

The Oxford Handbook Of The Economics Of The Biopharmaceutical Industry

Innovation and Commercialisation in the Biopharmaceutical Industry
The Oxford Handbook of the Economics of the Biopharmaceutical Industry
Biophysical Characterization of Proteins in Developing Biopharmaceuticals
Mucosal Delivery of Biopharmaceuticals
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Biosimilar Drug Product Development
Biopharmaceuticals
Innovation in the Biopharmaceutical Industry
Biopharmaceutics
Current Concepts in the Pharmaceutical Sciences: Dosage Form Design and Bioavailability
Biopharmaceuticals, an Industrial Perspective
Quality Assurance for Biopharmaceuticals
Biopharmaceuticals
PAREXEL's Bio/pharmaceutical R & D Statistical Sourcebook
Optimal Planning in Biopharmaceutical Supply Chains
Filtration and Purification in the Biopharmaceutical Industry, Third Edition
Biopharmaceuticals in Transition
Steroid Analysis in the Pharmaceutical Industry
Quality by Design for Biopharmaceuticals
Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics
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the processes of discovery testing and distribution of new medicines have undergone radical change in recent decades from a focus on small molecule drugs to biomedicine and related technologies
bruce rasmussen very effectively draws upon modern theories of the firm data analysis and case studies to provide important insights into the consequences of this change he offers convincing evidence that contradicts the widely held view that the biopharmaceutical sector has not generated considerable economic value
frank r lichtenberg columbia university us bio and pharmaceutical industry
discovery is a distressed asset today why
bruce rasmussen s book is a timely and very informative work building on rich data sources and extensive economic research on a subject of concern to us all
is medicine discovery in permanent decline are the biotechnology and traditional pharma groups on a collision course will the traditional group absorb the new will integration take place will a new discovery model emerge i commend bruce s book to all who wish to understand what is happening david w anstice

merck co inc this path breaking book addresses the ongoing implications for traditional pharmaceutical companies and biopharmaceutical start ups of the realignment of the industry knowledge base the theoretical approach draws on the modern theory of the firm and related ideas in order to better define the concept of the business model which is employed to guide the case studies and empirical analysis in the book the author shows that while traditional pharmaceutical companies have successfully adjusted their business models to meet the challenges of biotechnology biopharmaceutical start ups have experienced more problems despite the poor financial performance of the vast majority of these firms the biopharmaceutical sector as a whole has created significant value however this has been captured disproportionately by a handful of large fully integrated biopharmaceutical firms and to a lesser extent by the largest dozen pharmaceutical companies this highly focused book will be a captivating read for innovation and biopharmaceutical industry analysts as well as advisers formulating policies to support the development of the biopharmaceutical sector academics working on innovation and biotechnology as well as scientists engaged in research in the life sciences will also find this book of particular interest

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

biophysical characterization of proteins in developing biopharmaceuticals second edition presents the latest on the analysis and characterization of the higher order structure hos or conformation of protein based drugs starting from the very basics of protein structure this book explains the best way to achieve this goal using key methods commonly employed in the biopharmaceutical industry this book will help today s industrial scientists plan a career in this industry and successfully implement these

biophysical methodologies this updated edition has been fully revised with new chapters focusing on the use of chromatography and electrophoresis and the biophysical characterization of very large biopharmaceuticals in addition best practices of applying statistical analysis to biophysical characterization data is included along with practical issues associated with the concept of a biopharmaceutical's developability and the technical decision making process needed when dealing with biophysical characterization data presents basic protein characterization methods and tools applicable to biopharmaceutical research and development highlights the capabilities and limitations of each technique discusses the underlining science of each tool empowers industrial biophysical chemists by providing a roadmap for applying biophysical tools outlines the needs for new characterization and analytical tools in the biopharmaceutical industry

biopharmaceutical medicines the newest class of therapeutics are quite heterogeneous and include a range of molecules such as proteins peptides vaccines and nucleic acids with use in virtually all therapeutic fields e.g. cancer and infectious diseases vaccination metabolic dysfunctions and diagnostics this edited book gives a concise and up to date overview of the biological features justifying the use of different human mucosa as delivery routes for biopharmaceuticals the technological strategies that have been followed so far regarding the optimization of mucosal potentialities as well as the challenges that arise with the advent of new biopharmaceutical drugs and alternative means of administration following a brief introduction the first section addresses general aspects of the biology of mucosal tissues and their unique aspects toward beneficial or deleterious interaction with biopharmaceuticals and their delivery systems the second part reviews the different delivery strategies that have recently been investigated for different mucosal sites the third section describes the development and clinical applications of drug delivery systems and products enclosing biopharmaceuticals for mucosal delivery with a focus on the most successful case studies of recent years the last section briefly centers on relevant aspects of the regulatory toxicological and market issues of mucosal delivery of biopharmaceuticals scientists and researchers in the fields of drug delivery material science biomedical science and bioengineering as well as professionals regulators and policy makers in the pharmaceutical biotechnology and healthcare industries will find in this book an important compendium of fundamental concepts and practical tools for their daily research and activities

this volume examines the economics of the biopharmaceutical industry with eighteen chapters by health economists

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

biopharmaceuticals biochemistry and biotechnology provides a comprehensive and up to date overview of the science and medical applications of biopharmaceutical products specific chapters detail therapeutic substances such as interferons interleukins and growth factors as well as hormones therapeutic enzymes blood products antibodies and vaccines while the emphasis is placed upon polypeptide based therapeutic agents the potential applications of nucleic acids with regard to gene therapy and antisense technology are considered in the final chapter in addition other chapters detail

regulatory issues as applied to biopharmaceuticals and how such products are manufactured in practice the author has produced an up to date easy to read book and each chapter is supplemented with a substantial further reading section it is of particular relevance to students undertaking advanced undergraduate or postgraduate courses in biotechnology biochemistry pharmaceutical science or medicine its scope also renders it an ideal reference for those already employed in the bio pharmaceutical sector who wish to gain a better overview of the industry in which they work

innovation is at the heart of all advances and has the capacity to solve problems facing humanity societies which have turned away from innovation and technological development have failed in their ability to support their populations understanding the nature of innovation in the life sciences and in particular healthcare how it operates what enables and hinders it is therefore of great importance to meeting the challenges ahead this book originally and concurrently published in the international journal of innovation management vol 11 no 2 2007 offers the latest research and insights concerning innovation in the biopharmaceutical industry

explore the latest research in biopharmaceutics from leading contributors in the field in biopharmaceutics from fundamentals to industrial practice distinguished scientists from the uk s academy of pharmaceutical sciences biopharmaceutica focus group deliver a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development this edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves beginning with an expansive introduction to the basics of biopharmaceutics and the context that underpins the field the included resources go on to discuss how biopharmaceutics are integrated into product development within the pharmaceutical industry explorations of how the regulatory aspects of biopharmaceutics function as well as the impact of physiology and anatomy on the rate and extent of drug absorption follow readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations the book goes on to discuss thorough introductions to biopharmaceutics basic pharmacokinetics and biopharmaceutics measures comprehensive explorations of solubility permeability and dissolution practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization as well as biopharmaceutics tools for rational formulation design in depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics as well as regulatory biopharmaceutics and the impact of anatomy and physiology perfect for professionals working in the pharmaceutical and biopharmaceutical industries biopharmaceutics from fundamentals to industrial practice is an incisive and up to date resource on the practical pharmaceutical applications of the field

biopharmaceuticals an industrial perspective provides a unique and up to date insight into the biopharmaceutical industry largely written by industrial authors its scope is multidisciplinary several chapters overview the production and medical applications of specific biopharmaceuticals other chapters detail additional relevant issues including the stabilisation of biopharmaceutical products eu biopharmaceutical regulatory affairs and biopharmaceutical patent law a series of four chapters reviews important validation issues as applied to biopharmaceutical manufacturing additional issues considered include biopharmaceutical information technology as well as viral and non viral gene therapy the book is of particular relevance to scientists and allied professionals already employed in the biopharmaceutical industry or to those seeking employment within this industry its scope also renders it an ideal reference source for students undertaking advanced undergraduate or postgraduate courses in biotechnology pharmaceutical

science biochemistry or medicine

dr jean huxsoll and a team of distinguished biotechnology industry experts from the u s and europe offer a wealth of practical guidelines to designing implementing and managing qa systems to assure that biopharmaceutical products meet standards for safety purity and potency quality assurance for biopharmaceuticals covers all important theoretical and practical concerns including detailed guidelines to meeting gmp compliance quality assurance of production quality assurance of analytical methods advanced documentation sampling and validation techniques comprehensive coverage of regulatory issues in the u s europe and japan and much more

the latest edition of this highly acclaimed textbook provides a comprehensive and up to date overview of the science and medical applications of biopharmaceutical products biopharmaceuticals refers to pharmaceutical substances derived from biological sources and increasingly it is synonymous with newer pharmaceutical substances derived from genetic engineering or hybridoma technology this superbly written review of the important areas of investigation in the field covers drug production plus the biochemical and molecular mechanisms of action together with the biotechnology of major biopharmaceutical types on the market or currently under development there is also additional material reflecting both the technical advances in the area and detailed information on key topics such as the influence of genomics on drug discovery

since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing the third edition of filtration and purification in the biopharmaceutical industry greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology it provides state of the science information on all aspects of bioprocessing including the current methods processes technologies and equipment it also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries the book is an essential comprehensive source for all involved in filtration and purification practices training and compliance it describes such technologies as viral retentive filters membrane chromatography downstream processing cell harvesting and sterile filtration features addresses recent biotechnology related processes and advanced technologies such as viral retentive filters membrane chromatography downstream processing cell harvesting and sterile filtration of medium buffer and end product presents detailed updates on the latest fda and ema regulatory requirements involving filtration and purification practices as well as discussions on best practises in filter integrity testing describes current industry quality standards and validation requirements and provides guidance for compliance not just from an end user perspective but also supplier requirement it discusses the advantages of single use process technologies and the qualification needs sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs the book has been compiled by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing each specific topic has been thoroughly examined by a subject matter expert

the concepts applications and practical issues of quality by design quality by design qbd is a new framework currently being implemented by the fda as well as eu and japanese regulatory agencies to ensure better understanding of the process so as to yield a consistent and high quality pharmaceutical product qbd breaks from past approaches in assuming that drug quality cannot be tested into products rather it must be built into every step of the product creation process quality by design perspectives and case studies presents the first systematic approach to qbd in the biotech industry a comprehensive resource it combines an in depth explanation of basic concepts with real

life case studies that illustrate the practical aspects of qbd implementation in this single source leading authorities from the biotechnology industry and the fda discuss such topics as the understanding and development of the product s critical quality attributes cqa development of the design space for a manufacturing process 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 to qbd relevant pat tools and applications for the pharmaceutical industry the uses of risk assessment and management in qbd filing qbd information in regulatory documents the application of multivariate data analysis mvda to qbd filled with vivid case studies that illustrate qbd at work in companies today quality by design is a core reference for scientists in the biopharmaceutical industry regulatory agencies and students

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