

BIOPHARMACEUTICAL PRODUCTION: INNOVATIONS AND TRENDS



Single-Use Bioprocessing

Single-use bioprocessing systems consist of disposable components, such as bags, tubing, and filters, which are used once and then discarded.

Bioprinting and 3D Biomanufacturing

In the future, biopharmaceutical production may involve printing tissues and organs for transplantation. This innovation has the potential to address the organ shortage crisis and significantly impact healthcare.



Continuous Bioprocessing

Continuous bioprocessing is revolutionizing the industry by enabling the uninterrupted production of biopharmaceuticals.



Gene and Cell Therapies

Gene and cell therapies involve the introduction of genetic material or modified cells into a patient's body to treat or prevent disease.

Biopharmaceutical Trends & Innovations

Personalized Medicine

Personalized medicine takes into account an individual's genetic, environmental, and lifestyle factors to customize treatment plans. It offers the potential for more effective therapies with fewer side effects.



Biosimilars and Biogenerics

Biosimilars are biologic products that are highly similar to an already approved reference biopharmaceutical. Biogenerics, on the other hand, are generic versions of biopharmaceuticals, similar to traditional generic drugs.



Artificial Intelligence and Big Data Analytics

AI can optimize bioprocesses, predict potential failures, and analyze vast datasets for research and development.

Single-Use Bioprocessing

Single-use bioprocessing systems consist of disposable components, such as bags, tubing, and filters, which are used once and then discarded.



Biopharmaceutical In Transition

David J. Jeremy, Geoffrey Tweedale



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Solid-State Materials in Pharmaceutical Chemistry Stephen R. Byrn,George Zografi,Xiaoming (Sean)

Chen,2025-10-28 Updated and expanded information on the properties of pharmaceutical solids and their impact on drug product performance quality and stability Solid State Materials in Pharmaceutical Chemistry provides readers with a comprehensive and up to date resource for understanding and controlling the solid state properties of pharmaceutical materials enabling the development of safe and effective medicines including small molecule compounds peptides proteins and nucleotides This new edition covers the significant transformations in the landscape of pharmaceutical research development and manufacturing since the previous edition was published presenting both novel challenges and unprecedented opportunities New chapters in this edition cover physical and chemical properties of RNA therapeutics a frontier to many life saving medicines and vaccines including Covid vaccines and final stage drug substance manufacturing and control addressing challenges in API process development including impurity purging chiral separation final form preparation particle size reduction and nitrosamine control Readers will also find other updated topics including bulk and surface properties of solids lipid nanoparticles applications of pharmaceutical solvates in impurity purging and final form preparation pharmaceutical cocrystal engineering to enable chiral separation the emerging technique of microcrystal electron diffraction in solid form characterization poor wettability of APIs oral delivery of peptides such as semaglutide injectable drug device combination products and N nitrosamine control in drug product This updated and revised Second Edition still features Physical and chemical properties of solid state pharmaceuticals such as amorphous forms mesophases polymorphs hydrates solvates salts co crystals nano particles and solid dispersions Characterization techniques for solid form identification and physical attribute analysis such as X Ray powder diffraction thermal analysis microscopy spectroscopy solid state NMR particle analysis water sorption mechanical property testing solubility and dissolution Applications of pharmaceutical chemistry and physical characterization techniques in developing and testing drug substances and drug products for small molecules and biopharmaceuticals This book is an essential resource on the subject for formulation scientists process chemists medicinal chemists and analytical chemists The book will also appeal to quality control quality assurance and regulatory affair specialists and advanced undergraduate and graduate students in pharmaceutical chemistry drug delivery material science crystal engineering pharmaceutics and biopharmaceutics

The Thriving Biopharma Business Alain Eudarc,Jean-Noël Pellegrin,2025-10-31 In today s fiercely innovative and complex biopharmaceutical industry successfully managing a pharmaceutical or biotech company from concept to patients requires exceptional strategic leadership and managerial abilities This book is a definitive reference that uniquely integrates critical business strategy finance M A regulatory and intellectual property concepts Bringing new therapies to market is both a sought after experience

and a distinguished accomplishment A biopharma leadership team that is able to master the critical levers covered in this book will drive unparalleled value creation through tremendous competitive advantage in the industry Chapter by chapter you ll delve into innovation valuation intellectual property strategy financing pitching transactions contracts and regulatory affairs Through numerous case examples and concepts you ll learn practical avenues to avoid pitfalls drive value creation and navigate the intricate world of the biopharma industry This book equips decision makers founders investors and industry professionals with frameworks illustrations and actionable ideas enabling them to tackle the strategic and managerial challenges inherent in the evolution of a biopharma company Elevate your strategic decisions unlock new opportunities and lead your company to success with this indispensable resource

Biophysical Characterization of Proteins in Developing Biopharmaceuticals Damian J. Houde, Steven A. Berkowitz, 2019-11-13 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 bio pharmaceutical 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

PAREXEL's Bio/pharmaceutical R & D Statistical Sourcebook ,2008 **PAREXEL's Pharmaceutical R & D Statistical Sourcebook** ,2005 *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

Medical Device Development Jonathan S. Kahan, 2000 *Genetic Engineering News* ,2006 **Molecular Mobility, Physical Stability, and Transformation Kinetics of Amorphous and Hydrated Pharmaceutical Solids** Deliang Zhou, 2003 **Encyclopedia Of Biopharma- Ceutical Statistics** Shein-Chung

Chow,2000 This reference covers all key topics for evaluation of data at critical stages in the pharmaceutical research and development process highlighting the vital areas of statistical design and regulatory requirements Each entry of the Encyclopedia includes self contained self explanatory and accessible data to nonbiostatisticians real world examples of statistical design and practice in the pharmaceutical industry thoroughly up to date standards on good laboratory practice GLP good clinical practice GCP current good manufacturing practice cGMP and good statistics practice GSP Written by over 75 acclaimed international experts the Encyclopedia of Biopharmaceutical Statistics explores interrelations among physiochemical properties of drugs in dosage form and their pharmacological toxicological and clinical effects elucidates new applications of computer telephony technology surveys the crucial relationship of the Food and Drug Administration FDA to pharmaceutical development clinical trials and testing and marketing showcases monoclonal antibodies cytokines hematopoietic growth factors tumor vaccines xenotherapies and cell selection devices describes one sided equivalence and noninferiority trials investigates genetic toxicology tests and other animal studies illustrates assay technologies measuring gravimetric mass potency and physical or biological properties of analytes discusses proposals for internationally standardized systems of data collection and analysis and supplies vital economic data on factors such as reference based pricing burden of illness studies cost utility analysis and cost benefit analysis Containing over 2200 references equations tables and drawings the Encyclopedia of Biopharmaceutical Statistics serves as a reference for biostatisticians chemists pharmaceutical scientists clinical researchers and development pharmacists in the pharmaceutical industry and regulatory agencies as well as upper level undergraduate and graduate students in these disciplines BOOK JACKET Title Summary field provided by Blackwell North America Inc All Rights Reserved **ICIS Chemical Business** ,2007 *Cross Sections* ,1995 *Genetic Engineering & Biotechnology News* ,2009 *Business History: pt. 1, Business environment* David J. Jeremy,Geoffrey Tweedale,2005 *GEN Guide to Biotechnology Companies* ,1998 **Innovation in Pharmaceutical Biotechnology** Organisation for Economic Co-operation and Development,2006-04-11 This publication examines the innovation system in pharmaceutical biotechnology in eight OECD countries Belgium Finland France Germany Japan the Netherlands Norway and Spain and makes recommendations advocating an integrated policy approach **Index** ,1998

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