

Understanding biological & biosimilar medicines

Frequently Asked Questions

Q. What is a biological medicine?

A. Biological medicines, including biosimilars, are derived or manufactured from a living biological system. They include hormones (e.g. insulin), enzymes (to speed up chemical reactions), blood factors (to regulate clotting), antibodies (to support the immune system), vaccines and advanced therapies (such as cell, gene and tissue therapy products).

Biological medicines are among many of today's most important medicines. By 2020, it is predicted that seven of the top ten medicines worldwide will be biological.*

Q. What is a biosimilar medicine?

A. A biosimilar is a biological medicine that is developed to be similar to an approved biological medicine (the 'originator' biological medicine) and can only be marketed after the patent and data exclusivity period has expired. As its name suggests, a biosimilar is not an exact copy of its originator biological medicine due to its complex molecular structure and unique manufacturing process. Manufacturers of biosimilars are required to demonstrate that there are no clinically meaningful differences between the biosimilar and originator biological medicine in terms of safety, quality and efficacy.*

Q. What is a small molecule medicine?

A. Small molecule medicines are made by combining certain chemicals in a defined series of chemical reactions. Because these molecules are smaller and involve fewer process steps than biological medicines, they are easier to duplicate. This kind of medicine is often taken orally, most often as a pill.

Generic medicines: A medicine that contains an exact copy of the active pharmaceutical ingredient of the small molecule originator medicine.

Biological medicines: Biological medicines, including biosimilars, that have been developed in living organisms.

Originator medicines: The original medicine on which a biosimilar or generic drug bases its application for marketing authorisation.

Q. How are biological medicines different?

A. There are several key differences between biological and small molecule medicines:

- **Molecular structure** – biological medicines are much larger and more complex than small molecule medicines.
- **Development and manufacture** – biological medicines have complex manufacturing processes that must be tightly controlled to provide a consistent product.
- **Immunogenicity** – due to their size and complexity, biological medicines have the potential to induce unwanted or unexpected immune reactions.
- **Administration** – most biological medicines, including biosimilars, must be administered by injection or infusion.
- **Transport and storage** – biological medicines generally degrade quickly if subject to high temperatures. Therefore, biological medicines, including biosimilars, usually need to be stored in a refrigerator.

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Biosimilar Clinical Development: Scientific Considerations and New Methodologies Kerry B. Barker, Sandeep M. Menon, Sr. D'Agostino, Siyan Xu, PhD Jin, 2016-11-25 Biosimilars have the potential to change the way we think about identifying and managing 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.

Challenges in Nonhuman Primate Research in the 21st Century Gerhard F. Weinbauer, Friedhelm Vogel, 2013 In continuation of the Covance Primate Symposium Series, the 19th Covance Primate Symposium took place in Münster on 23rd-24th of May 2012. Altogether 70 participants representing 43 organisations gathered for this symposium. The 2012 Primate Symposium focussed on Challenges in Nonhuman Primate Research in the 21st Century. The broad participation and the lively discussions during the symposium underlined the timeliness and importance of this topic. Expert speakers covered four major topics: i.e. biosimilars development, regulatory implications, key considerations, and next steps; optimizing nonhuman primate use in nonclinical safety assessment; trends in nonhuman primate developmental/reproductive toxicology; DART and juvenile toxicity evaluation and relevance, and importance of nonhuman primate models in regulatory toxicology. The development of biosimilars has taken up speed considerably, and meanwhile needs to be considered a significant factor of potential drug development. Yet there are still some uncertainties, and guidelines are under development. With the increased focus on biopharmaceuticals and the associated increase for using nonhuman primates as the relevant animal model, it became necessary to optimize the use of this animal model, e.g. refine study designs and animal numbers, but still execute meaningful preclinical studies. It appears that significant progress has been achieved in that context. In the area of nonhuman primate DART and juvenile toxicity evaluation, recent guideline changes had a major impact on species selection and the experimental design, plus the timing of these studies within the preclinical programmes. Finally, given the increasing regulations and justifications of using nonhuman primates as experimental models, it is paramount to understand the essential and indispensable role that nonhuman primates can play in drug safety evaluation and medical drug development.

Contemporary Issues in Pharmaceutical Patent Law Bryan Mercurio, Daria Kim, 2017-02-17 This collection reflects on contemporary and contentious issues in international rulemaking in regards to pharmaceutical patent law. With chapters from both well-established and rising scholars, the collection contributes to the understanding of the regulatory framework governing pharmaceutical patents as an integrated discipline through the assessment of relevant laws, trends, and policy options. Focusing on patent law and related pharmaceutical regulations, the collection addresses the pressing issues governments face in an attempt to resolve policy dilemmas involving competing interests, needs, and objectives. The common theme running throughout the collection is the

need for policy and law makers to think and act in a systemic manner and to be more reflective and responsive in finding new solutions within and outside the patent system to the long standing problems as well as emerging challenges

Handbook of Biologics & Biosimilars in Dermatology Shekhar Neema, Manas Chatterjee, 2024-02-21 A drug is typically manufactured through chemical synthesis which means that it is made by combining specific chemical ingredients in an ordered process. Biologics are medicines made from living cells through highly complex manufacturing processes and must be handled and administered under carefully monitored conditions. Biologics are used to prevent, treat, diagnose or cure a variety of diseases including cancer, chronic kidney disease, autoimmune disorders and infectious diseases. A biosimilar is a biologic that is similar to another biologic drug already that has already been approved. This book is a complete guide to the use of biologics and biosimilars in the treatment of dermatologic disorders. Beginning with an overview of the history and classification of biologics and the concept of biosimilars, the following chapters explain their therapeutic use for different skin conditions. The final sections cover related topics such as cost effectiveness and quality of life with biologic therapy and the book concludes with discussion on future developments and the use of small molecule treatment. This second edition has been fully updated to provide clinicians with the latest advances in the field. Previous edition 9789352703647 published in 2018

Biosimilar Drug Product Development Laszlo Endrenyi, Dr. Paul Declerck, Shein-Chung Chow, 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.

Regulatory Toxicology in the European Union Tim Marrs, Kevin Woodward, 2018-02-21 Consumer and environmental protection depend on the careful regulation of all classes of chemicals. Toxicology is the key science used to evaluate safety and so underpins regulatory decisions on chemicals. With the growing body of EU legislation involved in chemical regulation, there is a concomitant need to understand the toxicological principles underlying safety assessments. **Regulatory Toxicology in the European Union** is the first book to cover regulatory toxicology specifically in Europe. It addresses the need for a wider understanding of the principles of regulatory toxicology and their application and presents the relationship between toxicology and legislative processes in regulating chemical commodities across Europe. This title has a broad scope covering historical and current chemical regulation in Europe, the role of European agencies and institutions and also the use of toxicology data for important classes of chemicals including human and veterinary medicines, animal feed and food additives, biocides, pesticides and nanomaterials. This book is therefore extremely pertinent and timely in the toxicology field at present. This book is an essential reference for regulatory authorities, industrialists, academics, undergraduates and postgraduates working within safety and hazards, toxicology, the biological sciences and the medicinal

and pharmaceutical sciences across the European Union Handbook of Bioequivalence Testing Sarfaraz K.

Niazi,2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m

Advances in Novel Formulations for Drug Delivery Raj K. Keservani,Rajesh Kumar Kesharwani,Anil K.

Sharma,2023-03-14 ADVANCES in NOVEL FORMULATIONS for DRUG DELIVERY The 27 chapters describe novel strategies for drug nutraceutical delivery and embrace the development of formulations with herbal ingredients while also highlighting disease therapeutics Drug delivery technology has witnessed many advancements purported to cater to the customized needs of its ultimate beneficiaries the patients Today dosage forms are not confined to conventional tablets capsules or injectables but have evolved to cover novel drug carriers such as particulates vesicles and many others Nanotechnological advancements have played a major role in this paradigm shift in ways of delivering active pharmaceutical ingredients A new dimension in the use of food as medicine has also gained prominence in recent years A portmanteau of nutrition and pharmaceuticals is nutraceuticals also known as functional foods and dietary supplements The technologies which were earlier included in drug delivery have been attempted for the delivery of nutraceuticals as well Herbal actives have received increased attention due to their low risk to benefit ratio The field of drug delivery is quite dynamic in nature as witnessed by its evolution from conventional dosage forms to nanotechnology assisted drug products A variety of formulations via different drug delivery routes have been developed to treat cure mitigate diseases or disorders This book comprising of 27 chapters is a thorough compilation of information relevant to drug delivery systems with an emphasis on products based on nanotechnology Audience Researchers scientists industry professionals formulators and product developers regulatory agencies in a variety of settings including novel drug delivery research laboratories pharmaceutical and pharmacy industries biomedical sciences food and nutraceuticals manufacturers and nanotechnology *Pharmaceutical Medicine and Translational Clinical Research* Divya Vohora,Gursharan Singh,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 **Novel Approaches for Drug Delivery** Keservani, Raj K., Sharma, Anil K., Kesharwani, Rajesh Kumar, 2016-07-15 Providing optimal care to patients is a primary concern in the healthcare field By utilizing the latest resources and research in biomedical applications the needs and expectations of patients can be successfully exceeded Novel Approaches for Drug Delivery is an authoritative reference source for the latest scholarly research on emerging developments within the pharmaceutical industry examining the current state and future directions of drug delivery systems Highlighting therapeutic applications predictive toxicology and risk assessment perspectives this book is ideally designed for medical practitioners pharmacists graduate level students scientists and researchers

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