

DRUG APPROVAL AND LICENSING PROCEDURES IN JAPAN 2018

Drug Approval And Licensing Procedures In Japan 1991

Daniela Niemeyer



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Drug Stereochemistry Irving Wainer, 1993-02-24 Maintaining and enhancing its focus on key issues in the development regulatory approval and use of stereoisomeric compounds this edition continues to cover in detail all aspects of chiral drugs from the academic governmental industrial and clinical points of view Completely rewritten and updated throughout Drug Stereochemistry illustrates current indirect chromatographic methods for the resolution of drug enantiomers treats the rapidly growing area of enantioselective gas chromatography discusses the latest in HPLC resolution of enantiomeric drugs uses verapamil as a model to show how stereoselective pharmacokinetics affect pharmacodynamics and supplies an in depth study on the effect of stereoselective plasma protein binding This edition offers entirely new chapters that discuss the recent decisions and present position of the US Food and Drug Administration on the development of stereoisomeric drugs explicate enzymatic synthesis of stereochemically pure drugs review the toxicological pharmacokinetic and pharmacodynamic differences found among stereoisomers elucidate the stereoselective transport of drugs across epithelia and give a physician's perspective on the questions and problems caused by stereoisomeric drugs in practice as well as the pharmaceutical industry's collective viewpoint based on a national survey

International Pharmaceutical Product Registration

Anthony C. Cartwright, Brian R. Matthews, 2016-04-19 Discover the latest ICH news from international experts in the pharmaceutical industry academia and regulatory bodies The recent International Conference on Harmonisation ICH revisions of regulatory requirements for quality nonclinical and clinical pharmaceutical product registration are the focus of this timely update This cutting edge resource

National Library of Medicine Current Catalog National Library of Medicine (U.S.), 1992

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Research and Development of Vaccines and Pharmaceuticals from Biotechnology Jens-Peter Gregersen, 2008-07-11 Unique in approach exhaustive in coverage this book provides information usually not available to scientists It explains the basic scientific and technical requirements which apply to the patenting and registration of human or veterinary vaccines and therapeutic biomedicinal products Pragmatic and practice oriented it helps users select and manage successfully the most attractive research and development projects An impressive number of topics is covered including planning and managing product development product development phases requirements for a patentable invention patent costs user safety ecotoxicity The book will rapidly pay for itself by more successful fund applications increased protection and remuneration of intellectual property and by faster and more efficient product development

Safety Pharmacology in Pharmaceutical Development and Approval Shayne C. Gad, 2003-08-26 The Propulsid and Seldane drug disasters could have easily been avoided with more rigorous safety pharmacology studies of these compounds prior to any human clinical trials Unfortunately

safety pharmacology has been overlooked by all but a few developers With recent drug withdrawals from the market and the implementation of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals

Safety Pharmacology in Pharmaceutical Development Shayne C.

Gad,2012-04-26 Safety pharmacology is the evaluation and study of the pharmacological effects of a potential drug that are unrelated to the desired therapeutic effect These effects often present a hazard particularly in individuals with compromised or limited organ system functions Safety Pharmacology in Pharmaceutical Development Approval and Post Marketing Surveillance Second Edition covers safety pharmacology from the regulatory requirements down to the studies that must be done to justify them Using the author s more than 30 years of direct experience the book incorporates tricks and practical insights for making studies work and understanding why they fail The second edition includes current regulations including USFDA and those from Europe and Japan Presenting a clear description of what is needed and why for supporting drug development the book focuses on updated test methods interpretation and science It covers the core and supplemental batteries of test procedures and how to do them and provides an overview of available facilities and contract organizations for performing studies

Books on Japan and Asian Countries in Foreign Languages Published in Japan ,1992

List of Publications, Governmental & Similars Japan. Government Publications Service Center,1993

Biotechnology and Biopharmaceuticals ,2013-09-19 The essential single source on drug discovery and biotechnology products newly revised and updated Since the first edition of Biotechnology and Biopharmaceuticals was published biotechnology has continued to drive therapeutic product development The majority of new medicines coming on the market today are developed based on tools created by biotechnology and healthcare providers who are concerned with optimum drug therapy need to understand the principles underlying the discovery development and application of these biological drugs and therapies of the future 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 It provides research pharmacologists biopharmaceutical R D personnel toxicologists and biotechnologists with cutting edge research 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 Presented in three parts and containing several appendices Biotechnology and Biopharmaceuticals Integrates information from pharmacology biotechnology and the medical sciences Covers the science and art of transforming proteins and genes into drugs Offers new coverage of cell based therapeutics including stem cells and immune cell therapy Highlights the unique applications of biologics proteins and macromolecules as therapeutics Includes new chapters on the clinical trial and approval process of individualized medicine Discusses the future direction of the field Ideal for research pharmacologists biopharmaceutical R D personnel toxicologists and biotechnologists Biotechnology and Biopharmaceuticals will also appeal to clinical pharmacologists pharmacists physicians and health scientists

Containing Health Care Costs in Japan John Creighton Campbell,1996-11-08 A comprehensive picture of costs in Japan s effective and efficient health care system

Cosmetic and Pharmaceutical Applications of Polymers T. Cheng, C.G. Gebelein, Victor C. Yang, 2012-12-06 Polymers continue to show almost amazing versatility We have always known that polymers could be used for trinkets toys and dishes Now however we are no longer surprised to encounter these adaptable materials in almost every place we look We find them in our cars tools electronic devices building materials etc The use of polymeric materials in medicine is also well documented in previous books by one of the Editors Gebelein and by others Likewise the use of polymeric materials in pharmaceutical applications especially in controlled release systems is also well established Nevertheless the use of these ubiquitous chemicals is far less obvious in the field of cosmetics although modern cosmetic preparations rely heavily on polymers and this trend is certain to increase This book brings together much of the basic information on polymers in cosmetics and compares this usage with similar applications in pharmaceutical and medical applications Cosmetics like medicine and pharmacy dates back to antiquity We can find uses of perfumes balms and ointments in various old books such as the Bible For example the use of ointments and balms is noted more than thirty eight times and perfumes and related materials are cited at least twenty nine times in the Bible

Patient Compliance Faiz Kermani, 2016-05-23 Vast global resources are ploughed into the delivery of treatment interventions ranging from diet and lifestyle advice to complex surgery In all cases whatever the intervention unless the recipient is engaged with the process and understands why the intervention has been offered and the part they play in its success compliance is an issue Even where the individual does engage and understand he or she may choose not to comply Non compliance is estimated to cost the pharma industry US 70 billion per year No figures exist for the cost to healthcare insurers and public health but non compliance is undoubtedly one of the top five issues facing both drug developers and healthcare providers During clinical trials non compliance undermines the accuracy of the data generated from the whole trial as well as particular aspects such as the efficacy of different dosages This book explores the key factors which drive compliance and the part that healthcare professionals can play in improving this with the key underlying goal of improving public health in its broadest sense

The Impact of Stereochemistry on Drug Development and Use Hassan Y. Aboul-Enein, Irving W. Wainer, 1997-04-11 The past fifteen years have seen a revolution in the field of stereochemistry with breakthrough analytical techniques in enantiomeric separation profoundly affecting drug development and use This practical reference written by leading researchers focuses on the important roles chirality and stereoisomerism play in drug development efforts presenting for the first time a comprehensive overview of this rapidly evolving area of pharmacological research The book explores analytical pharmacological and regulatory topics in dealing with the theory and practice of stereochemistry in the pharmaceutical industry today This exciting broad appeal treatment extends from the analytical viewpoint in enantiomeric separation to the regulatory issues involved in the racemate versus enantiomer debate The authors include numerous examples and case studies and integrate material from a wide range of studies publications and workshops The introductory chapters outline the pharmacological effects of stereochemistry cover

stereochemistry in drug metabolism and discuss problems inherent in the duality of enantiomers chemically identical yet spatially different molecules Contributions on the specific aspects of chirality and drug activity explore the toxicological effects of stereoselectivity illustrate how an understanding of the stereochemical composition of certain drugs can help avoid problems and offer tips on new clinical applications for existing drugs A full chapter is devoted to research opportunities in the development of new chirally pure drugs Other practical research topics range from the preparation of chirally pure compounds to the analytical determination of stereochemical composition to applications of circular dichroism CD spectroscopy Regulatory issues concerning the development and approval of stereoisomeric drugs are discussed in the final chapters This section offers an international perspective as well as a historical review of the ongoing debate surrounding regulatory guidelines Impact of Stereochemistry on Drug Development and Use is an essential reference for medicinal and analytical chemists pharmacologists drug metabolism and pharmacokinetic scientists and personnel of regulatory agencies It is also a useful text for graduate students in stereochemistry and for anyone who wants to keep up with the swift pace of change in this dynamic field Impact of Stereochemistry on Drug Development and Use is an essential reference for medicinal and analytical chemists pharmacologists drug metabolism and pharmacokinetic scientists and personnel of regulatory agencies It is also a useful text for graduate students in stereochemistry and for anyone who wants to keep up with the swift pace of change in this dynamic field IMPACT OF STEREOCHEMISTRY ON DRUG DEVELOPMENT AND USE Twenty three expert contributions on the stereochemical revolution of the last fifteen years covering analytical pharmacological and regulatory topics show that drug development can no longer occur without consideration of drug stereochemistry We have come full circle and stand alongside Pasteur in amazement of nature's duality symmetry and dissymmetry and its chemical and pharmacological consequences from the Preface *Biotechnology and Biopharmaceuticals* Rodney J. Y. Ho, Milo Gibaldi, 2004-09-21 *Biotechnology and Biopharmaceuticals* Transforming Proteins and Genes into Drugs defines biotechnology from the perspective of pharmaceuticals The first section focuses on the process of transforming a biologic macromolecule into a therapeutic agent while the second section provides a brief overview of each class of macromolecule with respect to physiological role and clinical application Additional detail is also provided in the second section for each FDA approved recombinantly derived biopharmaceutical for each category of macromolecule The final section looks to the future and the new advances that will enhance our ability to develop new macromolecules into effective biopharmaceuticals This last section discusses various drug delivery strategies while also describing gene and cell therapy strategies *Japan English Publications in Print*, 1998 Pharmaceutical R&D, 1993 Analyzes the costs risks and economic rewards of pharmaceutical R Government regulation product liability market competition Federal tax policy and Federal support of prescription drug research 12 appendices including a glossary of terms **Federal Register**, 1992-03 **Thaumatococcus** Michael Witty, John D. Higginbotham, 1994-07-12 *Research Anthology on Recent Advancements in Ethnopharmacology*

and Nutraceuticals Management Association, Information Resources, 2021-08-27 For hundreds of years indigenous populations have developed drugs based on medicinal plants Many practitioners especially advocates of traditional medicine continue to support the use of plants and functional foods as methods by which many ailments can be treated With relevance around the world as a complementary and alternative medicine advancements for the use of both ethnopharmacology and nutraceuticals in disease must continually be explored especially as society works to combat chronic illnesses increasingly resilient infectious diseases and pain management controversies The Research Anthology on Recent Advancements in Ethnopharmacology and Nutraceuticals discusses the advancements made in herbal medicines and functional foods that can be used as alternative medical treatments for a variety of illness and chronic diseases The anthology will further explain the benefits that they provide as well as the possible harm they may do without proper research on the subject Covering topics such as food additives dietary supplements and physiological benefits this text is an important resource for dietitians pharmacists doctors nurses medical professionals medical students hospital administrators researchers and academicians

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