book is an ideal resource. Includes detailed coverage of current trends and key topics in pharmaceutical medicine, including biosimilars, biobetters, super generics, and Provides a comprehensive look at current and important aspects of the science

and regulation of drug and biologics discovery

Innovative Statistics in Regulatory Science Shein-Chung Chow 2019-11-14 Statistical methods that are commonly used in the review and approval process of regulatory submissions are usually referred to as statistics in regulatory science or regulatory statistics. In a broader sense, statistics in regulatory science can be defined as valid statistics that are employed in the review and approval process of regulatory submissions of pharmaceutical products. In addition, statistics in regulatory science are involved with the development of regulatory policy, guidance, and regulatory critical clinical initiatives related research. This book is devoted to the discussion of statistics in regulatory science for pharmaceutical development. It covers practical issues that are commonly encountered in regulatory science of pharmaceutical research and development including topics related to research activities, review of regulatory submissions, recent critical clinical initiatives, and policy/guidance development in regulatory science. Devoted entirely to discussing statistics in regulatory science for pharmaceutical development. Reviews critical issues (e.g., endpoint/margin selection and complex innovative design such as adaptive trial design) in the pharmaceutical development and regulatory approval process. Clarifies controversial statistical issues (e.g., hypothesis testing versus confidence interval approach, missing data/estimands, multiplicity, and Bayesian design and approach) in review/approval of regulatory submissions. Proposes innovative thinking regarding study designs and statistical methods (e.g., n-of-1 trial design, adaptive trial design, and probability monitoring procedure for sample size) for rare disease drug development. Provides insight regarding current regulatory clinical initiatives (e.g., precision/personalized medicine, biomarker-driven target clinical trials, model informed drug development, big data analytics, and real world data/evidence). This book provides key statistical concepts, innovative designs, and analysis methods that are useful in regulatory science. Also included are some practical, challenging, and controversial issues that are commonly seen in the review and approval process of regulatory submissions. About the author Shein-Chung Chow, Ph.D. is currently a Professor at Duke University School of Medicine, Durham, NC. He was previously the Associate Director at the Office of Biostatistics, Center for Drug Evaluation and Research, United States Food and Drug Administration (FDA). Dr. Chow has also held various positions in the pharmaceutical industry such as Vice President at Millennium, Cambridge, MA, Executive Director at Covance, Princeton, NJ, and Director and Department Head at Bristol-Myers Squibb, Plainsboro, NJ. He was elected Fellow of the American Statistical Association and an elected member of the ISI (International Statistical Institute). Dr. Chow is Editor-in-Chief of the Journal of Biopharmaceutical Statistics and Biostatistics Book Series, Chapman and Hall/CRC Press, Taylor & Francis, New York. Dr. Chow is the author or co-author of over 300 methodology papers and 30 books.

Biopharmaceuticals Ming-Kung Yeh 2018-09-19 Biopharmaceuticals are derived from biological sources, either live organisms or their active components; nowadays, they are mainly produced by biotechnologies. Biopharmaceuticals are extensively used in the treatment of various diseases such as cardiovascular, metabolic, neurological diseases, cancer, and others for which there are no available therapeutic methods. With the advance of science, biopharmaceuticals have revolutionized the treatment, prevention, and diagnosis of many patients with disabling and life-threatening diseases. Innovative biopharmaceuticals definitely improve the life quality of patients and enhance the effectiveness of the healthcare system. This book encompasses the discovery, production, application, and regulation of biopharmaceuticals to demonstrate their research achievement, prospects, and challenges.

We expect the significance of biopharmaceuticals to be revealed and emphasized by this book.

Targeted Therapies in Cancer Manfred Dietel 2007-06-10 From its introduction, oncological chemotherapy has been encumbered by poor selectivity because antiproliferative drugs are often toxic not only to tumor cells but also to important populations of the body's non-neoplastic cells. Modern targeted therapies interact with defined molecules present on cancer cells, adding increased selectivity to their toxic effects. This book presents an integrated critical view on the theories, mechanisms, problems and pitfalls of the targeted therapy approach.

Biopharmaceuticals Basanta Kumara Behera 2020-12-08 Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals

Proceedings of 11th European Biosimilars Congress 2018 ConferenceSeries April 26-27, 2018 Rome, Italy Key Topics : Current Challenges in Developing Biosimilars, Emerging Biosimilars in Therapeutics, Analytical Strategies for Biosimilars, Regulatory Approach of Biosimilars, Innovative Approach for Biosimilars, Consequences of Brexit on Biosimilars, Globalization of Biosimilars, Clinical Development of Biosimilars, Biosimilar Market and Cost Analysis, Challenges in Biosimilars Pharmacovigilance, Entrepreneurs Investment Meet, Legal Issues and BPCI Act, Biosimilars Research Pipeline, Intellectual Property Rights, Bioequivalence Assessment, BCS and IVIVC Based Biowaivers, Biosimilar Companies and Market Analysis, Biologic Drugs, Biological Medicine, Biowaiver, Biobetters,

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

Methodologies in Biosimilar Product Development Sang Joon Lee 2021-09-30 Methodologies for Biosimilar Product Development covers the practical and challenging issues that are commonly encountered during the development, review, and approval of a proposed biosimilar product. These practical and challenging issues include, but are not limited to the mix-up use of interval hypotheses testing (i.e., the use of TOST) and confidence interval approach, a risk/benefit assessment for non-inferiority/similarity margin, PK/PD bridging studies with multiple references, the detection of possible reference product change over time, design and analysis of biosimilar switching studies, the assessment of sensitivity index for assessment of extrapolation across indications without collecting data from those indications not under study, and the feasibility and validation of non-medical switch post-approval. Key Features: Reviews withdrawn draft guidance on analytical similarity assessment. Evaluates various methods for analytical similarity evaluation based on FDA’s current guidelines. Provides a general approach for the use of n-of-1 trial design for assessment of interchangeability. Discusses the feasibility and validity of the non-medical switch studies. Provides innovative thinking for detection of possible reference product change over time. This book embraces innovative thinking of design and analysis for biosimilar studies, which are required for review and approval of biosimilar regulatory submissions.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 Great Britain. Medicines and Healthcare products Regulatory Agency. Inspection and Standards Division 2007-01-01 Since its first publication in 1971 this text, commonly known as the Orange Guide, has been an essential reference for all involved in the manufacture or distribution of medicines in Europe. the Orange Guide collates in one convenient and authoritative source European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. Compliance with Good Manufacturing Practice and Good Distribution Practice requirements is essential in the production and distribution of medicines for human use to safeguard public health and compl

A Quick Guide to Clinical Trials Madhu Davies 2008