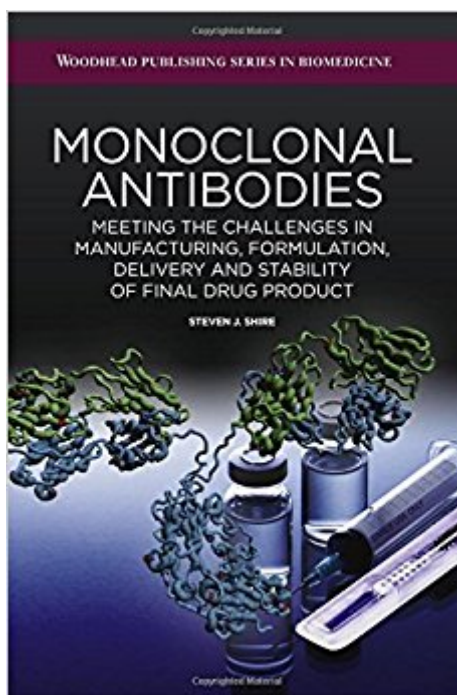




Ebook Directory
the best source of ebook

The book was found

Monoclonal Antibodies: Meeting The Challenges In Manufacturing, Formulation, Delivery And Stability Of Final Drug Product



Synopsis

Monoclonal antibodies (MAbs) are currently the major class of protein bio therapeutic being developed by biotechnology and pharmaceutical companies. Monoclonal Antibodies discusses the challenges and issues revolving around development of a monoclonal antibody produced by recombinant DNA technology into a therapeutic agent. This book covers downstream processing which includes design of processes to manufacture the formulation, formulation design, fill and finish into closure systems and routes of administration. The characterization of the final drug product is covered where the use of biophysical methods combined with genetic engineering is used to understand the solution properties of the formulation. The latter has become very important since many indications such as arthritis and asthma require the development of formulations for subcutaneous delivery (SC). The development of formulations for IV delivery is also important and comes with a different set of challenges. The challenges and strategies that can overcome these limitations are discussed in this book, starting with an introduction to these issues, followed by chapters detailing strategies to deal with them. Subsequent chapters explore the processing and storage of mAbs, development of delivery device technologies and conclude with a chapter on the future of mAbs in therapeutic remedies. Discusses the challenges to develop MAbs for intravenous (IV) and subcutaneous delivery (SC) Presents strategies to meet the challenges in development of MAbs for SC and IV administration Discusses the use of biophysical analytical tools coupled with MAb engineering to understand what governs MAb properties at high concentration

Book Information

Hardcover: 224 pages

Publisher: Woodhead Publishing; 1 edition (May 7, 2015)

Language: English

ISBN-10: 0081002963

ISBN-13: 978-0081002964

Product Dimensions: 0.8 x 6.2 x 9.2 inches

Shipping Weight: 15.5 ounces (View shipping rates and policies)

Average Customer Review: Be the first to review this item

Best Sellers Rank: #1,661,574 in Books (See Top 100 in Books) #27 inÂ Books > Medical Books > Pharmacology > Product Development #144 inÂ Books > Business & Money > Industries > Pharmaceutical & Biotechnology #287 inÂ Books > Textbooks > Medicine & Health Sciences > Medicine > Basic Sciences > Immunology

Customer Reviews

Steven J. Shire is currently consulting and serving as an adjunct faculty member of the USC School of Pharmacy and University of Connecticut School of Pharmaceutical Sciences. He was at Genentech for 32 years where the majority of his career was in the pharmaceutical development department. He retired in June 2013 as Staff Scientist in the Late Stage Pharmaceutical Development Department. He has been responsible for directing research and development of formulations for a variety of recombinant human proteins including Pulmozyme® and Xolair®. Dr. Shire has served as the chair of the American Association of Pharmaceutical Scientists (AAPS) Biotechnology Section, and was elected as a Fellow of AAPS in 1998 and member at large to the AAPS Executive Council in 2001. He has published over 80 reviews and papers dealing with various aspects of formulation and pharmaceutical development of therapeutic proteins.

[Download to continue reading...](#)

Monoclonal Antibodies: Meeting the Challenges in Manufacturing, Formulation, Delivery and Stability of Final Drug Product Monoclonal Antibodies Entering the Psalms, Participant's Workbook (Meeting God in Scripture) (Meeting God in Scripture Meeting God in Scripture) Agile Product Management: Product Owner: 27 Tips To Manage Your Product And Work With Scrum Teams (scrum, scrum master, agile development, agile software development) Biomimetic Materials And Design: Biointerfacial Strategies, Tissue Engineering And Targeted Drug Delivery (Manufacturing Engineering & Materials Processing) Electrochemotherapy, Electrogenetherapy, and Transdermal Drug Delivery: Electrically Mediated Delivery of Molecules to Cells (Methods in Molecular Medicine) Formulation and Delivery of Proteins and Peptides (ACS Symposium Series) Protein Formulation and Delivery (Drugs and the Pharmaceutical Sciences) Introduction to Aircraft Flight Mechanics: Performance, Static Stability, Dynamic Stability, Classical Feedback Control, and State-Space Foundations (AIAA Education) Controlled Drug Delivery: Challenges and Strategies (ACS Professional Reference Book) Drug Delivery: Principles and Applications (Wiley Series in Drug Discovery and Development) Expert Systems and Decision Support in Medicine: 33rd Annual Meeting of the Gmds Efmi Special Topic Meeting Peter L. Reichertz Memorial Conference Ha (Lecture Notes in Medical Informatics, 36) Carol Rama: Antibodies Additive Manufacturing Technologies: 3D Printing, Rapid Prototyping, and Direct Digital Manufacturing Supply Chain Management in Manufacturing + Inventory Control in Manufacturing: 2 Books in 1 ISO 22716:2007, Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices s Delivery Locations: Delivery Locations Including One Hour Shipment Information Detail Product

Design for Manufacture and Assembly, Third Edition (Manufacturing Engineering and Materials Processing) Product and Furniture Design (The Manufacturing Guides) Composites Manufacturing: Materials, Product, and Process Engineering

[Contact Us](#)

[DMCA](#)

[Privacy](#)

[FAQ & Help](#)